

ORIGINAL

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: **MEETING WITH ADVISORY COMMITTEE ON
MEDICAL USES OF ISOTAPES (ACMUI) AND
BRIEFING ON PART 35 QM RULE --
PUBLIC MEETING**

Location: **Rockville, Maryland**

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1250 I St., N.W., Suite 300
Washington, D.C. 20005
(202) 842-0034

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2 NUCLEAR REGULATORY COMMISSION

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4 MEETING WITH
5 ADVISORY COMMITTEE ON MEDICAL USES OF
6 ISOTAPES (ACMUI)

7 AND

8 BRIEFING ON PART 35 QM RULE

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10 PUBLIC MEETING

11
12 Nuclear Regulatory Commission
13 One White Flint North
14 11555 Rockville Pike
15 Rockville, Maryland
16 Wednesday, June 17, 1998
17

18 The Commission met in open session, pursuant to
19 notice, at 2:06 p.m., the Honorable Shirley A. Jackson,
20 Chairman, presiding.

21 COMMISSIONERS PRESENT:

22 SHIRLEY A. JACKSON, Chairman of the Commission
23 GRETA J. DICUS, Member of the Commission
24 NILS J. DIAZ, Member of the Commission
25 EDWARD MCGAFFIGAN, JR., Member of the Commission

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1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

2 JOHN C. HOYLE, Secretary

3 KAREN D. CYR, General Counsel

4 L. JOSEPH CALLAN, NRC

5 CATHERINE HANEY, NRC

6 DONALD COOL, NRC

7 MAL KNAPP, NRC

8 JUDITH STITT, ACMUI

9 JOHN GRAHAM, ACMUI

10 NAOMI ALAZARKI, ACMUI

11 DENNIS SWANSON, ACMUI

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P R O C E E D I N G S

[2:06 p.m.]

CHAIRMAN JACKSON: Good afternoon, ladies and gentlemen. Today the NRC staff and the NRC Advisory Committee on the Medical Uses of Isotopes, a.k.a. ACMUI, will provide the Commission with its annual briefing. The Advisory Committee last met with the Commission in April 1997 and a lot has happened in the ensuing year.

In June 1997, in a June 30th staff requirements memorandum, the Commission approved the staff's plan for revision of both 10 CFR Part 35 and the Commission's Medical Use Policy Statement. The staff has proceeded in an expedited manner to develop the proposed draft rule language over the last year by establishing a working group and a steering group that included NRC headquarters and regional licensing and inspection staff, and representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The program to revise Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties than is provided by the typical notice and comment rulemaking process. The staff has held multiple meetings with the public and professional societies and boards, have placed a straw man version of the rule on the Internet for comment, and met extensively with

1 the ACMUI and members of its subcommittees. I should say,
2 parenthetically, that the Commission itself has had a number
3 of visits from various groups with interests in our revision
4 to the rule.

5 Today the staff will brief the Commission on the
6 results of these activities, focusing on the more
7 significant aspects of the proposed revision of 10 CFR Part
8 35 and the medical use policy statement. The ACMUI's
9 presentation will follow the staff's, since their slides
10 focus on points of agreement and disagreement with the
11 staff's proposal.

12 Now, I understand that copies of the viewgraphs
13 and copies of the two papers are available at the entrances
14 to the meeting, and I welcome Ms. Haney, who we have not had
15 the opportunity to hear from before. So, unless my
16 colleagues have anything to add, Mr. Callan, please.

17 MR. CALLAN: Thank you, Chairman. Good afternoon.
18 Good afternoon, Commissioners.

19 As you pointed out, Chairman, we are taking the
20 unusual step of having the staff to go first to brief you
21 for the reasons that you stated, and then we will be
22 followed -- I am not going to rely on the acronym, I am
23 going to say the Advisory Committee on Medical Uses of
24 Isotopes.

25 [Laughter.]

1 MR. CALLAN: But we promise we will not leave
2 after our presentation, we will stay and --

3 CHAIRMAN JACKSON: You didn't see the shackles
4 that we --

5 [Laughter.]

6 MR. CALLAN: And we will be ready to come back to
7 the table to respond to any questions you may have after the
8 Advisory Committee's presentation.

9 Ms. Cathy Haney will be our principal presenter.
10 Cathy.

11 CHAIRMAN JACKSON: Please, go ahead.

12 MS. HANEY: Basically, what I would like to do is
13 to tell you -- go over what we will start with. We will
14 discuss the process and the schedule, the approach, a
15 discussion on the medical policy statement, the
16 cross-cutting issues and the net impact on licensees from a
17 burden standpoint.

18 For the process, as you said, we did use a working
19 and steering group approach to develop the rule
20 alternatives. We also used that same approach in developing
21 alternatives for the medical policy statement. This group
22 also developed what we call alternatives for the
23 cross-cutting issues. The cross-cutting issues being things
24 that addressed all areas of the programs, whether we are
25 talking diagnostic or therapy uses, things such as Radiation

1 Safety Committee Quality Management Program.

2 We held several facilitated public meetings to get
3 input from the stakeholders. It was well attended by
4 professional societies. And, as you said, we placed a straw
5 man on the Internet in January. We received approximately
6 330 comments during this rulemaking process. The majority
7 of them focused on training and experience. The remainder
8 focused on the more technical areas of the rule.

9 With the approach -- as I said, we started out
10 with identifying cross-cutting issues. These were primarily
11 -- and the issues that were noted in the staff requirements
12 memorandum. We have -- or we are proposing a change in
13 licensing philosophy, as we have come to call it, which will
14 reduce the amount of paper work that the licensees will
15 bring to us at the time of amendment or license application.
16 This being that we -- NRC would no longer review the
17 procedures that the licensee has. They will still be
18 required to have those procedures, but the licensing staff
19 would not be reviewing. We estimate that this could impact
20 -- reduce the amount of licensing, the time to review a
21 license application by up to 50 percent, in that area.

22 CHAIRMAN JACKSON: What is a typical time frame
23 for reviewing a license application?

24 MS. HANEY: It varies whether you are talking a
25 broad scope, which is the larger. In that case, the average

1 may be as high as 70 to 100 hours. In the routine -- I say
2 routine -- specific licensees, your smaller community
3 hospital, maybe in the 10 hour range. Then license
4 amendments, depending upon the complexity of the issue,
5 would be slightly less.

6 We have developed a guidance document. It's
7 following the same format that was used for the consolidated
8 licensing guidance that we have put together before. We
9 have been careful not to include any specific requirements
10 in the guidance documents. This was one of items that the
11 public mentioned that we should not do, if there were any
12 requirements, they should appear in the rule.

13 The last thing that we did from an approach
14 standpoint was to rely on requirements in other portions of
15 Title 10. For example, if there was a requirement in Part
16 20, we did not -- we deleted the requirement from Part 35,
17 figuring that the requirement in Part 20 was adequate.

18 To move right into the medical policy statement,
19 this was an area where we received a large amount of
20 comments from the public, and there were also a wide variety
21 of viewpoints that were expressed by these individuals. The
22 key elements that are the items that the working group felt
23 were key elements in developing a proposed policy statement
24 was that the policy statement should provide for the
25 radiation safety of workers and the public, that we did not

1 want to intrude into medical judgments, that was at the
2 discretion of the physician and, also, we wanted to focus
3 our regulation on assuring that the use of radionuclides is
4 in accordance with the physician's directions.

5 With those things in mind, the staff is proposing
6 a revision to the medical policy statement. I won't go
7 through line by line, but there are a few items that I want
8 to focus you to. In the first item -- bullet, basically, we
9 are just doing a change in terminology there. There is no
10 change in the scope or intent of the regulations. The
11 current policy statement says medical use of radioisotopes,
12 and we are just changing it to radionuclides to be more
13 accurate.

14 In the second item, we are changing -- proposing a
15 change from "minimize intrusion", which is what is in the
16 current policy statement, to "will not intrude". We made
17 this change at the advice of the ACMUI.

18 In the third item, this is where we bring in the
19 focus that radionuclides are used in accordance with the
20 physician's direction.

21 And in the last item, we have made a change there.
22 The corollary statement in the present policy statement says
23 that we will rely on industry standards. We are proposing
24 that we use the term "will consider industry and
25 professional standards" and we believe that this is more

1 consistent with identifying key objectives in the rule,
2 putting the requirements for the objective in the rule that
3 the licensee needs to meet and then putting the putting the
4 more prescriptive requirement -- or more prescriptive
5 requirements would fall to the industry standards for
6 implementing the objective.

7 CHAIRMAN JACKSON: Let me ask you a question. I
8 mean you have in this bullet 3, the phrase "where justified
9 by risk" and that seems to indicate somehow perhaps a set
10 point that would justify NRC's intervention or interceding
11 on behalf of a patient. Do you have a qualitative, a
12 quantitative idea of how you would arrive at that judgment?

13 MS. HANEY: What I would offer is that in the low
14 -- the diagnostic uses of medicine are your low risk areas
15 and your therapy area, therapeutic uses, for example, the
16 teletherapy, the use of high dose rate remote after-loaders,
17 those would be the high risk therapy areas, and that --
18 that's really where we would be looking at were justified by
19 the risk.

20 CHAIRMAN JACKSON: And what do you -- do you
21 define what you mean by radiation safety for a patient?

22 MS. HANEY: I think we do in the last statement
23 where we are saying to assure the use of radionuclides is in
24 accordance with the physician's directions. We would not
25 question the physician's judgment. However, once the

1 physician makes a determination of how much radiation the
2 patient should receive or the treatment, at that point NRC
3 would pick up their regulatory authority and there we would
4 be looking at instrument calibration, things such as that.

5 CHAIRMAN JACKSON: So exposures beyond what the
6 physician would --

7 MS. HANEY: Correct. Or that differ from what the
8 physician said.

9 CHAIRMAN JACKSON: Okay. Thanks.

10 COMMISSIONER McGAFFIGAN: Could I? I am having a
11 little problem with the "will not intrude" into medical
12 judgments as opposed to "minimize intrusion", which is what
13 the 1979 policy statement says. I am a Commissioner who is
14 going to be reluctant to give up patient notification, and I
15 don't know whether the -- and I believe the medical
16 community will say I am, therefore, intruding medical
17 judgment affected patients. And so, can one be for patient
18 notification and for "will" -- you know, the blanket "will
19 not intrude", as opposed to "minimize intrusion"? The 1979
20 Commission was consistent. They minimized intrusion but
21 they felt patient notification was important.

22 MS. HANEY: I believe you could support patient
23 notification under Statement 3 of the proposed medical
24 policy statement, provided we maintain the clause in the
25 rule that says that if it is the -- at the discretion of the

1 physician, the patient should not be notified. I felt it
2 could be justified under 3 because you are requiring
3 notification following a medical event, and the medical
4 event would be an example of where the physician's
5 directions were not carried out and, therefore, that would
6 give us the step into being able to notify the patient,
7 justified under this statement. Even with the "not intrude"
8 in Statement 2.

9 COMMISSIONER McGAFFIGAN: Okay. The 2 statement
10 -- it may be more honest to say "minimize intrusion" rather
11 than "do not intrude". Just, at first -- at first glance --
12 but we don't have to dwell on that. We will probably have a
13 good discussion later.

14 CHAIRMAN JACKSON: And certainly in the Commission
15 process. Thanks. Okay.

16 MS. HANEY: As I said, there were several
17 cross-cutting issues that the group addressed, and I will go
18 briefly through these. We do have some backup slides that
19 go into greater depth if you would like us to go there, but
20 I will just give you a two sentence version on each one.

21 On Radiation Safety Committee, in accordance with
22 the performance-based approach to the rule, we are proposing
23 that the Committee no longer be required. We have
24 identified key elements that the Radiation Safety Committee
25 currently perform and those items we have listed in the rule

1 and made them the responsibility of the licensee management.

2 COMMISSIONER McGAFFIGAN: Are your two sentences
3 finished on that?

4 CHAIRMAN JACKSON: Let her finish. Let her
5 finish.

6 [Laughter.]

7 MS. HANEY: Well, my two sentences are finished.
8 That's two sentences. I'm okay.

9 COMMISSIONER McGAFFIGAN: On that item, I just
10 want to make a -- the Radiation -- the basic rationale for
11 giving up the Radiation Safety Committee is that there are
12 other committees at hospitals that might be able to carry
13 out this function, is that the thought?

14 MS. HANEY: That is one of the reasons. Another
15 reason is that we want the licensee to have flexibility in
16 how they manage their program and, in that, if there are
17 other committees in a hospital forum that would allow them
18 to address this problem. But we are also extending this
19 particular proposed section to cover all licensees, just,
20 again, to make it more explicit that there are some basic
21 things in the Radiation Protection Program that we expect
22 the licensees to do.

23 COMMISSIONER McGAFFIGAN: But is there a chance
24 that radiation safety gets lost, if there isn't a Radiation
25 Safety Committee, in a big hospital where people have lots

1 of other things to worry about besides radiation safety?

2 MS. HANEY: It's always a potential for that to
3 happen. I think, given today's structure for the hospital
4 setting with the Joint Commission on Accreditation of Health
5 Care Organizations, JCAHO, they require certain committees
6 in a hospital now, one being a committee to review risk, and
7 that would be an ideal location for radiation safety to fall
8 under. So, yes, there is a potential, but I think in the
9 hospital setting where the risk is the greatest, there are
10 other committees that are in place, required by other
11 organizations, that would address this item.

12 COMMISSIONER DIAZ: If I may follow on that
13 question. I don't think it's the issue of the committee,
14 are the functions that are required for the protection of
15 health and safety that we envision should be carried out,
16 are they going to be addressed by someone that will have
17 accountability on those issues?

18 MS. HANEY: I believe the rule as proposed does
19 that, in the Section 3524 where we --

20 CHAIRMAN JACKSON: Makes it clear that is a
21 fundamental requirement.

22 MS. HANEY: I believe -- I believe so.

23 CHAIRMAN JACKSON: Okay. Why don't you do on.

24 MS. HANEY: Okay. Moving into quality management,
25 again, we took a performance-based approach there. We have

1 deleted the current requirements as seen for the Quality
2 Management Program. However, we have focused in on
3 confirming patient identify, requiring written directives,
4 and verifying dose. The licensees would still need to be
5 required to have written directives and then they would need
6 to develop procedures, develop, implement and maintain
7 procedures for verifying patient identity and verifying that
8 the correct dose is given to the correct patient.

9 COMMISSIONER DIAZ: Is this risk-informed on a
10 certain way, or are you cutting across all procedures?

11 MS. HANEY: I believe it is risk-informed because
12 the requirements for the written directive are in your
13 therapy area and your high risk procedures. We really did
14 not make any changes, or I should say significant changes to
15 when a written directive is required and the procedures, the
16 requirement for having procedures flow out of if you need a
17 written directive.

18 The third issue is that of reportable events.
19 There are two items that fall under this -- one, it being
20 medical events, which we are proposing to change the term
21 from misadministrtion to medical event, and then the second
22 item being precursor events.

23 We have made some minor changes in the Medical
24 Event Reporting to address two items that were brought to
25 our attention by the public, one being patient intervention,

1 and the second being wrong treatment site.

2 In the area precursor events, we have included a
3 requirement for reporting precursor events. We have,
4 however, focused the definition for precursor events to
5 events that would have implications beyond that specific
6 licensee's facility.

7 In the case of notification following a medical
8 event, the proposed rule contains the essential requirements
9 as they appear in the current Part 35.

10 Then moving into training and experience, training
11 and experience was one of the big issues of this rulemaking
12 and if you would turn to the next slide, I do have a slide
13 on this one.

14 CHAIRMAN JACKSON: Let me just ask you this
15 question as a generalized comment. On all the cross-cutting
16 issues, you know, obviously I think we are interested in
17 moving to a risk-informed and as appropriate
18 performance-based approach question is the rule enforceable
19 in your opinion?

20 MS. HANEY: Yes.

21 CHAIRMAN JACKSON: Okay.

22 MS. HANEY: Staff is proposing the requirements
23 for training and experience be risk informed and focused on
24 radiation safety. That was really our focus on going into
25 making any proposed changes in the training and experience

1 criteria. We believe that individuals should complete a
2 structured educational program and that educational programs
3 should consist of a didactic training portion, which is your
4 classroom training in physics and biology, things like that,
5 and then practical experience, which would include
6 experience in ordering, receiving packages and safety
7 precautions, ways to prevent medical events and calibrating
8 dose calibrators and eluting generators.

9 In some cases we have proposed some clinical
10 experience where we believe that there is a greater risk
11 posed by the procedure. An example of that would be in your
12 use of unsealed radiopharmaceuticals for thyroid treatment,
13 for example with your Iodine-131s.

14 We also believe that an exam should be given to
15 assess clinical competency. The idea of an exam grew out of
16 meetings with the professional societies, the facilitated
17 public meetings, and also comment letters. The majority,
18 vast majority of the individuals, did support an exam to
19 assess clinical competency and because of that we are
20 proposing that an item be included in the rule.

21 If you would like I can get into the specific hour
22 requirements, but I think I will stop there.

23 CHAIRMAN JACKSON: Commissioner Diaz and then
24 Commissioner McGaffigan.

25 COMMISSIONER DIAZ: On the issue of Iodine-131,

1 which is specifically separated -- it is a special
2 category -- is the training then going to be Iodine-131
3 specific or are you still thinking of generic training plus?
4 I mean there is a difference in how much you can provide
5 generic training and how much you can go into a specific
6 radionuclide use.

7 MS. HANEY: The proposed rule would require the
8 didactic training and in that case I think it would be very
9 general and really with the didactic training that is
10 adequate, because you are learning decay formula. You are
11 learning the radiobiological implications, things like that,
12 so that would be very general.

13 In the practical that we are proposing, and in
14 this case we are talking 40 hours of practical experience,
15 we are also looking at five cases and we believe that this
16 practical experience would be more tailored to what that
17 individual is using.

18 For example, if an endocrinologist was coming
19 in -- was wishing to become an authorized user, and for
20 hyperthyroidism treatments or thyroid cancer, there would be
21 a requirement for five cases. Some of that practical
22 experience could be obtained while they were doing those
23 five cases. They would still need to receive a package.
24 They would need to order the material. They would need to
25 assay it -- things like that -- so there is some overlap

1 there.

2 To answer your question, some would be very
3 general, but I could see some of it being specific to the
4 type of use the individual is doing because we are focusing
5 in on radiation safety.

6 COMMISSIONER DIAZ: Yes. It would seem that as an
7 equity issue that in some specific areas like Iodine-131 you
8 really want to become very specific, not broad.

9 CHAIRMAN JACKSON: Let me make sure -- this is a
10 piggyback to his question -- so then is the point that the
11 didactic part is some baseline knowledge level --

12 MS. HANEY: Right.

13 CHAIRMAN JACKSON: -- that you would expect
14 everyone working with radionuclides to have, and then where
15 the specificity comes is in what you would call the
16 practical training that is tailored to the particular
17 radionuclide or set of radionuclides that are being used or
18 tailored to the risks involved.

19 MS. HANEY: It would be tailored to the risks. I
20 would like to say a flat yes to that, but in the case of the
21 endocrinologist their five cases would be very specific, but
22 if you are looking at a physician that is doing general
23 nuclear medicine, that practical would be a little bit
24 broader.

25 CHAIRMAN JACKSON: Right.

1 MS. HANEY: So I just wanted to give the full
2 story.

3 CHAIRMAN JACKSON: I appreciate that.
4 Commissioner?

5 COMMISSIONER McGAFFIGAN: I am going to follow on
6 the same line of questioning. There basically are two
7 categories of specialist who are adversely affected by the
8 rule in that their hours of training is going to have to go
9 up, and one of them, I understand, the Strontium-90 eye
10 applicator folks -- we have had all sorts of problems in
11 that area -- and misadministrations and damage to eyes and
12 whatever.

13 The endocrinologists argue that you are trying to
14 fit them in a one-size-fits-all box, that they have had zero
15 problem, that this is straightforward. These are smart
16 people and the 80 hours that are required at the moment is
17 all they need for dealing with basically one radionuclide
18 and one organ. If there were a backfit rule, which there
19 isn't, for materials licensees, this would never pass a
20 backfit test because there is no health and safety benefit
21 that is going to accrue from upping -- in fact, they would
22 argue and have argued that there will be an adverse health
23 and safety benefit because it is a larger entry barrier and
24 people will not bother to get -- to get certified and they
25 will send people off to other specialists and the patient

1 has to now deal with a more complex medical system and all
2 that.

3 But what is the rationale for increasing the time
4 for the endocrinologists?

5 MS. HANEY: Staff's approach to the rulemaking in
6 the training and experience area was to focus in on the
7 radiation safety and from the comments that we received, the
8 input that we received across the board from diagnostic
9 therapy users, a certain amount of practical experience was
10 needed as part of a training program.

11 To use the example of the endocrinologist, right
12 now they are required to have three cases if they are in the
13 hyperthyroidism area and 10 cases if they are treating the
14 cancer, so there is some practical that they are getting
15 there right now inherent in the fact that they are in the
16 clinic, that they are handling the pharmaceuticals, and
17 treating the patients, and our pulling it out as an hour of
18 a 40-hour practical -- well, it looks like an increase -- in
19 the rule it is an increase.

20 I believe that you could get the clinical -- the
21 practical training and the clinical at the same time, so it
22 may not be as great as an actual net 40 hours that they must
23 be in the clinic.

24 COMMISSIONER McGAFFIGAN: Why fix something that
25 isn't broken is the question that they will ask, surely, in

1 the process that you are about to enter?

2 MS. HANEY: All I can offer to that is that we
3 have attempted to focus on radiation safety and this is what
4 we were -- the comments that we received across the board,
5 that this was needed.

6 COMMISSIONER MCGAFFIGAN: Okay.

7 CHAIRMAN JACKSON: Actually, this is probably more
8 directed at Dr. Cool or Dr. Knapp, because it actually lifts
9 it out of, strictly speaking, Part 35 rulemaking.

10 You know, since these training and experience
11 requirements that you are focusing on have to do with
12 radiation safety, do you anticipate any effort to require
13 similar training and examination requirements for,
14 experience requirements for other licensed individuals using
15 the same types of licensed materials and faced with the same
16 radiation safety risks but from a non-strictly medical point
17 of view, industrial or research applications, possibly
18 veterinary, which some people call medical, some say not,
19 but you know -- what can you say about that from a
20 consistency perspective?

21 MR. COOL: That is an extremely good question and
22 one that we have done at least a little bit of thinking
23 about.

24 In fact, the case in Part 35 here is not the first
25 place where we have gone with an examination type of

1 approach. The radiography arena and the certification of
2 radiographers by independent testing organizations for which
3 there is one test plus several states are doing it, was a
4 stalking horse, if you will, a similar kind of approach.

5 What we learned from this in terms of working in
6 the unsealed arenas and how this scales out I think we ought
7 to use to then look to see whether there are other arenas
8 and other uses as we go back and look at it, to see whether
9 or not it also makes sense.

10 There is an advantage in this arena, I would
11 note -- that we have a number of professional societies and
12 organizations who are in the business of testing and
13 certifying people in terms of these particular fields, so we
14 have that baseline which is not present to varying degrees
15 in some of the other areas.

16 MR. KNAPP: And I would say that obviously we have
17 a diverse set of licensees. In some cases in ways that
18 perhaps we hear from the auto industry, it's better to have
19 an automated breaking system than to train each driver to
20 pump their breaks. In some cases there are other fixes
21 which literally if we have some classes of licensees we can
22 solve a problem with an engineered fix, but the fundament
23 questions you asked, Chairman, I agree entirely with Don.

24 This is something we should consider across the
25 board and to the extent that we have similar risks and

1 similar needs I think we should take some more steps.

2 CHAIRMAN JACKSON: Okay.

3 MS. HANEY: Now I would like to move into some
4 areas where there is a reduction in the regulatory burden on
5 licensees.

6 In the slide that you see, the deletion of the
7 Radiation Safety Committee and a requirement for the Quality
8 Management Program, this would represent a significant
9 reduction in the burden on licensees.

10 If we look at the diagnostic and the therapy areas
11 as separate areas, some minor changes that we are proposing
12 to the rule and more the technical orientation would also
13 decrease burden. In the diagnostic area and the therapy
14 area we are also proposing that the medical physicist --
15 change in the medical physicist, no longer requiring
16 amendment to the license. This is a similar consistency
17 with how we are doing it with other users in the rule.

18 There are some areas where there is an increase in
19 the regulatory burden on licensees because of the proposed
20 rule change, the first being that the rule now specifies
21 that the licensee develop, maintain, and implement
22 procedures.

23 The vast majority of the procedures that the rule
24 is proposing to be included are already developed by the
25 licensee and this is part of their license application.

1 There are however a few procedures that they currently do
2 not have that they would need to develop if they were going
3 to be in compliance with the rule.

4 We have also added the two reporting requirements,
5 one for reporting unintended dose to the embryo fetus, or
6 nursing child, and also for precursor events. While we do
7 believe that there is a small impact here, there is however
8 an impact.

9 Finally we would be requiring an output
10 measurement for all brachytherapy sources, and this would be
11 just to make our regulations more consistent. Right now we
12 require it in the teletherapy area and the high dose rate
13 remote afterloader area, but we are not requiring it in the
14 manual brachytherapy, so here we are looking for
15 consistency.

16 CHAIRMAN JACKSON: Did you get many comments in
17 these three areas?

18 MS. HANEY: Where did we get the most? I'll start
19 at the bottom first again.

20 The medical physics community was very supportive
21 of requiring output measurements on the sources. We did not
22 receive comment on the reporting requirements for the
23 unintended dose to the embryo fetus because the version of
24 the rule that went up on the Internet really had totally
25 different language than what we are proposing now, so we

1 were talking apples and oranges and therefore I can't say
2 that they -- the public has seen this.

3 I would expect that we will receive a lot of
4 comment in both the area of the embryo fetus and the
5 precursor events.

6 In the area of the procedures, the big comment
7 there was don't put requirements for procedures in the
8 license or in your reg guides. If you want us to have
9 procedures, put it in the rule and state it upfront, which
10 is what we have done.

11 CHAIRMAN JACKSON: Okay. Commissioner?

12 COMMISSIONER McGAFFIGAN: Can you give an example
13 of a procedure that is not currently part of the license
14 application that would be required by the new rule?

15 MS. HANEY: Right. An example would be that we
16 have deleted the prescriptive requirements for labelling of
17 vials and syringe shields and have gone to what we think and
18 believe to be more performance-oriented, which is that the
19 licensee should develop procedures for how they will label
20 and under what conditions they will label.

21 The only other requirement would be falling back
22 to the requirements in the Radiation Safety Committee. How
23 we have resolved that area, we have asked for procedures for
24 the interdepartmental, interdisciplinary communication
25 between departments, and that was one of the things to

1 offset the fact that we would no longer require a Radiation
2 Safety Committee.

3 COMMISSIONER MCGAFFIGAN: Can I --

4 CHAIRMAN JACKSON: Please.

5 COMMISSIONER MCGAFFIGAN: On the Radiation Safety
6 Committee, which wasn't -- isn't it true that most of the
7 written comments that we received from Radiation Safety
8 Officers and the health physics community were against
9 giving up the Committee for fear that it would get lost and
10 other reasons, that the main impetus for doing it came from
11 the hospital administrators.

12 I am not arguing for retaining all the
13 prescriptive elements of the current rule, but that the
14 notion of having a Radiation Safety Committee that doesn't
15 get lost in the hospital infrastructure is something that
16 the people who are in the field working in these hospitals
17 are arguing for. Maybe they are all about to get fired by
18 their hospital administrators, I don't know, but I am a
19 little troubled by the disconnect there.

20 MS. HANEY: It is true that the comments from the
21 Health Physics Society and the American Association of
22 Physicists in Medicine supported retention of the Radiation
23 Safety Committee.

24 We do have a lot of other comments from other
25 organizations, however, that do support the deletion of the

1 Committee.

2 Again, I believe the proposed rule would still
3 address the concerns of the Radiation Safety Officer. The
4 authority for the day-to-day running of the program is
5 delegated from licensee management to the Radiation Safety
6 Officer. We are looking for that delegation in writing, so
7 there is a clear path between the licensee, Chief Executive
8 Officer, and the Radiation Safety Officer and because of
9 that I don't think it would get lost.

10 COMMISSIONER DIAZ: If I understand the proposal,
11 it's not to delete the Radiation Safety Officer --

12 MS. HANEY: No.

13 COMMISSIONER DIAZ: -- but the Radiation Safety
14 Committee.

15 MS. HANEY: That's correct, yes. We would still
16 maintain the Radiation Safety Officer.

17 COMMISSIONER DIAZ: For functions and
18 communications that are important to safety should be
19 maintained through the Radiation Safety Officer.

20 MS. HANEY: Yes.

21 CHAIRMAN JACKSON: And to have that specific
22 delegation in writing of which you spoke.

23 MS. HANEY: Right.

24 CHAIRMAN JACKSON: Okay.

25 MS. HANEY: And with that, this concludes our

1 formal presentation.

2 CHAIRMAN JACKSON: Any comments?

3 I do have one. This is on one of your backup
4 slides having to do with resolution of reportable events.
5 You almost got away.

6 It talks about the situation that meets the above
7 criteria would not be reportable if it was the result of
8 patient intervention in the treatment that could not have
9 been reasonably prevented by the licensee.

10 Now will the final determination of what is
11 reasonable be left to our licensees to make, or will that
12 determination be left to the NRC Office of the General
13 Counsel to judge on a case by case basis? Is this the
14 General Counsel Full Employment Act?

15 [Laughter.]

16 MS. HANEY: There will be some events that the
17 licensee will rule out automatically and say that it was the
18 result of patient intervention, and we would never hear
19 about them unless for example we were out doing an
20 inspection and an inspector identified it by reviewing a
21 dose log and then questioned why wasn't this reported.

22 In that particular case we would -- the inspector
23 would bring it back through the regional office through NMSS
24 and into OGC for determination of whether this falls into
25 that category or not.

1 There also will be some cases where a licensee
2 wanting to be on the safe side would call NRC and say in my
3 opinion it was caused by the patient, but I just want to
4 make sure.

5 I would expect too that in these cases where it
6 did come to NRC's attention and that there was some question
7 about what was reasonably prevented that we would also rely
8 heavily on the use of our medical consultants and the ACMUI
9 for whether they believed that it should have been a
10 reportable event.

11 CHAIRMAN JACKSON: Are inspectors going to be
12 directed to review logs from time to time?

13 MS. HANEY: No more so than what they are doing
14 now, as far as going in and looking at doing a sampling of
15 records to make sure that the program is functioning
16 properly.

17 CHAIRMAN JACKSON: All right. Commissioner?

18 COMMISSIONER DIAZ: Yes. Since you were going
19 away too easy --

20 [Laughter.]

21 COMMISSIONER DIAZ: -- I decided there's just a
22 little bit of a problem in here. In the process of
23 developing the new rule, have you come into some additional
24 knowledge of how our particular procedures and regulations,
25 or the absence of, in the area that we do not regulate --

1 say, accelerators and isotopes made by accelerators -- you
2 know, is there a compatibility or are we so far apart that
3 we don't even want to look at it right now?

4 MS. HANEY: I would say that it was mentioned at
5 some of the meetings about whether NRC would be going into
6 other areas of medicine, but we did not spend a lot of time
7 in that particular area. The Working Group had
8 representatives from an agreement state and from a state
9 that is trying to become an agreement state on the
10 committee, so there were times during the process where they
11 brought to our attention, well, this is the way it's done in
12 x-ray, this is the way that it is done in nuclear medicine.

13 There was nothing that came to our attention that
14 was a gross problem.

15 COMMISSIONER DIAZ: Yes, because I am not
16 concerned whether we do it or not. I am concerned with the
17 compatibility and consistence between processes that are
18 used in this large, growing area, compared to what we do,
19 and I think you have just kind of said that it came in bits
20 and pieces but we really didn't look at it.

21 MS. HANEY: Correct. We didn't focus on that.

22 CHAIRMAN JACKSON: Yes, Commissioner?

23 COMMISSIONER McGAFFIGAN: Not to let them off too
24 easily --

25 CHAIRMAN JACKSON: I'm sorry, Ms. Haney --

1 [Laughter.]

2 COMMISSIONER MCGAFFIGAN: -- the cardiologists
3 whom we may hear about from the next panel, one of the
4 issues that they have raised, aside from training and
5 experience, where they obviously support the proposed --
6 what the Staff is proposing -- is the issue of these
7 treatments for restenosis I think is the right medical term
8 get routinized?

9 At the moment I guess you are going to treat them
10 under 35.900, and there is a requirement that there be a
11 team including a radiation oncologist who participates in
12 the various and sundry experiments underway with various
13 treatment modalities, but when that gets routinized, and
14 they are respectfully suggesting that the radiation
15 oncologist doesn't need to be there and indeed in a real
16 medical setting where it is now a routine practice, getting
17 the cardiologist, the radiation specialist at the hospital,
18 et cetera there, that that is enough and in getting an
19 oncologist who at the moment, when it is an experimental
20 thing, they can all come together and schedule it, but that
21 is not how cardiology is practiced, so how will that,
22 whatever treatment modality wins the horse race and gets the
23 approval of the community and becomes the routine treatment
24 for restenosis or maybe there will be several, how does that
25 then transfer from 900 in your rules to some other place and

1 do you see a need at that point for a radiation oncologist
2 to be part of the team administering the health care?

3 I know we are in an impossible position as a bunch
4 of nondoctors to basically settle the scrap between the
5 cardiologists and the radiation oncologists, but we probably
6 are going to have to at some point.

7 MS. HANEY: Right now, the current rule is
8 structured with the 35.900 -- what we refer to as "emerging
9 technology" section, that you could license the
10 intervascular use under that and in fact we have had
11 conversations with the oncologists that this would be the
12 ideal place for the intervascular use to come into play.

13 There is a lot of discussion though that the
14 intervascular use that they are proposing does not differ
15 significantly from that of what is being done currently with
16 high dose rate remote afterloaders, so shouldn't it in fact
17 fall under the medical device use.

18 Right now the current framework, as you said, is
19 to have a group with an oncologist involved. As they become
20 more familiar in whichever treatment is going to end up
21 being their preferred route and as Part 35 is finalized next
22 year, I could see us having to make some tough decisions
23 next year about whether it does in fact fall under this
24 emerging technology where we would be looking at some
25 possibly different training requirements for these

1 individuals or in fact is the use that of a medical device
2 in an HDR unit and therefore it should just be treated as a
3 medical therapy device and the cardiologist should be
4 expected to have the same amount of training as a radiation
5 oncologist if they wanted to become an authorized user.

6 So I think this is an evolving process that we
7 will have to --

8 COMMISSIONER MCGAFFIGAN: I am not sure we are
9 going to have to make the decision in the next year given
10 the rate at which the technology is emerging, but I think it
11 is an issue that we are going to have to deal with at some
12 point and the cardiologists obviously do not believe that it
13 is likely that they are going to need the full training of
14 radiation oncologists to administer whatever, whichever
15 technology wins the day.

16 CHAIRMAN JACKSON: Commissioner?

17 COMMISSIONER DIAZ: Yes. Looking at the detail
18 that we are going to require on precursor events, as you
19 know, root cause analysis is deeply rooted in this
20 Commission and I am not sure if it's the Commission or the
21 entire Staff but I just want to make sure that when we go
22 into this precursor event issue that we have constrained it
23 to things that actually are licensable and can be of use
24 rather than getting into a habit of saying this has a
25 precursor.

1 What is the, from your viewpoint, what is the
2 dividing line on how you actually get into trying to
3 determine precursors?

4 MS. HANEY: What we are proposing as the dividing
5 line would be an event that would have implications outside
6 that licensee's facility.

7 Let me give you an example. That might be the
8 best way to say it.

9 You have a manufacturer that gives you a procedure
10 for calibrating -- let's use the high dose rate remote
11 afterloader where there is risk involved with use of this
12 procedure. The physicist takes and tries to implement that
13 procedure and realizes that if he does exactly what that
14 procedure says that significant exposure could occur.

15 In that case one would like to think that the
16 physicist would go back to the manufacturer and the
17 manufacturer would correct these procedures, but we also
18 believe that it would be important for NRC to hear about
19 these events so that we could consider generic
20 applicability, possibly issue an information notice, or
21 given the nature of the error, issue an NRC bulletin that
22 would require further action than just an information
23 notice.

24 COMMISSIONER DIAZ: Okay. I don't want to be a
25 broken record, but again this would be a process that would

1 be fully risk-informed in the sense that you are not going
2 to start looking for --

3 MS. HANEY: Correct. Right.

4 COMMISSIONER DIAZ: Thank you.

5 CHAIRMAN JACKSON: Okay. Well, I think before
6 they ask any more questions, or I, thank you very much.

7 We will now hear from the Advisory Committee on
8 the Medical Uses of Isotopes.

9 Good afternoon.

10 DR. STITT: Good afternoon. Good to be here, I
11 think.

12 My colleagues and I are here today representing
13 the Advisory Committee on Medical Uses. We would like to
14 start with our first viewgraph, the process. We would like
15 to say the NRC staff has been very responsive and forthright
16 in dealing with these issues with the ACMUI, both in areas
17 of agreement, as well as disagreement.

18 The regulated community has had significant
19 opportunities for input and for participation, and Cathy
20 Haney defined the myriad way we have been involved.

21 The web site has been an efficient use of
22 technology to facilitate our communication. This has
23 certainly been a very intensive time and labor process with
24 a lot of demands on the NRC staff, but we appreciate the
25 benefits that it should provide to the community.

1 In our presentation today, all of my colleagues
2 get the opportunity to speak and we will speak when spoken
3 to by you. John Graham is going to discuss the
4 recommendation for medical policy statement.

5 DR. GRAHAM: Good afternoon. I hope it was
6 serendipity that my name tag was placed at this seat since
7 it seems to be the hot one so far.

8 In its staff requirement memorandum,
9 COM-SECY-96-057, dated March 20, 1997, the Commission stated
10 that it supported continuation of the ongoing medical use
11 regulatory program with improvements, decreased oversight of
12 low risk activities, and continued emphasis on high risk
13 activities. This SRM directed staff to revise 10 CFR Part
14 35 and, if necessary, the Commission's 1979 medical policy
15 statement.

16 This policy statement has been the subject of
17 considerable review and discussion by the ACMUI since it
18 represents the guiding policy for our review and
19 recommendation on proposed regulation governing the medical
20 use of isotopes.

21 As stated in the draft proposed policy statement
22 on the medical use of byproduct material, dated June 4th,
23 1998, certain themes have emerged in ACMUI meetings,
24 public-facilitated work shops and written and electronic
25 comments that have convinced the staff that some revisions

1 of the medical policy statement are warranted.

2 These themes include insuring that the Nuclear
3 Regulatory Commission will regulate the medical use of
4 byproduct material, as necessary, to provide for the
5 radiation safety of workers and the general public, but it
6 will not intrude in the practice of medicine or with medical
7 judgments affecting patients. It limits its role in
8 regulating the radiation safety of patients to requiring
9 that the physician's directions are followed and that it
10 regulate the radiation safety of patients only where the
11 voluntary standards or compliance with these standards are
12 inadequate.

13 The ACMUI concurs with the staff-proposed revision
14 of the medical policy statement which essentially retains
15 Statement No. 1, that NRC will continue to regulate the use
16 of radionuclides in medicine, as necessary, to provide for
17 the radiation safety of workers and the general public.

18 The ACMUI is gratified by the proposed Revision
19 Statement No. 2 that NRC will not intrude into medical
20 judgments affecting patients except as necessary to provide
21 for the radiation safety of workers and the general public.

22 The ACMUI continues to advocate an alternative to
23 the staff-proposed Statement No. 3, that the NRC will, where
24 justified by risk to patients, regulate the radiation safety
25 of patients primarily to insure -- to assure the use of

1 radionuclides is in accordance with the physician's
2 directions.

3 The ACMUI recommends that NRC will regulate the
4 radiation safety of patients only where justified by the
5 risk to the patients and only where voluntary standards or
6 compliance with these standards are inadequate. Assessment
7 of the risks justifying such regulations will reference
8 comparable risks and comparable voluntary standards and
9 modes of regulation for other types of medical practice.

10 CHAIRMAN JACKSON: Let me stop you for a second
11 there. You have referenced the Atomic Energy Act in coming
12 up with this statement, because -- this is the lawyer's
13 question. You could have such a statement, is that
14 consistent with what the law requires? As opposed to saying
15 that the NRC will regulate the radiation safety of patients
16 in a manner justified by the risk to patients?

17 MS. CYR: I think -- I don't know that the Atomic
18 Energy Act requires that you -- only where justified by the
19 risk to patients. I mean I did not view this as a
20 jurisdictional statement, I viewed this as sort of a
21 judgment statement about where it was appropriate to --

22 CHAIRMAN JACKSON: Give attention.

23 MS. CYR: Right. To give attention.

24 CHAIRMAN JACKSON: Okay. And then my question to
25 you, Mr. Graham, is there a compendium of risk from medical

1 treatments that would provide this reference that you are
2 talking about here?

3 DR. GRAHAM: There is certainly not, to my
4 knowledge, having sat on the Advisory Committee for three
5 and a half years now, I believe, any simple document that we
6 could go to that would, in clear black and white, draw those
7 lines of risk. And I think what we are suggesting in the
8 next part of our recommendation gets to the issue of having
9 an ongoing process over the review of those risks and
10 separating them into low risk versus high risk categories.
11 And we speak specifically to the concerns that were raised
12 by General Counsel and some of the background documentation
13 that we received. So maybe it will become clearer in a
14 couple of minutes.

15 COMMISSIONER DIAZ: Okay. Because I have got a
16 little problem with assessment of risk, comparable. It
17 seems like in certain cases when the assessment methodology
18 is sharply defined or it is better defined, that that should
19 be taken not as an additional imposition but as a
20 definition, that when you do risk analysis or you actually
21 establish risk inside a regulation as a goal or as a
22 guidance, we might have better information that are
23 available from voluntary methods or comparable voluntary
24 standards in medicine, and we should not forsake those.

25 Am I making myself clear? In other words, I have

1 got a problem with this phrase "assessment of the risk
2 justifying" -- "will reference comparable risks and
3 comparable voluntary standards" and you just say that, you
4 know, there is really not a medical compendium, like the
5 Chairman said, that actually will reference risk. Shouldn't
6 we serve better by, in the cases which we have a risk
7 assessment, that it is well defined even it is not
8 comparable to other practice of medicine.

9 My impression is that medicine has so many
10 variations that are based in the practice of medicines, the
11 different biological responses of individuals, et cetera, et
12 cetera, that we might be able to focus more on the use of
13 radioisotopes or radionuclides in medicine and address that,
14 you know, specifically, rather than trying to compare it
15 always to other areas of medicine. I think some comparisons
16 might be valid. I am concerned that you are trying to put
17 this in a context that is very, very broad and I am not sure
18 that that breadth is justified.

19 DR. GRAHAM: Well, I think it was a concern, and I
20 will request clarification from other committee members, as
21 appropriate. But I think it was a concern of the ACMUI
22 that, in particular, it was the threshold of risk and the
23 definition of threshold that needed to be evaluated in the
24 broader context of risk assessment as it would occur in the
25 other practice of medicine.

1 DR. STITT: I can add to that. If you understand,
2 and you do understand the composition of the committee,
3 basically, clinicians who are working in various parts of
4 medicine, and so radiation medicine and radiation risk is a
5 part of what we do. And so there are some philosophic
6 differences. A patient who is having an anaesthetic to have
7 radioactive isotopes used, a clinician would view several
8 parts of that risk, in addition to, potentially, the
9 antibiotic that might be used.

10 But when you strictly extract out, as you are
11 probably more likely to do, looking at the radiation risk
12 only, I think this helps to explain, at least to you, where
13 we are using this in a broader context than you might be
14 willing to do.

15 CHAIRMAN JACKSON: Okay. Commissioner.

16 COMMISSIONER McGAFFIGAN: I'll ask the question I
17 asked earlier. If a majority of the Commission decides that
18 it wants to retain patient notification, would it be more
19 honest to say, in 2, which is essentially the same -- or at
20 least start's the same as the staff -- or is the same, "will
21 not intrude" go to -- back to the "will minimize intrusion"?
22 I mean every letter that I have seen on patient notification
23 starts off by saying that this is an intrusion into medical
24 judgment.

25 DR. GRAHAM: If I could, I would like to

1 specifically discuss patient notification as an example of
2 this.

3 COMMISSIONER MCGAFFIGAN: We'll get to that.

4 DR. GRAHAM: It's about two paragraphs. I think
5 it will sharpen or focus the discussion. It would help me
6 in answering that question.

7 COMMISSIONER MCGAFFIGAN: Okay.

8 DR. GRAHAM: So let me put it in that context.

9 COMMISSIONER MCGAFFIGAN: We can come back --

10 DR. GRAHAM: And I will pursue it more
11 specifically after about a minute from now.

12 COMMISSIONER MCGAFFIGAN: Okay. The second
13 question, my sense is that the whole medical policy
14 statement stuff, that we told the staff to go do Part 35,
15 and we said, as appropriate, you know, argue about this
16 stuff, because this isn't rules. This is a policy
17 statement. Policy statements don't amount to all that much,
18 to be honest with you, in regulatory space.

19 But I regard -- I look at this and I say, oh, my
20 gosh, this is Institute of Medicine and all that
21 regurgitated. We are back to arguing about whether there is
22 a function for the NRC in this area, and the purpose of your
23 policy statement, as opposed to the staff's policy
24 statement, is to constrain us down into the smallest box you
25 think we can tolerate for what the NRC role is. I mean is

1 that an honest -- it that a factual assessment?

2 DR. STITT: Commissioner Jackson, I think that as
3 we have worked and worked this, we feel that the medical
4 policy statement is the centerpiece from which regulation
5 emanates. And I think that when you look at our
6 conversations and our minutes and compare them to the
7 proposal, they actually have many areas of inter-digitation
8 and are very close, and I don't feel that the sense of our
9 work has been a reflection of the Institute of Medicine
10 report. We took our direction from you, as well as from the
11 staff, after we had that Institute of Medicine discussion, I
12 believe two years ago. And I really believe that we are
13 looking at some fine points here, and probably different
14 interpretations based on whether you are coming from the
15 regulated community or the regulator community.

16 John, do you want to continue?

17 DR. GRAHAM: In the proposed rule revision of 10
18 CFR Part 35, Medical Use of Byproduct Material, which is
19 dated June 4th, 1998, the Commission directed the
20 restructuring of Part 35 into a risk-informed, more
21 performance-based regulation. The ACMUI recognizes the
22 challenge of defining comparable risk and we look forward to
23 working with the staff of the NRC to achieve the
24 Commissioners' goal of developing risk-informed, more
25 performance-based regulation.

1 The regulation of patient notification following a
2 medical event, which is slide No. 7 in your packet,
3 represents a concrete example of regulation where there is
4 no clear data documenting risk which justifies such
5 regulation due to risk to the patient. Patient notification
6 is fundamental to the practice of the medicine and there is
7 widespread agreement regarding the need to notify the
8 patient and the patient's attending physician, but the
9 requirement by federal regulation to present the patient
10 with an official written notification which will be sent to
11 the Nuclear Regulatory Commission distorts these lines of
12 communication and can create unwarranted fear and concern on
13 the part of the patient.

14 The ACMUI has a fundamental concern that these
15 medical events, at the threshold defined in the regulation,
16 may not constitute a serious risk to the patient's health.
17 The ACMUI advocates continued discussion with NRC staff to
18 protect the patient's safety and promote the practice of
19 medicine.

20 CHAIRMAN JACKSON: Now, let me make sure, you said
21 something. Is the fundamental issue what the threshold is,
22 or having a requirement at all?

23 DR. GRAHAM: Speaking as one member of the
24 Advisory Committee on the Medical Use of Isotopes, I have
25 sat through hours and hours of meetings discussing how to

1 define the threshold and how to balance out the public
2 safety, the safety of workers, the legitimate protection of
3 the safety of patients and yet retain the practice of
4 medicine. So, yes, I think it is an issue of the threshold.

5 CHAIRMAN JACKSON: So it is the issue of the
6 threshold.

7 Commissioner McGaffigan.

8 COMMISSIONER MCGAFFIGAN: There are a couple of
9 other issues. You mentioned sending the same notification
10 -- the current rule requires that we pretty much -- the
11 report you submit to us has to be potentially made available
12 to the patient, and, indeed, that probably is the practice
13 out there, you just give them the report you send to us.
14 The report you send to us is written in, presumably,
15 bureaucratic gobbledygook that we are good at receiving, and
16 the patient may not be. So what if you distinguished the --
17 or you weren't required any longer to provide the report
18 that you give to us, but something that was more
19 patient-friendly in the way of describing what the impact of
20 this medical event might be on the patient? Would that
21 relieve some of the concern?

22 DR. STITT: John is looking at me. John is a
23 hospital administrator so he is not notifying patients.

24 There are some very specific time periods in the
25 rule as to who is notified when and some if it is

1 notification. Other parts is sending a copy of the report
2 and I think that is one of the issues. It's one thing to
3 send a notice to an individual and it is another thing to
4 send a copy of a report that may engender a lot of anxiety
5 because they simply don't understand what is in it.

6 COMMISSIONER MCGAFFIGAN: Right.

7 COMMISSIONER DIAZ: I'm sorry -- no, go ahead.

8 COMMISSIONER MCGAFFIGAN: This issue of risk
9 levels, I mean I suspect the medical community is not wild
10 about this either, but there's currently passed by the
11 Senate and under consideration in the House a Mammography
12 Standards Act that will authorize the FDA to have patient
13 notification to individuals who receive bad mammograms, and
14 my recollection is mammogram -- you know, I'll refer it to
15 the doctors -- but if we are talking about thresholds, if
16 Congress were to pass that law, what is the judgment they
17 are making about rems to a woman which may have been
18 misapplied, that they now want the patient to be notified
19 on? Is it of comparable magnitude to the numbers that we
20 have in our rule, the 5 rem and 50 rem to an organ and all
21 that?

22 DR. STITT: No. The mammogram quality standards
23 refer to deficiencies in the mammography program so it is a
24 systematic program approach.

25 COMMISSIONER MCGAFFIGAN: You are talking about

1 the laws that exist today but I am talking about the law
2 that the Senate has passed, the House is considering which
3 goes to individuals.

4 DR. STITT: Are you talking about a particular
5 dose from a mammogram or are you talking -- the mammogram
6 quality standards have several issues.

7 One is the quality of the program, the units that
8 are being used, and also reflect the potential for serious
9 harm from the mammograms.

10 The reporting that we have been talking about in
11 patient notification really is any particular patient, a
12 specific event involving that patient, and my understanding
13 of what we discuss in our Part 35 is quite different from
14 mammography standard requirements.

15 COMMISSIONER McGAFFIGAN: As they exist today but
16 not as the Senate and the Congress may -- I think
17 Congresswoman Morella and various Senators, Snowe and
18 others, are advocating an amendment to that law that would
19 require something very similar to what we require today, so
20 my question was just laying that aside, if Congress were to
21 pass a law that requires patient notification for --
22 individual patient notification in the case of mammography,
23 would they be essentially endorsing a threshold similar to
24 the threshold that we have today in our rules, if you try to
25 convert it to personrem?

1 DR. STITT: Mammography is diagnostic. It's a
2 screening. It's a diagnostic test. This is entirely
3 different from the therapeutic, so you are not measuring
4 doses. In a woman's having a mammogram there is no dose
5 that is being measured at that point in time so I think the
6 two are very difficult to compare.

7 Now there is a notification requirement in the
8 mammography standards and that is a notification as to the
9 report -- that is, the report that is generated from that
10 study, and that is one level of reporting and the other
11 level is the program and how that program is carried out in
12 an institution.

13 If there are programs that are poorly monitored
14 with poor equipment, screens, films, et cetera, my
15 understanding is that is where the reporting to the health
16 care provider or the referring physician and the patient
17 comes in.

18 CHAIRMAN JACKSON: Commissioner?

19 COMMISSIONER DIAZ: Yes. Let me go back to
20 something you say -- just trying to refocus on the risk and
21 if I might quote, it says, you know, the medical event might
22 not constitute a serious risk to the patient health, and
23 that may not constitute it becomes an issue.

24 How about if a physician determines that it does
25 constitute a serious risk to the patient health? What will

1 be your recommendation regarding a patient notification?
2 Just assume you make the determination it is a serious risk.
3 Then what should be done regarding patient notification?

4 DR. STITT: It would be in keeping with what we
5 would do in that circumstance or any other. You talk to the
6 patient about what has transpired, be it a surgical event, a
7 medication event --

8 COMMISSIONER DIAZ: But I mean in relationship to
9 our obligations.

10 DR. STITT: I guess off the top of my head my
11 response would be this is something that needs give and take
12 with the NRC Commissioners and the Staff and the ACMUI.

13 If we are looking at specific thresholds, that
14 would open up an area of discussion for the future.

15 CHAIRMAN JACKSON: Would you go on?

16 DR. STITT: We are going to look at a viewgraph
17 entitled Radiation Protection Program. This brings up some
18 issues that have already been discussed.

19 The entire section has become less prescriptive
20 and the ACMUI concurs with the proposed rule. In
21 particular, we agree that the elimination of the
22 prescriptive requirement for Radiation Safety Committee is
23 one that can be workable throughout the programs in the
24 country.

25 The proposed regulation permits the licensee to be

1 flexible and to maintain a Radiation Safety Committee
2 consistent with the scope of their operations or to unfold
3 that within the other requirements for the hospital
4 operation.

5 CHAIRMAN JACKSON: Go on.

6 DR. STITT: Viewgraph on Written Directives.
7 Dennis Swanson.

8 MR. SWANSON: Written Directives in COMSECY
9 96-057, the Commission directed NRC Staff to re-evaluate and
10 revise the Quality Management Program requirements to focus
11 on those requirements that are essential for patient safety.
12 For example, requiring written directives confirming patient
13 identity and verifying the correct dose.

14 The proposed rule addresses these concerns of the
15 Commission, minimizes prescriptive requirements, provides
16 for a performance-based approach to the Quality Management
17 Program, and ensures patient safety. Thus, the ACMUI
18 concurs with the proposed ruling which I think it's probably
19 to emphasize however that when you go to a performance-based
20 rule where you are going to have individual institutions
21 developing their own procedures, that is going to definitely
22 a change in how your inspection people take a review of that
23 program.

24 Your inspections can't be as prescriptive either.
25 Your inspectors are not going to have prescriptive guidance,

1 prescriptive NRC approved procedures by which to evaluate
2 those programs so it's going to require certain changes in
3 how the inspections work. That's important to point out.

4 CHAIRMAN JACKSON: Yes.

5 COMMISSIONER MCGAFFIGAN: How do you violate this
6 rule? Given how it is written, the Chairman asked earlier,
7 is it enforceable, of the Staff, but it is how hard you have
8 to work to violate the rule as it is drafted at the moment.

9 MR. SWANSON: Well, it is a performance-based rule
10 so obviously if you have problems with misadministrations or
11 medical events -- then those problems can derive from
12 different mechanisms.

13 Number one, you may not as an institution have the
14 appropriate set of procedures in place to appropriately
15 provide those protections, okay, so that could be a
16 violation in itself, that you do not have the appropriate
17 procedures in place to address verification of identity,
18 verification of the proper dose, et cetera.

19 Then a second way that medical events could occur
20 is you could have the appropriate procedures in place and
21 the individuals aren't properly following those procedures.
22 In that case, then you have violated the training
23 requirements for the people working at institutions with
24 regard to them following the appropriate procedures and what
25 those procedures are.

1 CHAIRMAN JACKSON: Go ahead.

2 DR. STITT: Written Directors and Procedures --
3 Dennis?

4 MR. SWANSON: I think we just did that.

5 DR. STITT: I'm sorry, Reportable --

6 MR. SWANSON: Unless you would like me to repeat
7 it?

8 [Laughter.]

9 DR. STITT: I think we got it the first time.
10 Reportable Events.

11 MR. SWANSON: With regard to medical events, the
12 ACMUI concurs in general with the proposed rule as it
13 relates to the definition of medical events and the
14 reporting of medical events to the NRC.

15 It is recognized that medical events associated
16 with patient interventions or exposure of the wrong
17 treatment site are difficult issues to define.

18 The ACMUI has noted that the background section to
19 the proposed rule addresses specifically these gray areas
20 and requests respective public comment. The ACMUI will
21 continue to address these two problem areas in particular.

22 With regard to the proposed regulations addressing
23 the unattended dose to the embryo fetus and nursing child,
24 the ACMUI recognizes the Congressional mandate for the NRC
25 to capture and report abnormal occurrences and that the NRC

1 has defined the unintentional radiation exposure of an
2 embryo fetus or nursing child to be an abnormal occurrence.

3 The proposed rule appropriate relies on industry
4 standards for the prevention of such exposures. ACMUI
5 recommends a final regulation that avoids a real or de facto
6 requirement for the mandated pregnancy testing of women of
7 childbearing potential.

8 And with regard to precursor events, ACMUI does
9 not feel that it is necessary to have a Part 35 rule
10 addressing the reporting of precursor events, that the
11 reporting of precursor events as defined in the proposed
12 rule is adequately addressed through existing NRC and FDA
13 regulations and voluntary reporting programs.

14 However, should the reporting of precursor events
15 be retained within the Part 35 rule it's imperative that the
16 responsibility of determining what needs to be reported be
17 defined. In other words, the clause "in the opinion of the
18 Radiation Safety Officer" or "authorized user" or a clause
19 which states "in the opinion of the licensee" must be
20 retained in order to prevent second-guessing on the part of
21 NRC inspectors.

22 DR. STITT: Training and experience will be
23 discussed by Dr. Alazarki.

24 COMMISSIONER McGAFFIGAN: Could I just stop on
25 that one for a second. That is in there at the moment, this

1 "in the opinion of the Radiation Safety Officer" or
2 "authorized user" -- the precursor events, if they are
3 precursors of the sort that were discussed earlier, is the
4 one day no later than the next calendar day overly
5 burdensome? These are things that were -- that when we get
6 them we are going to do things like put out an information
7 notice or watch, just monitor the process as the
8 manufacturer modifies the device or whatever, but it is not
9 of the urgency that perhaps would require a one-day notice.

10 Is that something you all talked about, the one
11 day in the precursor?

12 MR. SWANSON: No, I don't think we have
13 specifically discussed that specific reporting requirement.
14 My personal opinion on that is if you are going to leave it
15 in the opinion of the Radiation Safety Officer or the
16 opinion of the licensee is it one day from their
17 determination that it is a precursor event? In that case,
18 it is probably not a major burden.

19 If it was within one day of when the event
20 occurred, that would be a burden because it does take some
21 time to evaluate that event.

22 DR. STITT: Go ahead, Dr. Alazarki.

23 DR. ALAZARKI: In formulating ACMUI's
24 recommendations for training and experience requirements and
25 in keeping with Chairman Jackson's opening remarks, ACMUI

1 did attempt to heed stakeholder input but this has not been
2 easy and in fact it's quite problematic because there are so
3 many diverse views among the stakeholders.

4 Nonetheless, for 35.100 and .200 recognizing low
5 risk of diagnostic procedures, ACMUI supports the proposed
6 significant decreases in training and experience
7 requirements to reflect only competence in radiation safety.
8 ACMUI chose not to define criteria to determine clinical
9 competence, which is in contrast to ACMUI's recommendation
10 about 35.400 and .600 where high risk of the procedures
11 mandated linkage to clinical competence.

12 ACMUI did strongly recommend that the decreased
13 training and experience requirements for 35.100 and .200 be
14 conditioned on physician candidates passing an
15 NRC-administered examination designed to assure competence
16 in radiation sciences and practices.

17 Further, central to its recommendation is that the
18 currently recognized appropriate certifying bodies for
19 radiation medical practice competence continue to be relied
20 upon for assurance of clinical competence of individual
21 physicians. We recommend a clear statement as part of the
22 regulatory language from NRC that licensure does not
23 constitute credentialing for radiation medical practice.

24 ACMUI was split in its voting on the
25 recommendation of training and experience for 35.300 --

1 35.300 provides training and experience requirements for
2 unsealed source radiation therapies, often using very high
3 doses of Iodine-131, which are certainly high risk
4 procedures to patients and personnel and require special
5 consideration for protecting the general public.

6 As such, there is a definite similarity to 35.400
7 and .600 which ACMUI agreed required linkage to clinical
8 competence upholding the current 500 plus 200 hours, as part
9 of a three year ACGME approved residency program in
10 Radiation Oncology as training and experience requirements.

11 Part of the committee would have favored
12 comparable requirements for unsealed source byproduct
13 radionuclide therapy procedures. As written however, the
14 proposal is not to distinguish between the high dose usage
15 and low dose, low risk diagnostic training and experience
16 requirements.

17 We anticipate that there will be an abundance of
18 spirited comments, hopefully, polite, in response to the
19 Federal Register request for comments. The ACMUI advocates
20 continued involvement with staff in reviewing these comments
21 and formulating modifications, as deemed warranted.

22 As we understand it, the comment period planned is
23 75 days, starting in July, but because of the importance of
24 these issues to so many diverse groups of practitioners and
25 institutions, we urge the comment period to be extended

1 beyond the summer, when so many people are away on vacation,
2 for 120 days. Thank you.

3 CHAIRMAN JACKSON: Okay.

4 DR. STITT: Shall we go ahead?

5 CHAIRMAN JACKSON: Any further questions?

6 COMMISSIONER MCGAFFIGAN: Well, why don't I try
7 the questions I asked earlier. The endocrinologists, and
8 you just discussed it some degree, but they basically take
9 the point of view that their 80 hours which are in the rules
10 at the moment are adequate and there isn't a risk basis for
11 extending the 80 to 120 and making the other conforming
12 changes, and they are arguing that the staff took a cookie
13 cutter approach to that area.

14 What is your opinion on that?

15 DR. ALAZARKI: Let me first call attention to a
16 few other things and then bring it together on the
17 endocrinologists. There are about, probably in the
18 neighborhood of 15,000 board certified radiologists who use
19 radiation material, radioactive byproduct material in their
20 practices. There are about -- the Society of Nuclear
21 Medicine and the American College of Nuclear Physicians
22 jointly have a membership of about 12- to 14,000, but, of
23 those, probably about 4,000 actively practicing physicians
24 use these materials.

25 As I understand the numbers, there are about 300

1 NRC licensed endocrinologists using these materials, and
2 --out of about 7,000. So less than half a percent of all of
3 endocrinology, but a very small number compared to the other
4 users. And, further, I believe that most of the
5 endocrinologists who are using radioactive materials are
6 using it to treat hyperthyroidism, not thyroid cancers,
7 although there may be some.

8 The high risk in radionuclide therapy with I-131
9 is the cancer therapies, not the hyperthyroidism. So there
10 may be some compromise that might be -- that might work very
11 well for all concerned in terms of taking out the
12 hyperthyroids and putting them perhaps closer to the
13 diagnostic groups, which would not alter their requirements
14 significantly, I don't think.

15 CHAIRMAN JACKSON: But it would introduce the need
16 to have a restriction.

17 DR. ALAZARKI: Yes. It would change the way in
18 which --

19 CHAIRMAN JACKSON: Right.

20 DR. ALAZARKI: Right. It would.

21 CHAIRMAN JACKSON: And so it would create a
22 bimodal distribution --

23 DR. ALAZARKI: Alternatively --

24 CHAIRMAN JACKSON: -- of endocrinology.

25 DR. ALAZARKI: Alternatively, they are such a

1 small number participating that, you know, if you don't want
2 to start making exceptions like that, which I think is
3 totally understandable, then that is it, these are the
4 requirements.

5 COMMISSIONER McGAFFIGAN: But for the physician
6 who is just treating hyperthyroidism, it is an increase and
7 it is an additional entry barrier for somebody who is --

8 DR. ALAZARKI: Only 300 though out of multiple
9 thousands who we are talking about.

10 CHAIRMAN JACKSON: Are there endocrinologists that
11 do both treatments, for hyperthyroidism --

12 DR. ALAZARKI: There may be. Very, very few.

13 CHAIRMAN JACKSON: Very few.

14 DR. ALAZARKI: Very, very few.

15 CHAIRMAN JACKSON: Okay.

16 COMMISSIONER McGAFFIGAN: Then the brachytherapy
17 -- not the brachytherapy. The Strontium-90 applicators, you
18 would agree that the increase there is warranted given the
19 history --

20 DR. ALAZARKI: Absolutely.

21 COMMISSIONER McGAFFIGAN: -- that we have had with
22 that?

23 DR. ALAZARKI: Right.

24 COMMISSIONER McGAFFIGAN: Okay.

25 DR. ALAZARKI: Right.

1 CHAIRMAN JACKSON: Commissioner? You wanted to
2 make a comment, Mr. Swanson?

3 MR. SWANSON: Yes. With regard to that, from my
4 perspective, probably why the ACMUI was split on the vote on
5 Part 300 deals with, if you are truly taking a risk-informed
6 approach to these regulations, and if you look at the risk
7 of brachytherapy, for example, versus the risk of giving
8 four millicuries or 100 millicuries of I-131, it is hard to
9 argue that, you know, the internal administration of a
10 radioactive drug, I-131, is just as risky, if not more risky
11 than brachytherapy. So how can you justify having 700 hours
12 and three years of training here and 80 hours over here?
13 Okay.

14 So one of the problems with the training and
15 experience requirements, as I see it, is we are going to
16 have to look at uniformity across these sets of
17 requirements. And that's, in fact, what I think led to some
18 of the split vote in looking at the Part 300.

19 Let me also remind you that 40 hours is only week
20 of training, okay. It's not like we are talking a lifetime
21 on behalf of the endocrinologist.

22 CHAIRMAN JACKSON: Thank you. Well, I would like
23 to thank each member of the staff and each of the members of
24 the Advisory Committee on Medical Uses of Isotopes for
25 today's briefing.

1 COMMISSIONER McGAFFIGAN: Did they get finished?

2 CHAIRMAN JACKSON: Were you done?

3 COMMISSIONER McGAFFIGAN: There is one more
4 viewgraph.

5 CHAIRMAN JACKSON: I'm sorry.

6 DR. STITT: One more viewgraph. There is one
7 viewgraph. We had very little to say. I would be glad to
8 -- I'll let you continue.

9 COMMISSIONER McGAFFIGAN: Well, that's an
10 interesting viewgraph because the word "enforcement" --

11 CHAIRMAN JACKSON: Why don't we talk about that
12 viewgraph.

13 COMMISSIONER McGAFFIGAN: So I don't want to let
14 them off the hook that easily.

15 CHAIRMAN JACKSON: Thank you.

16 DR. STITT: No, we would like to -- in fact, I was
17 pushed to leave this in. We were thinking about putting
18 this one aside. The ACMUI recognizes the performance-based
19 approach taken by the NRC staff in the development of
20 guidance documents and license submission requirements. The
21 ACMUI looks forward to continuing our work with the NRC
22 staff in these areas. That's pretty simple.

23 COMMISSIONER McGAFFIGAN: That covers this last
24 viewgraph?

25 DR. STITT: That covers that slide.

1 COMMISSIONER MCGAFFIGAN: Sorry.

2 COMMISSIONER DIAZ: The last bullet on that --
3 [Laughter.]

4 DR. STITT: No, it's easy to address, because as
5 we were having our pre-sessions, we didn't get into that, so
6 there is -- that is a non-entity right now.

7 CHAIRMAN JACKSON: So you put it on the slide for
8 purposes of stimulation.

9 Well, the Commission, as always, will give serious
10 consideration to the views expressed today as it reviews the
11 staff's proposal for the revision of 10 CFR Part 35, the
12 Medical Policy Statement.

13 It is clear that in many areas the staff and the
14 Advisory Committee are in agreement as to the revisions that
15 are necessary, but as in many things, the areas of
16 disagreement will obviously require more attention by the
17 Commission in its review of the two papers.

18 So let me thank again the staff and the Committee,
19 and I would not that the Commission recognizes that the
20 staff's development of the draft proposed rule, the
21 associated draft guidance and the recommendations for
22 revision of the medical policy statement in the time period
23 provided was no small feat. However, it is now the
24 performance standard.

25 [Laughter.]

1 CHAIRMAN JACKSON: Therefore, I would like to
2 thank the staff for their diligence over the last year on
3 this expedited rulemaking and let those in the reactor world
4 understand the standard.

5 And if there is nothing more, we are adjourned.

6 [Whereupon, at 3:32 p.m., the meeting was
7 concluded.]
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CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: MEETING WITH ADVISORY COMMITTEE ON
MEDICAL USES OF ISOTAPES (ACMUI) AND
BRIEFING ON PART 35 QM RULE -- PUBLIC
MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, June 17, 1998

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Rose Yenson

Reporter: Jon Hundley

Title: Meeting with Advisory Committee on Medical Uses of Isotopes (ACMUI) and Briefing on Part 35 QM Rule

Scheduled: 2:00 p.m., Wednesday, June 17, 1998 (PUBLIC)

Duration: Approx 1-1/2 hrs

Participants: ACMUI 30 mins

- Judith Anne Stitt, M.D., Chair
University of Wisconsin Hospital & Clinics
Department of Human Oncology
- Naomi Alazraki, M. D.
Professor of Radiology and Co-Director of Nuclear
Medicine, Emory University School of Medicine, and
Chief of Nuclear Medicine Veterans Affairs Medical
Center, Atlanta, GA
- Dennis P. Swanson, M.S., B.C.N.P.
Associate Professor and Assistant Dean
University of Pittsburgh, School of Pharmacy
- John Graham
Hospital Director, St. Mary Hospital

NRC 30 mins

- Joe Callan (or Hugh Thompson)
- Carl J. Paperiello
- Donald Cool
- Cathy Haney

- Topics:**
- Part 35 revision process
 - ACMUI recommendation for Medical Policy Statement
 - Radiation Protection Program
 - Written directives and procedures for administrations requiring written directives
 - Reportable Events
 - Notification following medical events
 - Training and experience
 - Licensing and enforcement programs

REC'D BY SECY

10 JUN 98 5: 20

ACMUI ANNUAL COMMISSION BRIEF

Judith Stitt, M.D., Chair

Naomi Alazarki, M.D.

Dennis Swanson

John Graham

PART 35 REVISION: PROCESS

- NRC staff interactive and responsive
 - ACMUI, subcommittees
 - Regulated community
 - Public meetings
- Website used extensively
- Time and labor intensive

ACMUI RECOMMENDATION FOR MEDICAL POLICY STATEMENT

- The NRC will continue to regulate the use of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
- The NRC will not intrude in the medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public.
- The NRC will regulate the radiation safety of patients only where justified by the risk to the patients and only where voluntary standards or compliance with these standards are inadequate. Assessment of the risk justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice.

RADIATION PROTECTION PROGRAM

- Concur with proposed rule (Section 35.24)
- Rely on Part 20 and Section 35.24
- RSO and RSC functions vary by licensee
- Licensee flexibility

WRITTEN DIRECTIVES AND PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

- Rule should list the minimum requirements for a program to provide high confidence that the treatment dose is implemented as written
- Concur with proposed rule

REPORTABLE EVENTS

- Medical event
 - Wrong treatment site (dose threshold)
 - Patient intervention
- Unintended dose to embryo/fetus and nursing child
- Precursor event

NOTIFICATION FOLLOWING A MEDICAL EVENT

- The ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing state laws and medical ethics.

TRAINING AND EXPERIENCE

- §35.100 (Unsealed - uptake, dilution, excretion) and §35.200 (unsealed - imaging and localization)
 - Concur with proposed rule
- §35.300 (unsealed - written directive required)
 - Clinical care and radiation safety cannot be separated
 - Concern by some ACMUI members rule does not contain adequate T&E requirements
- §35.400 (manual brachytherapy) and 35.600 (therapeutic medical devices)
 - Concur with proposed rule
 - Clinical care and radiation safety cannot be separated
- ANP, AMP, RSO
 - concur with proposed rule

OTHER AREAS

- Use of industry standards
- NRC review of licensee procedures as part of licensing process
- Licensee use of guidance documents
- Enforcement program



REVISION OF 10 CFR PART 35
"MEDICAL USE OF BYPRODUCT MATERIAL"
and
"MEDICAL USE POLICY STATEMENT"

BRIEFING OUTLINE

- Process and Schedule
- Approach
- Medical Policy Statement
- Cross-Cutting Issues
- Net Impact on Licensees

PROCESS

- Working Group and Steering Group used to develop rule alternatives, revised Medical Policy Statement, and proposed rule text with associated guidance.
- Facilitated public meetings held in
 - Philadelphia, PA (10/97)
 - Chicago, IL (11/97)
 - Los Angeles, CA (10/97)All Agreement States Meeting
- Strawman rule placed on INTERNET January 30, 1998

APPROACH

- Started with the identification and discussion of key cross-cutting issues, including SRM items.
- Changed licensing philosophy to significantly reduce level of effort for licensing reviews by no longer requiring submittal and approval of licensee procedures.
- Developed NUREG 1556, Volume 9, "Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Medical Use Licenses" in parallel with rule. No additional requirements in NUREG.
- Relied on requirements in other portions of Title 10 (e.g., Parts 20 and 30) and eliminated separate Part 35 requirements, where appropriate.

MEDICAL POLICY STATEMENT

- Major area of discussion at public meetings
- Wide variety of viewpoints
- Key elements
 - Provide for radiation safety of workers and public
 - Do not intrude into medical judgements
 - Focus NRC regulation on assuring that use of radionuclides is in accordance with physician's directions

PROPOSED MEDICAL POLICY STATEMENT

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgements affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, where justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

CROSS-CUTTING ISSUES

- Radiation Safety Committee
- Quality Management Program
- Reportable Events
- Notification Following a Medical Event
- Training and Experience

RESOLUTION OF TRAINING AND EXPERIENCE

- The requirements for T&E would be risk-informed and focused on radiation safety.
- Individuals would complete a structured educational program that consists of didactic training and practical experience.
- All individuals would demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization approved by NRC or an Agreement State.

AREAS OF SIGNIFICANT REGULATORY BURDEN REDUCTION

- All Modalities -

- Deletion of Radiation Safety Committee
- Deletion of Quality Management Program

REGULATORY BURDEN REDUCTION

- Diagnostic Uses -

- License amendment no longer required for changing areas of use
- Measurement of molybdenum-99 concentration no longer required for every elution. Proposed rule would require measurement only on first elution/extract of a generator

- Therapeutic Uses -

- License amendment no longer required for individual to work as a medical physicist if the individual is certified by specialty organization approved by NRC

AREAS OF INCREASED REGULATORY BURDEN

- Develop, maintain, and implement procedures required by rule, rather than as part of licensing application
- Reporting requirements added for unintended dose to embryo/fetus or nursing child and for precursor events
- Output measurements required for all brachytherapy sources

COMMISSION BACKUP VIEWGRAPHS

RESOLUTION OF RSC

- Requirement for a licensee to have a Radiation Safety Committee deleted
- New § 35.24, Authority and Responsibility for the Radiation Protection Program, provides licensee flexibility in meeting objectives of a RPP
 - Licensee management must approve request for license actions; AU, ANP, RSO, medical physicist; minor changes to RPP
 - Administrative procedures for interdepartmental/ interdisciplinary coordination
 - RSO sign statement indicating awareness of radiation safety responsibilities and willingness to accept them

RESOLUTION OF QMP

- Requirement for a licensee to have a Quality Management Program deleted
- New §§ 35.40 & 35.41 retain regulatory requirements for
 - Written directives
 - Written procedures for administrations requiring written directives to provide high confidence
 - in patient identity
 - that each administration is in accordance with written directive

RESOLUTION OF REPORTABLE EVENTS

- Medical Event -

- Dose threshold established as 0.05 Sv (EDE), 0.5 Sv to organ or tissue, or 0.5 Sv (SDE) to skin; and
- Represents
 - Total dose or dosage differs by more than 20%
 - Single fraction dose differs by more than 50% prescribed
 - Wrong pharmaceutical; wrong route; wrong site; wrong individual; wrong mode; leaking source
- Situation that meets the above criteria would not be reportable if it was the result of patient intervention in the treatment, that could not have been reasonably prevented by licensee.

RESOLUTION OF REPORTABLE EVENTS (Continued)

- Precursor Event -

- Objectives - Identify and capture events and circumstances that could lead to significant errors or systematic problems
- Precursor - Defect, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the RSO or AU, could lead to a medical event

RESOLUTION OF NOTIFICATION FOLLOWING A MEDICAL EVENT

- NRC
- Referring Physician
- Patient

STAFF PROPOSED TRAINING AND EXPERIENCE REQUIREMENTS

	Structured Educational Program		Other
	Didactic (hrs)	Practical (hrs)	
35.100, Unsealed - uptake, dilution, excretion	40	20	Physician, preceptor, exam
35.200, Unsealed - imaging and localization	80	40	Physician, preceptor, exam
35.300, Unsealed - written directive required	80	40	Physician, preceptor, exam, 5 cases
35.400, Manual brachytherapy	200	500	Physician, preceptor, exam, 1yr ACGME program, 2 yrs clinical experience
35.500, Sealed sources for diagnosis	8		Physician, Dentist, Podiatrist
35.600, Therapeutic medical devices	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
RSO	200		Preceptor, exam, 1 yr or AU
AMP			Preceptor, exam, MS, 2 yrs
ANP	700		Preceptor, exam

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- Precursor event

NOTIFICATION FOLLOWING A MEDICAL EVENT

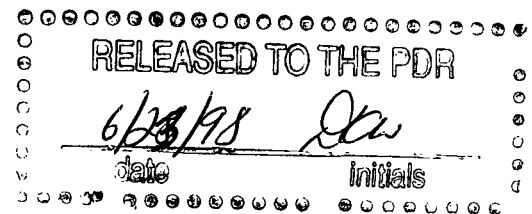
- The ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing state laws and medical ethics.

TRAINING AND EXPERIENCE

- §35.100 (Unsealed - uptake, dilution, excretion) and §35.200 (unsealed - imaging and localization)
 - Concur with proposed rule
- §35.300 (unsealed - written directive required)
 - Clinical care and radiation safety cannot be separated
 - Concern by some ACMUI members rule does not contain adequate T&E requirements
- §35.400 (manual brachytherapy) and 35.600 (therapeutic medical devices)
 - Concur with proposed rule
 - Clinical care and radiation safety cannot be separated
- ANP, AMP, RSO
 - concur with proposed rule

OTHER AREAS

- Use of industry standards
- NRC review of licensee procedures as part of licensing process
- Licensee use of guidance documents
- Enforcement program



POLICY ISSUE **(Notation Vote)**

June 4, 1998

SECY-98-127

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: DRAFT PROPOSED POLICY STATEMENT ON THE MEDICAL USE OF
BYPRODUCT MATERIAL

PURPOSE:

To request Commission approval to publish in the Federal Register a proposed revision of the Commission's 1979 Medical Use Policy Statement (MPS) (Attachment 1).

CATEGORY:

This paper addresses significant policy-making issues requiring Commission consideration and approval.

BACKGROUND:

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 2), the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the staff to revise 10 CFR Part 35, associated guidance documents, and, if necessary, the Commission's 1979 MPS. The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation.

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Marjorie U. Rothschild, OGC
(301) 415-1633

NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE AVAILABLE

An SRM of June 30, 1997, SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice" (Attachment 3), approved the staff's proposed plan for the revision of Part 35 and the MPS. The staff implemented that plan by establishing a Working Group and Steering Group, and by actively soliciting input through facilitated workshops and meetings involving the public, medical professional societies, States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The staff has benefitted from these interactions and has received many useful comments. An overview of comments on the MPS is set forth in the proposed Federal Register notice (Attachment 4). The Working Group considered this input in developing the draft proposed MPS and the MPS Statement of Consideration.

The 1979 MPS resulted from a U.S. Nuclear Regulatory Commission (NRC) review, starting in 1976, of its medical use program which included setting its future policy to provide a basis for such regulation ["Regulation of the Medical Uses of Radioisotopes," 43 FR 11208 (March 17, 1978)]. As promulgated in 1979, the MPS informed NRC licensees, other Federal and State agencies, and the general public of the Commission's general intention in regulating the medical use of byproduct material (43 FR 8242):

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal agencies, have been guided by this statement since 1979.

DISCUSSION:

The process that the staff has implemented for revising the regulation of medical use has included, as directed by the Commission, consideration of the necessity for revising the 1979 MPS. Certain themes have emerged in the meetings, public facilitated workshops, and written and electronic comments on a revised MPS, that have convinced the staff that some revisions of the MPS are warranted. Such themes include ensuring that NRC: follows the MPS in the future; does not interfere in the practice of medicine or with medical judgments affecting patients (notification following a medical event was a major concern raised by the medical community); regulates medical use of byproduct material based on the risk posed by the medical use (determined by a comparison of risk in medical use with risk involving other medical procedures) and only after determining that voluntary medical practice standards are inadequate; and limits its role in regulating the radiation safety of patients to requiring that the physician's directions are followed. Although not all these themes were incorporated into the

draft proposed MPS, they were all considered in regard to NRC's overall medical use program. Very few objections were made to NRC's current policy of regulating the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public (current MPS, Statement 1).

The ACMUI has recommended to the staff its own version of a revised MPS, most recently at its meeting on March 1-2, 1998. Generally speaking, the MPS proposed by ACMUI would make it clear that NRC will not intrude in the "medical judgments affecting patients" (rather than the current policy of minimizing such intrusions) and would drop from that statement the phrase "... into other areas traditionally considered to be a part of the practice of medicine." ACMUI also recommended that the MPS be modified to provide that an assessment of risks justifying NRC medical use regulations will reference comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice. Finally, ACMUI's recommended MPS would provide for NRC to regulate the radiation safety of patients only where voluntary standards or compliance with standards are inadequate. For the reasons stated below, the proposed MPS adopts some, but not all the ACMUI recommendations.

Based on the staff's consideration of the comments and advice of all the participants in the process described previously, as well as comments from members of the public on the Internet (via the NRC's Technical Conference Forum), the staff is proposing the following as a revised MPS to guide its future regulation of the medical use of byproduct material:

1. NRC will continue to regulate the uses of radionuclides in medicine¹ as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, where justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

This proposed MPS, in the staff's view, affirms the Commission determination that it shall continue its role in regulating the medical use of byproduct material, with emphasis on the goal of protecting the radiation safety of occupational workers, the public, and patients, while avoiding intrusion into medical judgments affecting patients. Assuring that the authorized user physician's directions for the administration of byproduct material are followed is the primary means of achieving this regulatory goal with respect to patients. The staff views this provision as limiting the area of focus, and clearly affirming that the Commission does not intend to question the physician's medical decision. Moreover, this proposed MPS continues the

¹The changes to this statement substitute the technically more accurate phrase "uses of radionuclides in medicine" for the phrase "medical uses of radioisotopes."

objective of utilizing industry and professional standards that define acceptable levels of radiation safety. As stated in the draft Federal Register notice (Attachment 4), the staff does not recommend adopting a policy of regulating medical use of byproduct material on the basis of "comparable risk" in other areas of medicine. The staff also believes that a policy of considering industry and professional standards in developing regulatory approaches is preferable to one in which determining licensee compliance with voluntary standards is a prerequisite for regulation (current MPS, Statement 2).


COORDINATION:

The Office of the General Counsel has reviewed the draft policy statement and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. Resources to develop this policy statement are included in those discussed in the paper transmitting the proposed revision of 10 CFR Part 35 to the Commission. The Office of the Chief Information Officer has reviewed the proposed policy statement for information technology and information management and concurs in it.

RECOMMENDATION:

That the Commission:

1. Approve the draft policy statement for publication in the Federal Register.
2. Note:
 - A. The proposed medical use policy statement will be published in the Federal Register for a 75-day public comment period (Attachment 4).
 - B. The appropriate Congressional committees will be informed (Attachment 5).
 - C. The Office of Public Affairs has determined that a press release should be issued (Attachment 6).
 - D. Copies of the Federal Register notice will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States and to other interested parties upon request.


E. Joseph Callan
Executive Director
for Operations

Attachments:

1. 1979 Medical Use Policy Statement
2. SRM-COMSECY-96-057, dtd 3/20/97
3. SRM-SECY-97-115, dtd 6/30/97
4. Proposed Federal Register Notice
5. Congressional Letters
6. Press Release

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Monday, June 22, 1998.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, June 15, 1998, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

DISTRIBUTION:

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ATTACHMENT 1

1979 Medical Use Policy Statement

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

COMMISSION NOTICES
POLICY STATEMENTS

MEDICAL USES

44 FR 8242
Published 2/9/79
Effective 2/9/79

Regulation of the Medical Uses of
Radioisotopes; Statement of General
Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.
FOR FURTHER INFORMATION CONTACT

Mr. Edward Podolaz, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-463-5880).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the *Federal Register* (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 *Federal Register* notice. The comments are discussed in Section II. Copies of the comments may be examined

in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

*NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term byproduct material means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term source material means (i) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any of the foregoing, but does not include source material.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public and the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1978 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for . . . medical therapy . . ." Section 81 directs NRC

POLICY STATEMENTS

to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of policy not authority, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of authority, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of policy, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.³ This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with

FDA's activities. It is harmony and regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

The NAS-BEIR³ report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgments. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to

be a part of the practice of medicine. The Commission believes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical de-

³National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation*. National Academy of Sciences—National Research Council, Washington, D.C. (1972).

³The term general public in this statement specifically excludes patients.

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VICES as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. DISCUSSION OF PUBLIC COMMENTS

A. COMMENTS ON THE POLICY STATEMENT

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diag-

nosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. COMMENTS ON SPECIFIC ISSUES

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the *Federal Register* for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is reviewing the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

ATTACHMENT 2

SRM-COMSECY-96-057



SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 1997

Action: Paperiello/NMSS
Morrison, RES
Cys: Callan
Thompson
Jordan
Norry
Blaha
Bangart, SP
Ross, AEOD

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations
FROM: *John C. Hoyte*
John C. Hoyte, Secretary
SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057
MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

- (1) Focusing Part 35 on those procedures that pose the highest risk.
- (2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.
- (3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.
- (4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.
- (5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.
- (6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
- (7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.
- (8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(NMSS/RES) (EDG - Program)	(SECY Suspense:	6/6/97)	9700065
(NMSS/RES) (EDG - Complete Rulemaking)	(SECY Suspense:	6/30/99)	9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
Commissioner Diaz
K. Cyr
D. Rathbun
H. Bell
A. Galante
R. Scroggins
W. Beecher

ATTACHMENT 3

SRM-SECY-97-115



OFFICE OF THE
SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 1997

Cys: Callan
Thompson
Jordan
Norry
Blaha
Thadani, RES
Bangart, SP
Shelton, CIO
Meyer, ADM
CHaney, NMSS
SWoods, NMSS

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-97-115 - PROGRAM
FOR REVISION OF 10 CFR PART 35, "MEDICAL USES
OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL
REGISTER NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.
2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.
3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.

SECY NOTE: SECY-97-115 WAS RELEASED TO THE PUBLIC ON JUNE 17, 1997. THIS SRM, SECY-97-131, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.

~~(EDD)~~- (NMSS)

(SECY Suspense:

9/5/97)
8/29/97

9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

ATTACHMENT 4

Proposed Federal Register Notice

U.S. NUCLEAR REGULATORY COMMISSION

Medical Use of Byproduct Material; Draft Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing for formal comment, revisions of its 1979 policy statement on the medical use of byproduct material. These proposed revisions are one component of the Commission's overall program, as previously announced in the Federal Register, for revising its regulatory framework for medical use, including its regulations that govern the medical use of byproduct material. The overall goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based, consistent with NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002."

DATES: Submit comments by (insert date 75 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able only to ensure consideration of comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff

You may also provide comments via NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). From the home page, select "Rulemaking" from the tool bar. The interactive rulemaking website can then be accessed by selecting "New Rulemaking Website." This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415-5905; E-mail: cag@nrc.gov.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays.

Copies of comments received may be examined at: NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6825, E-Mail: cxh@nrc.gov, or Marjorie U. Rothschild, Office of the General Counsel, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-1633, E-Mail: mur@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, the Nuclear Regulatory Commission published a policy statement, "Regulation of the Medical Uses of Radioisotopes" (44 FR 8242; February 9, 1979), in which it informed

NRC licensees, other Federal and State agencies, and the general public of the Commission's following general intention in regulating the medical use of byproduct material:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

NRC activities in the medical area, such as promulgation of regulations and development of regulatory guidance, as well as cooperative relationships with other Federal agencies, have been guided by this statement.

A Federal Register notice, "Medical Use of Byproduct Material: Issues and Request for Public Input" (62 FR 42219-42220; August 6, 1997), describes (as reflected below) NRC's detailed examination of the issues surrounding its medical use program during the last four years. This process started with NRC's 1993 internal senior management review; continued with the 1996 independent external review by the National Academy of Sciences (NAS), Institute of Medicine (IOM); and culminated in NRC's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In September 1997, the Commission issued its "Strategic Plan," which stated that its goal in regulating nuclear materials safety is to "prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials" (NUREG-1614, Vol. 1, at 9).

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057," Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise 10 CFR Part 35, associated guidance documents, and, if necessary, the Commission's 1979 "Medical Use Policy Statement." The Commission SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for use of the Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the medical policy statement. The Commission specifically directed the NRC staff to "consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process, but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination."

A June 30, 1997, SRM informed the NRC staff of the Commission's approval, with comments, of the NRC staff's proposed program in SECY-97-131, Supplemental Information on SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material,' and Associated Federal Register notice," dated June 20, 1997. After Commission approval of the NRC staff's program to revise Part 35 and associated guidance documents, the NRC staff initiated the rulemaking process, which includes revision of the Medical Use Policy Statement, as necessary (62 FR 42219). The Commission directed the NRC staff to consider certain issues, including recommendations on revising the policy statement by focusing regulation of medical use on those procedures that are essential to patient safety and that pose the highest risk, developing regulatory oversight alternatives for diagnostic procedures that are consistent

with the lower overall risk of these procedures, and considering the viability of using or referencing available industry guidance and standards to the extent that they meet NRC needs (62 FR at 42219). This notice solicited informal and formal public input during the rulemaking process on the development of proposed rule language and associated documents (62 FR at 42219-42220). At various stages in this process, the Working/Steering Group placed options for a revised Medical Use Policy Statement and major issues associated with 10 CFR Part 35, and a strawman draft of the proposed rule language on the Internet.

In developing a proposed revision of the policy statement, the Commission also has had the benefit of input from the Working/Steering Group, which met publicly in August, September, and December 1997 and in January, February, and March 1998; the ACMUI, at its meetings on September 25-26, 1997, and March 1-2, 1998; ACMUI subcommittee meetings in February 1998; "stakeholders" and members of the public at facilitated workshops in October and November 1997; professional medical organization meetings; and State regulators at a publicly noticed workshop at the 1997, "All Agreement States" Meeting. State participants have included representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors. State participation in this process is intended to further the Commission's strategy to "work with the Agreement States to assure consistent protection of public health and safety nationwide" (NUREG-1614, Vol. 1, at 11). Such State involvement also enhances development of corresponding rules in State regulations; provides an opportunity for early State input; and allows State staff to assess potential impacts of NRC draft language on

¹ An Agreement State is a State that has signed an agreement with NRC, pursuant to Section 274 of the Atomic Energy Act, allowing the State to regulate the use of radioactive material, other than use in reactor facilities, within the State. During the next 5 years, the total number of Agreement States may increase from 30 to 33. NRC "Strategic Plan" (Fiscal year 1997 - Fiscal year 2002), NUREG-1614, Vol. 1 (September 1997), at 9.

language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States.

At these meetings and workshops, the NRC staff presented alternatives and/or draft text for the Medical Use Policy Statement and 10 CFR Part 35. Alternatives generated by workshop participants were also discussed. To ensure that all interests were represented, to the degree possible, invited workshop participants included radiation oncologists, nuclear medicine physicians, other physician specialists (i.e., clinical endocrinologists and cardiologists), radiopharmacists, medical physicists, educators, patient rights advocates, oncology nurses, medical technologists, hospital administrators, State and Federal Government officials, and radiopharmaceutical manufacturers. Policy statement alternatives ranged from retaining the status quo to various modifications of the current medical policy such as statements limiting NRC's role in the regulation of medical use to ensuring that the physician's prescription is accurately delivered to the correct patient; making clear that NRC will not intrude into medical judgments affecting patients; and providing for NRC assessment of risks to the radiation safety of patients that would reference comparable risks, standards, and modes of regulations for other types of medical practice.

The normal pattern for NRC policy statement proposals is the development of a proposed policy statement by the NRC staff for Commission consideration, publication of the proposed statement for public comment, consideration of the comments by the NRC staff, and preparation of a final statement, as appropriate, for Commission approval. As directed and approved by the Commission, the NRC staff has increased participation in the early stages of this development process through meetings and workshops for affected interests and by making documents available on the Internet.

The meetings and workshops elicited informed discussions of options and approaches for developing a revised Medical Use Policy Statement, and the rationale for such options and approaches. Although these meetings and workshops were not designed to seek "consensus" in the sense that there is agreement on how each issue should be resolved, they were conducted at a very early stage of proposed policy statement development to increase participation of interested parties and the public with the following objectives:

- (a) To ensure that the relevant issues have been identified;
- (b) To exchange information on these issues; and
- (c) To identify underlying concerns and areas of disagreement, and, where possible, approaches for resolution.

The Commission hopes that the interactions among the participants in the meetings and workshops also fostered a clearer mutual understanding of the positions and concerns of all participants. Comments made at these workshops and meetings, and related written and electronic comments (as summarized below), were considered by the NRC staff in its preparation of a staff draft proposed policy statement, as described in the paragraphs below. Comments were also used, as appropriate, in developing proposed revisions of 10 CFR Part 35. The intent of an informal comment period, in advance of publishing a proposed policy statement in the Federal Register, was to provide an opportunity for interested parties to provide input during the development of the draft proposed medical policy statement.

ACMUI

At the ACMUI meetings referenced above, the ACMUI recommended to the NRC staff its versions of a revised medical policy statement, most recently at its meeting in March 1998, a

four-part revision of the current policy statement in which the more technically accurate term “radionuclides” in Statement 1 is substituted for “radioisotopes”; the order of Statements 2 and 3 is reversed; former Statement 3 (Statement 2 in the ACMUI version) is revised to make it clear that NRC “will not intrude into the medical judgments affecting patients” (rather than the current policy of minimizing such intrusions) and to drop from that statement the phrase “into other areas traditionally considered to be a part of the practice of medicine”; and to modify Statement 3 primarily to provide that an assessment of risks justifying NRC medical use regulations will reference comparable risks, comparable voluntary standards, and modes of regulation for other types of medical practice.

"All Agreement States" Meeting Workshop

This workshop, which included State participants in the meeting as well as members of the public, also discussed the issues associated with the revision of 10 CFR Part 35 and the Medical Use Policy Statement. Some participants at the workshop stated that NRC's regulatory framework had been, and in the future could be, properly developed under the existing policy statement. Those participants who found fault with the existing medical regulatory framework did so primarily on the basis that it is too prescriptive and intrudes into the practice of medicine, which they asserted is adequately regulated by existing medical practices, including voluntary standards, within the medical community. Many comments were made about the proposal for a revised policy statement under which NRC assessment of the risks justifying its regulations would reference comparable risks and comparable modes of regulation for other types of medical practice. Some participants questioned the capability of NRC to evaluate those risks and noted that such an evaluation would require some mechanism for judging appropriate risk.

Participants favoring a policy statement limiting NRC's role to ensuring the accurate delivery of the physician's prescription did so mainly on the basis that the statement specified those areas NRC would regulate and that it provided a regulatory role for NRC that would not intrude into the practice of medicine. Several participants drafted an alternative option in addition to those alternatives presented by the Working Group. That alternative primarily modified Statements 2 and 3 of the current policy statement to provide that NRC's role in regulating the radiation safety of patients is to ensure that the physician's prescription is accurately delivered to the correct patient, more strongly state NRC's policy not to intrude into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine, and commit NRC to regulate the radiation safety of patients only where justified by the risk to patients and only where voluntary standards or compliance with such standards are inadequate. Although no clear preference was evident, some States indicated their preference for certain alternatives.

Facilitated Public Workshops

The facilitated workshops considered alternatives for the Medical Use Policy Statement presented by the Working Group, as well as alternatives generated by the workshop participants (which were mainly modeled on the ACMUI or Agreement State recommended statements described above). Certain themes emerged in these workshop discussions, such as ensuring that NRC follows the policy statement in the future, does not interfere in the practice of medicine or medical judgments affecting patients, regulates medical use of byproduct material based on the risk posed by the medical use and only after determining that voluntary medical practice standards are inadequate, and limits its role in regulating the radiation safety of patients to ensuring that the physician's prescription is followed. At the

Philadelphia workshop, an alternative with this latter limitation generated the most favorable comments.

Some participants expressed the view that the objectives described above could be achieved by revisions to the current statement, whereas others asserted that mechanisms such as tort law or “physician practice review procedures” could substitute for NRC regulatory control in certain areas. On the other hand, participants expressed concern that certain policy statement alternatives could so limit NRC’s role that its regulation would not encompass either high-risk diagnostic or “emerging” medical use technologies. Another concern was that NRC regulation of only the administration of the byproduct material would not provide an adequate level of protection to the patient.

According to certain participants, there is an absence of data supporting the necessity of NRC regulation to ensure that the correct patient receives the correct dose. In view of the perception that NRC is not qualified to assess the risks associated with medical practice, the workshop participants voted in favor of a policy statement providing that in any assessment of such risks, NRC, as a matter of policy, will rely on the determinations of the ACMUI and representatives of major professional medical organizations and Government agencies (to include stakeholder participation). Supporters of this statement pointed out that one of its advantages is that it would provide for stakeholder participation in risk assessment decisions. However, other participants expressed concern that certain professional organizations might not necessarily have the best interests of patients in mind when developing a risk assessment.

Overview of Written and Electronic Comments

The Commission also received written comments in response to the above notice, some of which addressed the Commission’s Medical Use Policy Statement. Commenters on the

policy statement include a State, professional medical organizations, an industry trade group, universities, and members of the public. The Commission has provided an overview of comments below.

An Agreement State recommended that the Commission continue the status quo with respect to the Medical Use Policy Statement, but more strictly adhere to that policy. According to that State, any intrusion into medical judgments affecting patients should be based solely on radiation protection considerations.

A number of professional societies, e.g., the American Brachytherapy Society (ABS), the Society of Nuclear Medicine/American College of Nuclear Physicians (SNM/ACNP), and the American Association of Physicists in Medicine (AAPM) also provided comments on the Medical Use Policy Statement. ABS agrees with current Medical Use Policy Statements 1 and 3, but believes that Statement 3 needs revision to provide that NRC will regulate the radiation safety of patients only where justified by the risk to patients and only where voluntary standards or compliance with these standards are inadequate. According to ABS, Statement 2 should also make clear that “[t]he risk threshold justifying patient safety risks will be comparable to those of other types of medical practice.” ABS believes that the NRC concept of acceptable patient risk is zero.

The SNM/ACNP asserts that contrary to the clear language in the current policy statement, NRC has steadily increased its involvement in the regulation of nuclear medicine despite minimal changes in this area of medicine over the years and a lack of significant problems with this medical modality. The AAPM supports NRC’s efforts to revise the Medical Use Policy Statement to focus on radiation safety and not on the practice of medicine or medical physics. However, the AAPM urged NRC to publish its risk data so that the regulated community can understand the NRC’s actions in regulating the medical uses of radiation.

AAPM supports the concept of risk-based regulations, although noting that the licensees' response to regulatory actions will require the expenditure of health care funds.

A university of health sciences commented that NRC's current Medical Use Policy Statement is appropriate. This commenter believes that NRC should continue to regulate medical use to provide for the radiation safety of workers, patients, and the general public and that there is no need for changes to the particular statement of general policy. Another university's comments were very similar to those of the AAPM, described above.

Comments were also submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc., (CORAR). According to CORAR, any revision of the Medical Use Policy Statement is futile unless NRC takes direction from that statement. As to the first statement of the medical policy, CORAR believes that 10 CFR Part 35 is unnecessary because 10 CFR Part 20 is adequate for regulation of all other uses of radioactive material and could be expanded to ensure the safety of medical use. CORAR commented on the second and third statements of medical policy by asserting that regulation of the radiation safety of patients is neither justified nor inadequate. In support of this contention, CORAR cited several factors, including regulation by other bodies such as the Food and Drug Administration and State Boards of Medicine, the responsibility of physicians to adhere to standards and codes of medical practice, and the exemplary performance record of nuclear medicine. CORAR concludes that the current medical policy statement provides argument against perceived prescriptive regulation.

One member of the public questioned what constitutes "other areas traditionally considered to be part of the practice of medicine," within the meaning of the policy statement. This commenter agreed that although the ACMUI should be the primary source of "risk judgments," it can't be the only source of such judgments, and consideration should be given to

other groups and individuals. Another member of the public commented that the policy statement should not limit NRC's role to protection of workers and the general public. This commenter stated that the policy statement assumes there is some entity to ensure that clinical nuclear medicine physicians are qualified to protect those groups. According to the commenter, it is of considerable concern that the policy statement does not account for the fact that many private practice offices and outpatient centers are not components of hospitals.

Although the Commission has considered all of the comments provided, it is specifically responding to comments that raised major issues associated with revision of the Medical Use Policy Statement. At the outset, the Commission notes that its nationwide "performance goals" for measuring results toward meeting NRC's nuclear materials safety goal include "[z]ero radiation-related deaths due to civilian use of source, byproduct, and special nuclear materials" and for "no increase in the number of misadministration events which cause significant radiation exposures" (NUREG-1614, Vol. 1, at 9-10).² In response to comments, the Commission is proposing revisions of its policy statement (see Section IV., below) that make clear its intent to avoid intrusion into medical judgments affecting patients, rather than the current policy of minimizing such intrusions. The Commission rejects regulation of the medical use of byproduct material on the basis of "comparable risk," as the ACMUI and ABS have proposed. The Commission doubts that such an approach would meet the statutory standard in Section 161b. of the Atomic Energy Act of 1954, as amended (AEA), to regulate all uses of byproduct material "to protect health and minimize danger to life." The Commission (as well as others, such as NAS and the ACMUI) has recognized the lack of acceptable data to compare the risks from

² The Commission is proposing to amend its regulations to substitute the term "medical event" for "misadministration." However, in historical discussions, the term "misadministration" is still used.

medical use of byproduct material with risks in other medical modalities. In addition, there is not an expressed authorization in the AEA to regulate any use of byproduct material on the basis of “comparable risk.” Justifying the significant departure from the Commission’s established policy with respect to risk to patients would be, at a minimum, problematic.

II. Rationale

NRC’s principal statutory authority for regulating medical use of byproduct material rests on sections 81, 161, 182, and 183 of the AEA. See 42 U.S.C. §§ 2111, 2201, 2232, and 2233. Section 81 of the Act prohibits, without NRC authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material (42 U.S.C. § 2111).

Section 81 of the AEA directs that:

The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Id. (emphasis added).

By virtue of section 161 of the Act, the Commission is authorized to undertake a variety of measures “[in] the performance of its functions” (42 U.S.C. § 2201). As stated in subsection b, the Commission may “establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable . . . to protect health or to minimize danger to life or property” [42 U.S.C. § 2201(b) (emphasis added)]. Similarly, section 161i. authorizes the Commission to “prescribe such regulations or orders as it may deem necessary” to “(3) govern any activity authorized pursuant to this Act, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activities, in order to protect health and minimize danger to life or property” [42 U.S.C. § 2201(l) (emphasis added)].

The Commission is bound by statute to regulate byproduct material (as well as source and special nuclear material) to “protect health and minimize danger to life.” This statutory standard applies to the myriad of uses of byproduct material, including, not only medical use, but also, for example, radiography and irradiators. However, the Commission is not bound by the limitation in section 104a, of the AEA, which is often mistakenly cited for the proposition that, in regulating medical use of byproduct material, the AEA requires that the Commission “impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect health and safety of the public” [(42 U.S.C § 2134(a)]. This “minimum regulation” limitation does not apply to the medical use of byproduct material which falls within NRC’s broad standard-setting authority in sections 81 and 161. Section 104a, on its face, applies only to medical therapy licenses for “utilization facilities” (e.g., reactors) and “special nuclear material.” This “minimum regulation” directive does not govern the Commission’s regulation of the medical use of byproduct material.

For the most part, the regulations to carry out the broad statutory scheme for byproduct materials are set forth in 10 CFR Parts 30 through 36. In addition, the public and occupational dose limits in 10 CFR Part 20, "Standards for Protection Against Radiation," apply whether the use of byproduct material is for medical or other purposes. However, the scope of Part 20 in § 20.1002 states that, "[t]he limits in this part do not apply to doses due . . . to any medical administration the individual has received or due to voluntary participation in medical research programs." The Commission has clarified that "the medical administration of radiation or radioactive materials to any individual, even an individual not supposed to receive a medical administration, is regulated by the NRC's provisions governing the medical use of byproduct material rather than by the dose limits in the NRC's regulations concerning standards for protection against radiation" ("Medical Administration of Radiation and Radioactive Materials," 60 FR 48623; September 20, 1995). Thus, the Commission believes that "an administration to any individual is and should be subject to the regulations in Part 35" (60 FR 48623).

The provisions of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" "are in addition to . . . other requirements in this chapter" (Section 30.2). This section requires that "any conflict between the general requirements in Part 30 and the specific requirements in another part" are governed by those specific requirements (Section 30.2). The regulations in Part 35 that are designed "to provide for the protection of the public health and safety" reflect the broad statutory standard in the AEA, discussed above (Section 35.1). The Commission has determined that, as a matter of policy, "the patient . . . as well as the general public . . . are all members of the public to be protected by NRC" (44 FR 8242, at 8244). (See discussion following.)

The NRC and the Food and Drug Administration (FDA) have regulatory responsibilities concerning medical devices, drugs, and biological products utilizing byproduct, source, and

special nuclear material. NRC has responsibility, as described above, for regulating the actual medical use of byproduct material from the standpoint of reducing unnecessary radiation exposures to the public, patients, and occupational workers. In general, the FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products, i.e., drugs, devices, and biologics. NRC routinely relies on prior FDA approval of medical devices as an essential component of NRC's sealed source and device safety evaluations. In a "Memorandum of Understanding" (MOU), effective August 26, 1993, NRC and FDA coordinated existing NRC and FDA regulatory programs for these devices, drugs, and products (58 FR 47300; September 8, 1993). These regulatory programs include activities for evaluating and authorizing the manufacture, sale, distribution, licensing, and labeled intended use of these products. The specific "elements of coordination" cover notification of product complaints, medical events, and emergency situations; coordination of investigations; investigation information exchange; NRC and Agreement State notifications; product pre-marketing and pre-licensing information exchange, and sharing of other information such as special notifications to manufacturers, operators, licensees, or patients (58 FR at 47302).

III. The Proposed Commission Policy

Based on the comments and advice of all the participants in the process described previously, as well as members of the public on the "Internet" (via the NRC 's Technical Conference Forum), the Commission is proposing the following as a revised Medical Use Policy Statement to guide its future regulation of the medical use of byproduct material:

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.

2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

Statement 1

The first portion of the proposed policy statement restates the first part of the current policy statement with the substitution of the phrase "uses of radionuclides in medicine" for the phrase "medical uses of radioisotopes." As rephrased, this is a more accurate technical statement of the scope of NRC regulation in this area. Statement 1 conveys the traditional regulatory function of NRC for all uses of byproduct, source, and special nuclear material. Protection of the radiation safety of members of the public and workers is central to fulfillment of the Commission's statutory mandate to "protect health and minimize danger to life." This protection is provided for, in part, in the public and occupational dose limits in 10 CFR Part 20 cited previously. Those limits apply whether the use of byproduct material is for medical use or other purposes. The Commission has determined to retain its long-standing regulatory framework as necessary in the medical uses of byproduct material. As stated in the Federal Register notice initiating the Commission's request for public comment, the Commission "was not persuaded by the National Academy of Sciences (NAS), Institute of Medicine (IOM) report

that recommends that the NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine” [62 FR at 42219 (quoting SRM of March 20, 1997)].

Statement 2

The second portion of the proposed policy statement is based on the third part of the current statement. The modifications explicitly state the Commission’s proposed policy not to intrude into medical judgments affecting patients except to provide for the radiation safety of workers and the general public. As set forth above, providing for the radiation safety of the public and workers is essential for the Commission to carry out its statutory mandate. When this protection necessitates a degree of regulation of medical judgments affecting patients, the Commission may find it necessary to intrude, to a certain extent, into medical judgments to protect the public and workers. For example, release of patients administered radioactive materials has long been considered a matter of regulatory concern to protect members of the public, not just a matter of medical judgment (“Criteria for the Release of Individuals Administered Radioactive Material,” 62 FR 4120; January 29, 1997). Thus, from a strictly medical point of view, it may be appropriate for a physician to release a patient administered radioactive materials from the hospital. However, patient release criteria in NRC regulations (10 CFR 35.75) may require confinement of that patient if release of that patient could result in a dose to other individuals that exceeds the dose-based limit stated in 10 CFR 35.75(a).

In the current policy statement, the Commission stated its intent to “minimize intrusions into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine.” The modifications in this part of the proposed policy statement more strongly reflect the Commission’s long-standing recognition that physicians have the primary responsibility for the diagnosis and treatment of their patients. NRC regulations are

predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients. Therefore, in recent years, the Commission has moved away from a more rigid scheme of medical use regulation, which at one time, for example, restricted the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that had been approved by the FDA (44 FR 8242, at 8243).

NRC regulations no longer prohibit authorized user physicians from using diagnostic or therapeutic radioactive drugs containing byproduct material for indications or methods of administration not listed in the FDA-approved package insert. Further, NRC regulations now permit medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits. In addition, the recent amendment of 10 CFR 35.75, cited above, substituting a dose-based limit for patient release (rather than an activity-based limit), may provide medical use licensees greater flexibility in determining when such patients may be released from their control.

The Commission's proposed policy to avoid (rather than minimize) intrusion into medical judgments affecting patients is consistent with recent Federal legislation (specifically applicable to FDA), which is to be construed so as not to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." (There are certain exceptions to this mandate, which do not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.) "Food and Drug Administration Modernization Act of 1997," Pub. L. No. 105-115, § 906, 111 Stat. 2296 (1997).

Statement 3

Neither the AEA sections cited above nor the regulations in 10 CFR Part 35 use the term “risk.” The Commission’s current policy statement on medical use, quoted above, makes specific reference to “risk” to patients. As there stated and reaffirmed here, the Commission specifically rejects the notion that it should not regulate patient radiation safety (44 FR at 8243). The Commission will continue to regulate radiation safety of patients where justified by the risk to patients. However, proposed Statement 3 makes clear that the focus of NRC regulation to protect the patient’s health and safety is primarily to ensure that the authorized user physician’s directions are followed. The NRC goal in this aspect of medical use regulation is tied to the physician’s directions as they pertain to the application of the radiation or radionuclide, rather than to other, non-radiation related aspects of the administration. Consistent with the Commission’s statutory authority, if a situation should arise in the future which identifies an additional risk to the patient’s health and safety, the Commission will consider adopting an additional limitation or control on a particular radiation or radionuclide modality as necessary. “Prescription” is not being used for this purpose because it might typically include aspects of the administration that are outside NRC’s purview. Either the “written directive” or “clinical procedures manual” (as those terms are defined in Part 35) would contain the physician’s directions (i.e., the procedure to be performed and the dose) . This regulatory objective is currently reflected in certain provisions of Part 35 (e.g., 10 CFR 35.32(a) (requiring “high confidence” that byproduct material or radiation therefrom will be administered as directed by an authorized user physician) and as part of the rationale of the current policy statement. In the proposed revision of 10 CFR Part 35 and as explicitly stated above, NRC is emphasizing that protection of patient radiation safety is an overall NRC goal in regulating the medical use of byproduct material. Although the Commission recognizes that physicians have primary

responsibility for the protection of their patients, NRC has a secondary, but necessary, role with respect to the radiation safety of patients.

The Commission is attempting to make its medical use regulatory framework more “risk-informed,” based on its regulatory strategy of regulating “material uses consistent with the level of risk involved, by decreasing oversight of those materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities” (NUREG-1614, Vol. 1, at 11). In addition, this portion of the proposed policy statement reflects the Commission strategy of identifying those regulations and processes that are now or can be made risk-informed (NUREG-1614, Vol. 1, at 11. SRM of March 20, 1997, at 2).

Statement 4

According to Statement 2 of the current policy statement, NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. In its SRM of March 20, 1997, the Commission repeated its continued support of professional medical organizations and societies (as well as the ACMUI) in developing regulatory guides and standards (SRM, at 1). Proposed Statement 4 commits NRC to an approach for regulation of medical use which “will consider industry and professional standards that define acceptable levels of achieving radiation safety.” Such consideration, however, does not involve, as a prerequisite for regulation, the problematic determination of licensee compliance with a voluntary standard (as implied in current Statement 2). At a minimum, such an undertaking leaves NRC with the dilemma of how to deal with licensees that may not comply with voluntary standards. For this reason, the Commission’s proposed policy statement does not retain that aspect of the current policy statement.

The Statement of Consideration for the proposed 10 CFR Part 35 rulemakings specifically addresses NRC's current policy of consideration of "voluntary standards and compliance with such standards." Affirming consideration of industry and professional standards as part of the NRC policy in achieving radiation safety in medical use conforms to the Commission's Strategic Plan. The relevant strategy there stated is to increase the involvement of licensees and others in the NRC regulatory development process, based on the concepts in the "National Technology Transfer and Advancement Act of 1995" (the NTTAA), Pub. L. No. 104-113, 110 Stat. 775 (1995). Section 12(d) of the NTTAA requires "all Federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus bodies . . . as a means to carry out policy objectives or activities."

It is not clear that all "medical industry and professional standards" would meet the definition of "technical standards" in Section 12(d)(4) of the NTTAA ("performance-based or design-specific technical specifications and related management systems practices)."

Nevertheless, as indicated above, the Commission endorses, in regulating medical use of byproduct material, the concept in Section 12(3) of the NTTAA, of "emphasizing, where possible, the use of standards developed by private, consensus organizations." As also stated in the Strategic Plan, the Commission encourages "industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by industry."

IV. Policy Implications

This proposed policy statement affirms the Commission determination that it shall continue its role in regulating the medical use of byproduct material, but with emphasis on the

goal of protecting the radiation safety of occupational workers, the public, and patients, while avoiding intrusion into medical judgments affecting patients. Ensuring that the authorized user physician's directions for the administration of byproduct material are followed is the primary means of achieving this regulatory goal. Moreover, the Commission is renewing the objective of utilizing industry and professional standards that define acceptable levels of achieving radiation safety.

REFERENCE INFORMATION:

1. Strategic Assessment Direction-Setting Issues Paper Number 7 is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-0001, telephone: (202) 634-3273; fax: (202) 634-3343.
2. The memorandum "Management Review of Existing Medical Use Regulatory Program (COMIS-92-026)" (dated June 16, 1993) is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-0001, telephone: (202) 634-3273; fax: (202) 634-3343.
3. "Radiation in Medicine: A Need for Regulatory Reform" (1996) is available from the National Academy Press at 2101 Constitution Avenue, NW, Box 285, Washington, DC 20555.
4. Summary minutes and transcripts of the ACMUI March 1998 meeting or transcripts of the May 8, 1997, Commission briefing are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-0001, telephone: (202) 634-3273; fax: (202) 634-3343. Transcripts of the May 8, 1997, briefing are also available by Internet at <http://www.nrc.gov>.

5. The NRC Medical Policy Act Statement of 1979 was published in the Federal Register, Volume 44, page 8242, on February 9, 1979.

6. SECY-97-115, Program for Revision of 10 CFR Part 35, "Medical Uses of Byproduct Material" and Associated Federal Register notice; SECY-97-131, Supplemental Information on SECY-97-131, Supplemental Information on SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material,' and Associated Federal Register notice; and the associated SRM (dated June 30, 1997) are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-0001, telephone: (202) 634-3273; fax: (202) 634-3343.) Copies are also available on the NRC Technical Conference Forum at <http://techconf.llnl.gov/noframe.html>.

Dated at Rockville, Maryland, this ____ day of ____, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

ATTACHMENT 5

Congressional Letters



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed revision to a policy statement, to be published in the Federal Register for a 75-day public comment period (Enclosure 1). A copy of the press release for the proposed revision is provided in Enclosure 2.

The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise its 1979 "Medical Use Policy Statement," as part of an overall program to revise the Commission's regulatory framework for medical use. The goals of this program are to focus NRC regulation of medical use on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based. Another component of the program, the revision of 10 CFR Part 35, "Medical Uses of Byproduct Material," will be separately published and transmitted to the Subcommittee.

During the development phase of the proposed policy statement, NRC held public meetings with various interested groups, including physicians, medical associations, patient advocates, Agreement States, and NRC's Advisory Committee on Medical Uses of Isotopes. In addition, proposed alternatives for the revised policy statement were put on the INTERNET. NRC received many useful comments as a result of these interactions with the public, and has carefully considered them in the development of the policy statement.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Representative Ralph Hall



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed revision to a policy statement, to be published in the Federal Register for a 75-day public comment period (Enclosure 1). A copy of the press release for the proposed revision is provided in Enclosure 2.

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During the development phase of the proposed policy statement, NRC held public meetings with various interested groups, including physicians, medical associations, patient advocates, Agreement States, and NRC's Advisory Committee on Medical Uses of Isotopes. In addition, proposed alternatives for the revised policy statement were put on the INTERNET. NRC received many useful comments as a result of these interactions with the public, and has carefully considered them in the development of the policy statement.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham

ATTACHMENT 6

Press Release

Draft press release--5/18/98, 1:55 p.m.

NRC PROPOSES TO REISSUE POLICY STATEMENT ON MEDICAL USES OF RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission is proposing to revise its policy statement on medical uses of radioactive material. The agency intends to focus regulation on medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based.

The proposed policy statement stresses the Commission's determination to continue to regulate the use of radioactive materials in medicine, with the goal of protecting the radiation safety of occupational workers, the public and patients, without intruding into medical judgments affecting patients. When justified by the risk, the NRC will regulate the radiation safety of patients by ensuring that the physician's directions for administration of the radioactive material or radiation are followed.

The proposed statement and associated proposed revisions to the agency's regulations, which are expected to be published soon for public comment, result from the NRC's detailed examination of issues regarding its medical use program during the last five years. This process started with an NRC 1993 internal senior management review. It continued with the NRC-requested 1996 independent external review by the National Academy of Sciences, Institute of Medicine; and culminated in NRC's strategic assessment and rebaselining project. In September 1997, the Commission issued its strategic plan, which included the subject of medical oversight and stated that its goal in regulating nuclear materials safety is "to prevent radiation-related deaths or illnesses due to civilian use of...nuclear materials."

In its March 20, 1997, direction to its staff, the Commission stated that it supported

continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. The Commission expressed its support for the continued use of its Advisory Committee on the Medical Use of Isotopes (ACMUI), professional medical organizations and societies, and members of the public in the revision of the regulations and the medical policy statement.

In developing the proposed policy statement revision, the Commission established a working group and a steering group, made up of members of the NRC staff and state organizations, which held a series of public meetings and workshops in 1997 and 1998 to obtain public and stakeholder suggestions. To ensure that a wide cross-section of interests were represented, invited workshop participants included physicians, radiopharmacists, medical physicists, educators, patient rights advocates, nurses, medical technologists, hospital administrators, representatives of state and federal governments, and radiopharmaceutical manufacturers.

The NRC has received comments on the proposed revision of the medical policy (which was posted on the NRC web site), through meetings of the ACMUI, professional medical organization meetings and state regulators. It also has solicited written and electronic comments.

Under the proposed new policy statement:

“(1) NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.” This portion restates the first part of the current policy statement, issued in 1979, but substitutes the phrase “uses of radionuclides in medicine” for the phrase “medical uses of radioisotopes.” As noted in an August 6 Federal Register notice requesting public comments on development of revised regulations on medical uses, the Commission “was not persuaded by the National

Academy of Sciences, Institute of Medicine report that recommends that the NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine.”

“(2) NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.” This portion is based on the third portion of the current statement. It substitutes the phrase “will not intrude” for the current “will minimize intrusion,” as suggested by the ACMUI.

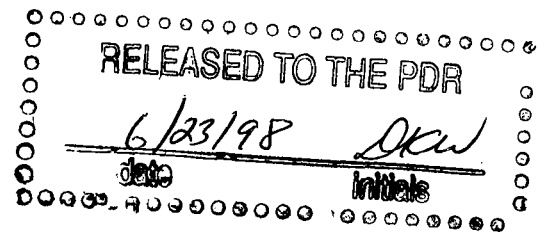
“(3) NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician’s directions.” This portion is based on the second part of the current statement, but makes clear that the focus of this regulation is primarily on ensuring that physician’s directions are followed. This part of the statement also reflects the Commission strategy of decreasing oversight of materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities.

“(4) NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.” This portion is also based on the second part of the current policy statement, which states that “The NRC will regulate the radiation safety of patients...where voluntary standards, or compliance with these standards, are inadequate.” The proposed revision indicates that NRC will consider industry standards in regulating medical uses of nuclear material, as part of its strategy to increase the involvement of licensees and others in its regulatory development process.

The proposed new policy statement will be published in the Federal Register shortly. Interested persons are invited to submit written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications

Staff, within 75 days of publication of the Federal Register notice. Comments may also be submitted electronically through the NRC's interactive rulemaking website at <http://www.nrc.gov/NRC/rule.html>.

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POLICY ISSUE (Notation Vote)

June 4, 1998

SECY-98-128

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROPOSED RULE: REVISION OF 10 CFR PART 35, MEDICAL USE
OF BYPRODUCT MATERIAL

PURPOSE:

To request Commission approval to publish in the Federal Register a proposed rule to amend 10 CFR Part 35, "Medical Use of Byproduct Material."

SUMMARY:

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997 (Attachment 1), the Commission directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. The program for revising Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties than is provided by the typical notice and comment rulemaking process. The draft proposed rule, that is attached for Commission approval to publish in the Federal Register for comment, is consistent with a risk-informed, performance-based approach to regulation.

CONTACT: Catherine Haney, NMSS/IMNS
(301) 415-6825

NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE AVAILABLE

Diane S. Flack, NMSS/IMNS
(301) 415-5681

BACKGROUND:

In its SRM dated June 30, 1997, "SECY-97-115, Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice" (Attachment 2), the Commission approved the staff's proposed plan for the revision of Part 35 and the Commission's 1979 Medical Use Policy Statement (MPS). The staff implemented that plan by establishing a Working Group and Steering Group that included headquarters and regional licensing and inspection staff and representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The program for revising Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited by requesting input through Federal Register notices; holding public meetings of the Working and Steering Groups; meeting with medical professional societies and boards; putting background documents, rulemaking alternatives, and a "strawman" draft proposed rule on the Internet and in the NRC's Public Document Room; and convening two facilitated public workshops. Significant regulatory issues were discussed at the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meetings in September 1997 and March 1998, and the ACMUI subcommittee meetings in February 1998. These interactions, and the comments received, are summarized in the proposed Federal Register notice (Attachment 3).

DISCUSSION:

In response to the SRM discussed above, staff has developed a draft proposed revision of Part 35, draft associated guidance, and a proposed revision of the MPS. The staff's proposed revision of the MPS has been transmitted separately for Commission approval for publication in the Federal Register. The draft proposed rule is consistent with the proposed revised MPS and is generally consistent with the current MPS (see Attachment 3, Section VII of the Supplementary Information).

Approach. The staff developed the proposed revision of Part 35 based upon the Commission's directions in the SRMs of March 20, 1997, and June 30, 1997. In addition, the staff moved to eliminate requirements from the draft proposed rule that were contained elsewhere in the Commission's regulations. Part 35 licensees will continue to be required to comply with these requirements, such as ALARA in Part 20, but the staff believes that there is no need to duplicate requirements, unless more specific requirements are needed for medical licensees, such as the frequency of area surveys.

The draft proposed rule provides for an overall change in regulatory philosophy. Consistent with a risk-informed, performance-based approach to medical use licensing, the amount of information needed from an applicant to possess and use byproduct material would be reduced. An applicant for an NRC medical use license would have to develop, maintain, and implement procedures, but would no longer be required to submit these procedures as part of the license

application. Furthermore, licensees would be provided maximum flexibility in developing their procedures because most of the requirements are stated in terms of the objectives to be achieved.

The staff has ensured, to the extent possible, that the regulations include all of the requirements for medical licensees. This responds to numerous comments that performance-based rules result in placement of requirements in guidance documents and license conditions. As a result, some prescriptive sections appear in the draft proposed rule where the requirements are necessary for safe operations. This approach was also taken with the development of the associated guidance document for medical use licensees. The draft guidance document provides model procedures to assist the applicant in developing various procedures required by the regulations, but it does not contain additional requirements. Licensees may choose to follow the specific models provided in the guidance document or develop alternatives to achieve the objectives (Attachment 4). Although the staff is providing this draft guidance for reference, it is not specifically seeking approval from the Commission on this draft guidance at this time.

The revised Part 35 includes several structural changes. The draft proposed rule has a modality-based structure; the current Teletherapy Subpart has been expanded to codify the requirements for remote afterloaders and gamma stereotactic radiosurgery devices, which are currently regulated through license conditions; a new subpart is proposed to allow for easier licensing of new medical procedures that use byproduct material or radiation from byproduct material for uses that are not specifically addressed in the current Part 35; and all of the requirements for records and reports have been moved to separate subparts.

In addition, the staff reviewed the applicable industry guidance and standards to determine if the needed standards are available; and, if they are available, to determine if they are consistent with NRC's regulatory needs and, if so, whether they should be incorporated or referenced in Part 35. The draft proposed rule takes into account industry standards, where appropriate. However, the staff has opted to codify the objectives to be accomplished, rather than referencing industry standards in the regulation, so that licensees would have increased flexibility in demonstrating compliance.

Specific Issues: Early in the rulemaking process, the staff identified five significant rulemaking issues, developed alternatives for them, and specifically sought public input on them. Two of the issues, patient notification and precursor events, were forwarded in SECY-98-054, "Commission Resolution of Significant Issues Associated with the Revision of 10 CFR Part 35, "Medical Uses of Byproduct Material" (March 22, 1998), for Commission direction (Attachment 5). Pending receipt of direction, the draft proposed rule includes the current requirements for patient notification and a requirement for capturing precursor events. (Attachment 6 contains the NRC Medical Visiting Fellow's view on patient notification following a medical event.) Revised requirements have been included in the proposed rulemaking for the other three issues: Radiation Safety Committee (RSC), Quality Management Program (QMP), and Training and Experience (T&E).

The requirement for a medical institution licensee to have an RSC has been deleted in the draft proposed rule. This change places the responsibility for the radiation safety program on the licensee management, but provides flexibility in using either an RSC, or other existing management committees and structures.

The requirements for a medical licensee to establish and maintain a written QMP, to annually review the QMP, and to submit the QMP for NRC review have been deleted. The draft proposed rule requires licensees to have written directives for high-risk procedures, and to develop, maintain, and implement procedures to provide high confidence that each administration is in accordance with the written directive. This approach is consistent with Commission direction to re-evaluate and revise the QMP provisions to focus on those requirements that are essential for patient safety.

T&E requirements in the draft proposed rule have been revised to focus on radiation safety. The didactic and practical training requirements are focused upon radiation safety and the safe handling of radioactive material, and have been scaled based upon the risk posed by the diagnostic or therapy modality. The T&E requirements were extensively discussed with medical societies and boards, and were the primary issue in public comments received on the rulemaking. Approximately 90 percent of these comments were from radiation oncologists who feel very strongly that the current requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the high risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices. As the rulemaking progressed, comments were also received expressing a viewpoint that T&E should not be reduced for diagnostic uses.

The draft proposed rule also addresses other ongoing medical issues, including a petition for rulemaking filed by the University of Cincinnati requesting a 500 mrem dose limit for visitation of individuals confined in accordance with § 35.75 (PRM-20-24); evaluation of the responsibilities of the authorized user and radiation safety officer, as a result of the Indiana, Pennsylvania brachytherapy incident; and the recommendations from internal staff audits. Revised requirements have also been developed in response to other ongoing rulemakings to address various technical and administrative issues identified in the Medical Management Plan, to revise brachytherapy procedures, and to eliminate or decrease the number of exemptions from the requirements for the medical uses of radiation by mobile services. In addition, a requirement for reporting unintended radiation exposure to an embryo, fetus, or nursing child has been proposed to respond to an ongoing rulemaking and to satisfy the NRC's requirement to report Abnormal Occurrences to Congress (Attachment 7, SRM-SECY-92-171, "Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May Be Pregnant or Nursing," June 25, 1992).

The schedule approved by the Commission in SRM-SECY-97-115 provides for the rulemaking to be completed by June 1999. Therefore, three facilitated public meetings are planned for August and September 1998 to discuss the proposed rule, as approved by the Commission for publication in the Federal Register, during the 75-day public comment period, projected to be from July 1 to mid-September 1998.

RESOURCES:

The resource levels expended on the proposed rulemaking have been somewhat greater than the resource levels identified in the FY 1998 and FY 1999 budget submissions. Resources have been reprogrammed from lower priority activities within NMSS. If the provisions in the proposed rule are approved in the final rule, increased resources to review and approve testing organizations and specialty boards will be required. The staff expects to refine the resource estimates based upon interactions with the public and professional societies during the public comment period, and to incorporate those resources within future program and budget reviews.

COORDINATION:


The Office of the General Counsel has no legal objection to this proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it.

RECOMMENDATION:

That the Commission:

1. Approve the notice of proposed rulemaking for publication in the Federal Register.
2. Note:
 - a. The rulemaking will be published in the Federal Register for a 75-day public comment period;
 - b. A Draft Regulatory Analysis has been prepared for this rulemaking (Attachment 8);
 - c. A Draft Environmental Assessment has been prepared for this rulemaking (Attachment 9);
 - d. The appropriate Congressional committees will be informed (Attachment 10);
 - e. The Office of Public Affairs has determined that a press release should be issued for this proposed rulemaking (Attachment 11);
 - f. A draft Office of Management and Budget (OMB) Clearance package is attached (Attachment 12);
 - g. Copies of the Federal Register notice of proposed rulemaking will be distributed to all affected Commission licensees, Agreement States, and potential Agreement States. The notice will be sent to other interested parties upon request;

- h. The Enforcement Policy and inspection procedures will be reviewed and revised, if necessary, prior to publication of the final rule.


L. Joseph Callan
Executive Director
for Operations

Attachments:

1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Proposed Federal Register Notice
4. Draft NUREG 1556, Vol. 9
5. SECY- 98-054, dtd 3/22/98
6. Memorandum dtd 5/27/98, M. Pollycove
to H. Thompson
7. SRM-SECY-92-171, dtd 6/25/92
8. Draft Regulatory Analysis
9. Draft Environmental Assessment
10. Congressional Letters
11. Press Release
12. OMB Clearance Package

Attachments provided to Commission offices, OGC, SECY and NMSS only. Copies of enclosures are available on request from Cathy Haney at (301) 415-6825.

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Monday, June 22, 1998.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, June 15, 1998, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

DISTRIBUTION:

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ATTACHMENT 1

SRM-COMSECY-96-057



SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 1997

Action: Paperiello/NMSS
Morrison, RES

Cys: Callan
Thompson
Jordan
Norry
Blaha
Bangart, SP
Ross, AEOD

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: *John C. Hoyle*
John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057
MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

- (1) Focusing Part 35 on those procedures that pose the highest risk.
- (2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.
- (3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.
- (4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.
- (5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.
- (6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
- (7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.
- (8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(NMSS/RES) (EDO - Program)	(SECY Suspense:	6/6/97)	9700065
(NMSS/RES) (EDO - Complete Rulemaking)	(SECY Suspense:	6/30/99)	9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
Commissioner Diaz
K. Cyr
D. Rathbun
H. Bell
A. Galante
R. Scroggins
W. Beecher

ATTACHMENT 2

SRM-SECY-97-115



OFFICE OF THE
SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 1997

Cys: Callan
Thompson
Jordan
Norry
Blaha
Thadani, RES
Bangart, SP
Shelton, CIO
Meyer, ADM
CHaney, NMSS
Swoods, NMSS

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-97-115 - PROGRAM
FOR REVISION OF 10 CFR PART 35, "MEDICAL USES
OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL
REGISTER NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.
2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.
3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.

SECY NOTE: SECY-97-115 WAS RELEASED TO THE PUBLIC ON JUNE 17, 1997. THIS SRM, SECY-97-131, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.

~~(EDO)~~- (NMSS)

(SECY Suspense: ~~9/5/97~~
8/29/97)

9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

ATTACHMENT 3

Proposed Federal Register Notice

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32 and 35

RIN 3150-AF97

Medical Use of Byproduct Material; Proposed Revision

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing a revision of its regulations governing the medical use of byproduct material. The proposed rule is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC's regulations on those medical procedures that pose the highest risk and to structure its regulations to be risk-informed and performance-based, consistent with the NRC's "Strategic Plan for Fiscal Year 1997- Fiscal Year 2002." A separate notice in the Federal Register announced the Commission's proposed revision of its 1979 "Medical Use Policy Statement."

DATES: The comment period expires [insert date 75 days after publication]. Comments received after this date will be considered if it is practical to do so, but the Commission is only able to ensure consideration of comments received on or before this date.

ADDRESSES: Comments may be sent to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm on Federal workdays.

Copies of comments received may be examined at: NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). From the home page, select "Rulemaking" from the tool bar. The interactive rulemaking website can then be accessed by selecting "New Rulemaking Website." This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-6825, e-mail CXH@nrc.gov or Diane Flack, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-5681, e-mail DSFI@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Petition for Rulemaking.
- III. Discussion and Input to Proposed Rule.

- IV. Discussion of Text of Proposed Rule.
- V. Coordination with the Advisory Committee on Medical Uses of Isotopes.
- VI. Coordination With NRC Agreement States.
- VII. Consistency with Medical Policy Statement.
- VIII. Implementation.
- IX. Issues of Compatibility for Agreement States.
- X. Finding of No Significant Environmental Impact: Availability.
- XI. Paperwork Reduction Act Statement.
- XII. Regulatory Analysis.
- XIII. Regulatory Flexibility Analysis.
- XIV. Backfit Analysis.

I. Background

Use of Byproduct Material in Medicine

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. Diagnostic nuclear medicine in most cases involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m

hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

State and Federal Regulations

Byproduct material or radiation from byproduct material is regulated by either State or Federal Laws. The NRC regulates the administration of byproduct material or radiation from byproduct material in 20 States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States. There are approximately 1900 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35, "Medical Uses of Byproduct Material." Thirty States, known as Agreement States, have entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act). These States issue licenses and currently regulate about 5000 institutions, e.g., hospitals, clinics, or physicians in private practice.

Revision of NRC's Regulatory Program

NRC's medical use program includes use of byproduct material in medical diagnosis, therapy, and research. NRC's requirements for medical licensees are in 10 CFR Part 35. Eleven million patients annually undergo medical procedures involving byproduct materials.

The Commission examined the issues surrounding its medical use program in detail during a 1993 internal senior management review, a 1996 independent external review by the National Academy of Sciences, Institute of Medicine, and the Commission's Strategic Assessment and Rebaselining Project (SA). In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996). In September 1997, the Commission issued its "Strategic Plan" (NUREG-1614, Vol. 1) which

stated that its goal in regulating nuclear materials safety is to "prevent radiation-related deaths or illnesses due to civilian use of source, byproduct, and special nuclear materials."

In its Staff Requirements Memorandum (SRM) - COMSECY-96-057, "Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. This SRM also directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Use Policy Statement (44 FR 8242; February 9, 1979). The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. In addition, the Commission expressed its support for the use of the Advisory Committee on the Medical Use of Isotopes (ACMUI) and professional medical organizations and societies in the revision of Part 35 and the medical policy statement. The Commission specifically directed the NRC staff to "consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination."

During development of the rule and associated guidance, as well as during the review of the Medical Use Policy Statement, the Commission considered the following issues:

- (1) Focusing Part 35 on those procedures that pose the highest risk;
- (2) Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures;

- (3) The best way to capture not only relevant safety-significant events, but also precursor events;
- (4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology;
- (5) Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;
- (6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety; and
- (7) The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs.

The proposed rule that would revise Part 35 has been developed in response to these issues and concerns.

The Commission, in its SRM of June 30, 1997, "SECY-97-115 - "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register notice," approved the NRC staff's proposed plan for the revision of Part 35. The Federal Register notice, "Medical Use of Byproduct Material: Issues and Request for Public Input" (62 FR 42219-42220; August 6, 1997), solicited early public input on the proposed rulemaking.

The NRC staff implemented the approved plan using an approach involving public Working and Steering Group meetings, with significant opportunities for input from the public, potentially affected parties, the ACMUI, and professional medical organizations. Publicly noticed Working and Steering Group meetings were held in August, September, and

December 1997, and in January, February, March, and April 1998. During the Working and Steering Group meetings, the groups identified significant crosscutting issues associated with the rulemaking. These issues included patient notification, precursor events, Radiation Safety Committee, quality management program, and training and experience for authorized users. Rulemaking alternatives were developed for these crosscutting issues and were made available on the Internet and in the NRC's Public Document Room for comment. These alternatives were discussed with (1) the ACMUI at its September 1997 meeting, (2) the public at facilitated public workshops held in Philadelphia, PA, in October and in Chicago, IL, in November 1997 (discussed below), (3) State regulators at a publicly noticed workshop that was conducted during the 1997 All Agreement States Meeting, and (4) meetings of medical professional societies.

In addition to the proposed revision of Part 35, the Commission is publishing for public comment, in a separate Federal Register notice, a proposed revision of its 1979 policy statement on the Medical Use of Byproduct Material (44 FR 8242; February 9, 1979). The proposed revision of the medical policy statement is another component of the Commission's overall program for revising its regulatory framework for medical use, including its regulations in Part 35. The proposed revision of Part 35 is consistent with the proposed revision of the Medical Use Policy Statement (MPS) and is generally consistent with the current MPS (see Section VII of the Supplementary Information section of this document).

Workshops

The Commission believes that it is important for interests affected by the medical use rulemaking to not only have an early opportunity to comment on the rulemaking issues, but also to have an opportunity to discuss the rulemaking with one another and the agency. Accordingly, the Commission convened two public workshops in which the interests that maybe affected by the rulemaking had the opportunity to discuss the rulemaking issues. Although the workshops were intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement or disagreement, it was not the intent of the workshop process to develop a consensus agreement of the participants on rulemaking issues.

In order to have a manageable discussion, the number of invited participants in the roundtable discussions at each workshop was limited. The Commission, through a facilitator for each workshop, attempted to insure participation by a broad spectrum of interests that may be affected by the rulemaking. These interests included nuclear medicine physicians, physician specialists such as cardiologists and radiologists, medical physicists, medical technologists, nurses, medical education and certification organizations, radiopharmaceutical interests, hospital administrators, patients rights advocates, Agreement States, Federal agencies, and experts on risk analysis. Other members of the public were invited to attend and had the opportunity to comment on the rulemaking issues and the workshop discussions at periodic intervals during the workshops.

The workshops had a common, predefined agenda focused primarily on alternatives for major ("crosscutting") issues, some with draft regulatory text. The workshop format was sufficiently flexible to allow for the introduction of additional related issues that participants wanted to raise. The workshop commentary was transcribed and summarized in "Summary of Discussion: Facilitated Public Workshop on Revisions to 10 CFR Part 35 Held in Philadelphia, Pennsylvania, on October 28-30, 1997" (date of document to be inserted) and "Summary of Discussion: Facilitated Public Workshop on Revisions to 10 CFR Part 35 Held in Chicago, Illinois, on November 12-14, 1997" (date of document to be inserted). The summary documents are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary documents are available as indicated in the For Further Information Contact section of this document. A brief summary of the participant's positions on the major crosscutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

The Commission plans to hold three public workshops during the formal comment period to facilitate public comments on the proposed rulemaking. Notices for these workshops will be published in the Federal Register.

II. Petition for Rulemaking

The Commission has incorporated into this rulemaking resolution of a Petition for Rulemaking (PRM) filed by the University of Cincinnati dated April 7, 1996 (PRM 20-24), because of its pertinence to Part 35. On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on this petition for rulemaking.

The petitioner requested that the NRC amend 10 CFR 20.1301, "Dose limits for individual members of the public" to:

(1) Provide medical licensees the discretion to permit those visitors determined by the physician to be necessary for the emotional or physical support of the patient to receive up to 5 mSv (0.5 rem) (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient);

(2) Exclude pregnant women and individuals younger than 18 years of age from receiving a dose in excess of 1 mSv (0.1 rem); and

(3) Document compliance by issuing radiation dose monitoring devices (i.e., pocket dosimeter, film badge, TLD, or electronic dosimeter) to each specified visitor.

In response to the request for public comments, the Commission received comments from four members of the general public. All commenters agreed with the petition. One of the commenters suggested that the previous 5 mSv (0.5 rem) dose limit for the general public be reinstated for a "specific" public and, under unusual circumstances, also permit the authorized user to authorize even higher exposure provided the latter does not "receive more radiation than a radiation worker." Another commenter suggested permitting the authorized user to authorize even higher exposure provided it did not exceed the occupational dose limit of 50 mSv (5 rem).

Although a 50 mSv (5 rem) dose limit for adult visitors exposed to radionuclide therapy patients is consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP Commentary No. 11, Dose Limits for Individuals Who Receive Exposure From Radionuclide Therapy Patients, February 28, 1995), this suggestion is not

consistent with release of patients in accordance with § 35.75, or with the approach to protection of the public in 10 CFR Part 20. For this reason, the NRC decided not to adopt the suggested 50 mSv (5 rem) dose limit.

The NRC reviewed the petitioner's request and comments received on the petition and believes there is merit in granting the petition in part as discussed in detail later. This proposed rule responds to the petition by amending 10 CFR Part 20 to allow the licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to hospitalized radiation patients.

III. Discussion and Input to Proposed Rule.

The program for revising Part 35 and the associated guidance documents has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and alternatives for revising the 1979 Medical Use Policy Statement on the Internet; and convening public workshops. The input received from the public during the development of the proposed rulemaking is categorized and summarized below, according to the significant regulatory issues that were identified very early in the rulemaking process.

A. Training and Experience.

1. Facilitated Workshops.

The issue of training and experience for authorized users generated the most discussion among workshop participants. Discussion of this topic was organized into segments that addressed "key current problems or advantages identified by participants"; certain "crosscutting" training and experience issues (including such questions as the role a professional degree, medical specialty certification, or testing should play in qualifying an authorized user); and various specific alternatives (developed by the Part 35 Working Group) for training and experience necessary to qualify a physician as an authorized user.

Based on specific questions posed to participants, certain issues emerged as important in determining the necessary training and experience for qualifying as an authorized user. For instance, some participants believed that the current requirements are unrealistically stringent. Other participants maintained that training and experience can be varied, based upon the degree of risk posed by a specific modality. (However, participants did not necessarily agree on how to rank various modalities based on risk.) One question raised was whether the training and experience requirements should be different for physicians already in practice, than for those physicians who are just starting out. Certain participants viewed Commission specification of clinical training and experience requirements as a serious intrusion into the practice of medicine, and, therefore, suggested that the term "clinical training and experience" should be replaced with the term "practical training and experience." The latter would cover safe handling of radioactive materials (i.e., such topics as: safe delivery of radionuclides to

patients; time, distance, and shielding; use of a dose calibrator; assessing contamination; decontaminating areas; half-lives of radionuclides; and consequences of contamination). However, some therapy practitioners supported the requirement for clinical experience as part of training and experience. Another suggested approach to establishing training and experience requirements would be to have different requirements for physicians who use radionuclides for very limited purposes (i.e., cardiology and endocrinology), as opposed to physicians engaged in the general medical use of byproduct material.

The range of options for a physician to become an authorized user that was discussed at the workshops included --

(1) Status quo (i.e., a physician who is certified in any one of a number of medical specialties, or has had a set number of hours of classroom and laboratory training and supervised clinical experience, or has completed an approved training program that included classroom and laboratory training, work experience, and supervised clinical experience);

(2) Medical speciality certification, plus a specified number of hours of training and experience;

(3) Medical specialty certification plus a specified number of hours of training and passing an examination;

(4) Possessing an M.D. degree;

(5) Passing an examination focused on radiation safety; and

(6) Passing an examination focused on radiation safety and having specified clinical experience.

The options were primarily analyzed in terms of therapeutic versus diagnostic uses of byproduct material. Many participants involved in therapeutic medical uses supported the status quo requirements for such uses (generally requiring either medical speciality board certification or a specified number of hours of classroom and laboratory training) because such requirements have served patients and the public well. They maintained that board certification ensures the appropriate level of training and experience and were cautious about any change that could diminish assurance of competency. However, some proponents of the status quo would accept the use of medical specialty boards other than those currently listed in Part 35. Some participants also felt that clinical experience in handling radionuclides and patient cases, especially across a broad range of developing therapy, is crucial. Representatives of diagnostic uses of byproduct materials asserted that the status quo effectively prohibits some medical practitioners from using byproduct materials which they could safely use if the training requirements were decreased. They believe that an examination component of the training and experience requirements is extremely important in setting a standard for authorized users. Some diagnostic users recommended that about 150 hours of didactic training and associated clinical experience would be sufficient.

The discussion of training and experience requirements addressed the viewpoint that all professionals involved in handling radionuclides, including medical physicists, authorized nuclear pharmacists, nurses, technologists, dosimetrists, and physician's assistants, should be subject to the training and experience requirements. Some participants supported degree requirements, such as a master's degree in health physics. Opposition to such a requirement was based on the concept that performance criteria, rather than a degree, should be the basis for determining competence for certain positions, such as the Radiation Safety Officer or

nuclear technologist. Another viewpoint expressed was that the nuclear medicine technologist, rather than the authorized user physician, should be the focus of training and experience requirements, because the technologist actually handles the radioactive material.

Participants believed that training and experience requirements are essential for ensuring the competency of a Radiation Safety Officer. They generally expressed support for the status quo for training and experience requirements for the Radiation Safety Officer, but questioned whether an authorized user should automatically qualify as a Radiation Safety Officer. Specifically, some participants believed that an authorized user should not also be the Radiation Safety Officer because of "potential conflicts of interest" (i.e., the Radiation Safety Officer should not be influenced by the "administration" of a facility). Other participants noted that an authorized user physician might be a specialist whose practice includes a limited application of the medical use of byproduct material, and who does not have sufficient training in radiation safety to address problems that might occur. Certain participants believed that it may be appropriate for an authorized user to be a Radiation Safety Officer at a small hospital, even if that authorized user did not have the breadth of training to be a Radiation Safety Officer at a large hospital. A concern of some participants is that there may not be anyone other than the authorized user to assume the responsibility as a Radiation Safety Officer at small community hospitals. In those cases, an authorized user, who is also the Radiation Safety Officer, was seen to be preferable to not having a Radiation Safety Officer.

Workshop participants generally did not question the current training and experience requirements for the Radiation Safety Officer. Some suggested changes for the Radiation Safety Officer's training and experience were discussed, such as varying the training and

experience to correspond to the type of license or duties performed by an individual Radiation Safety Officer; to have a "core competency" set of requirements (which could be supplemented with additional requirements for modalities posing greater risks); or to substitute a Masters of Science degree for the 200-hour training requirement.

Certain participants involved in "low-dose" medical uses were unanimous in concluding that Part 35 include training and experience for medical physicists. They noted that training and experience requirements should correspond to the duties and responsibilities of the physicist for different modalities (i.e., instrumentation for nuclear medicine, radiation treatment planning, or administration of doses for radiation therapy).

Comments by participants on this issue were favorable regarding training and experience for the authorized nuclear pharmacists. Some participants specifically stated that, based on risk, radiopharmacy training and experience should be handled similarly to other diagnostic modalities.

Training and experience requirements for ancillary personnel, such as technologists, were briefly discussed. Some participants supported training and experience requirements for technologists because the technologists, rather than the physicians, handle the radioactive materials. One participant, a nuclear medicine technologist, indicated that there are already organizations that have established voluntary training and experience requirements for technologist certification. The individual did not believe that these organizations would endorse other exams. The individual also indicated that, if proposed, training for technologists should be risk-based.

2. Agreement State Workshop.

Discussions at the Agreement State Workshop focused on whether NRC's training and experience requirements should focus exclusively on the radiation safety aspects of an authorized user's training, leaving issues such as patient selection and reading scans to be part of the "practice of medicine." Workshop participants were divided on this issue. Those answering this question affirmatively believed that NRC should focus on assuring that physicians are capable of safely handling and using byproduct material. One participant indicated that the level of education to demonstrate competence should be uniform regardless of the hazard posed by the material. Other participants believed that, from the patient's perspective, the physician's role goes beyond safety and into areas such as patient selection and scan interpretation.

One member of the public argued that NRC and Agreement States should require physicians to master quantitative radiation protection science before permitting them to become authorized users. The individual also believed that NRC and the Agreement States should rely solely on physician practice privilege committees, State Boards of Medicine, and the Joint Commission on the Accreditation of Health Care Organizations to determine the qualifications of physicians to practice nuclear medicine.

The Agreement States were concerned about the resources needed to develop and validate examinations. One participant stated that creating and validating a new exam would be costly in comparison to seeking out existing exams that were validated and acceptable to the NRC.

Training and experience requirements for ancillary personnel, such as technologists, were discussed. A representative of the nuclear medicine technologist profession stated that the role of the technologist entailed more than the safe handling of radioactive materials. The role of the technologist was to provide the physician with the information needed to treat the patient. The individual went on to indicate that the success of the entire diagnostic process correlated with the education and training of the technologist and physician. The individual indicated that groups currently certifying technologists support certification for technologists and State legislation mandating that technologists be licensed. The individual also indicated that these certifying groups did not favor NRC setting standards for training and experience for technologists because the NRC does not have the experience necessary to determine what the training requirements for technologists should be.

One workshop member confirmed that a number of States require that technologists be certified. The participant noted that the Conference of Radiation Control Program Directors (CRCPD) was planning on discussing minimum training and experience qualification criteria for technologists. These requirements would be added to the Suggested State Regulations.

3. Advisory Committee on Medical Uses of Isotopes (ACMUI).

Training and experience requirements have been discussed on numerous occasions with the ACMUI. The ACMUI most recently discussed training and experience for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers at its March 1-2, 1998, meeting. The ACMUI agreed with the Commission's proposed general approach to training and experience, i.e., delete reference in the rule to the speciality

boards names, require preceptor forms, and require that competency be demonstrated by successful completion of an examination. Members debated whether it is possible or prudent, with respect to authorized user physician training, to separate the hours required for radiation safety training from the entire clinical training period.

The ACMUI unanimously recommended that the current training requirements for authorized users of sealed sources and devices for therapeutic applications (proposed §§ 35.400 and 35.600) be maintained. Specifically, they recommended retaining the 3-year clinical training in an accredited program as an alternative to medical speciality board certification. The ACMUI agreed with the views expressed by members of the radiation oncology professional societies who made formal presentations at the March 1998, meeting. Specifically, they agreed that the current requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices.

The ACMUI unanimously recommended that the training requirements for authorized users of unsealed byproduct material for diagnostic uses (proposed §§ 35.100 and 35.200) be reduced to the levels proposed by the NRC staff (120 hours in a structured educational program). The ACMUI did not reach a consensus on the training requirements for authorized users of unsealed byproduct material for therapeutic uses. The NRC staff recommended reducing the training requirements to a 120-hour structured educational program and limited casework. Some members of the ACMUI were concerned that training for these uses should be addressed in a manner similar to that used for the therapeutic uses of sealed sources.

Finally, they unanimously agreed with NRC staff's recommendation for training requirements for authorized nuclear pharmacists (700 hours in a structured educational program) and medical physicists (Masters of Science degree and 2 years).

4. Written Comments.

Authorized Users Training and Experience Requirements for Unsealed Byproduct Material

The Commission received numerous comments from professional societies and individual physicians on the training and experience requirements for use of unsealed byproduct material.

Many professional societies, as well as individual physicians, were concerned that a reduction in training hours, as proposed in a January 20, 1998, "strawman" version of the proposed rule, would not provide adequate training and might result in approval of poorly trained practitioners. They believe that it is impossible to distinguish between safety and competence. They indicated that the current requirement for 500 hours of clinical experience is an important "patient safety regulation." Some professional organizations recommended that the Commission maintain the current training requirements in this area for authorized users, but also recommended that the training be provided only in programs accredited or approved by the American Council on Graduate Medical Education. Others believed that training and experience should be developed, administered, and monitored by medical specialty organizations with experience in clinical radiation-related technologies.

One professional society supported the reduction in training hours. This organization recommended that physicians, who are not certified by an NRC-approved medical speciality board, be required to pass an examination and to obtain a written certification from a preceptor that indicates that the individual is able to function independently on all aspects of radiation safety.

Another society suggested that competence in radiation safety be demonstrated in a performance-based manner, e.g., NRC would not specify a specific number of hours, but would assess competency through a comprehensive examination.

One society urged the Commission to maintain the current training and experience requirements for use of byproduct material to treat hyperthyroidism or thyroid carcinoma. This organization opposed the proposal in the "strawman" proposed rule to increase the number of training hours needed to use material to treat hyperthyroidism or thyroid carcinoma and opposed the requirement for an examination. This organization believed that the proposed increase in training and experience requirements would have a detrimental effect for patient care, such as referral of patients to other specialists using less desirable alternative treatments.

One commenter indicated that a minimum of 120 hours of classroom and laboratory training and 240 hours supervised practical experience, or a 3-month training program in nuclear medicine, was appropriate for diagnostic nuclear medicine.

Training and Experience for Use of Sealed Sources in Therapy

The NRC received approximately 330 letters providing input to the rulemaking process. Approximately 90 percent of these comments were from radiation oncologists who feel very strongly that the current training and experience requirements for authorized users of brachytherapy and therapeutic medical devices should be retained because of the high risk associated with use of these modalities and because radiation safety training and clinical competence are intertwined for uses of these devices.

Commenters believed that training and experience requirements should be consistent with that required for certification by the American Board of Radiology (i.e., 3 years of therapeutic radiology and at least 6000 hours of direct clinical experience). If the Commission were to consider other medical specialty boards for certification of physicians seeking approval as authorized users to perform brachytherapy and teletherapy, the training required by those boards should be the same as that required by the American Board of Radiology for certification in therapeutic radiology. Certain comments specifically objected to either an NRC-developed or NRC-approved examination, because that would mean that the standards of the American Board of Medical Specialties and its twenty-four member boards are “too high.”

Most commenters believed that thorough training in radiation oncology should be required for all physicians seeking to perform applications of ionizing radiation to treat disease. According to certain comments, therapeutic treatments of the heart and brain are high-risk procedures and “relaxing” these requirements would not be in the best interest of patients or the medical profession at large. They maintained that training requirements for coronary artery

brachytherapy and gamma stereotactic radiosurgery should be the same as those for other brachytherapy and teletherapy modes of treatment, respectively, and not broken into “tiny site-specific” modalities with different training requirements.

Other commenters noted that radiation oncologists should be involved, as part of a team with cardiologists and neurosurgeons, in brachytherapy treatment of the heart and use of gamma stereotactic radiosurgery of the brain. Other comments described the “full complement” of training for these medical uses as covering radiation biology, radiation physics, and radiation safety.

A professional organization offered criteria for training and credentialing of cardiologists performing brachytherapy involving coronary and vascular interventions. This organization believes that cardiologists should perform intravascular brachytherapy in collaboration with medical physicists, Radiation Safety Officers, and medical dosimetrists.

5. Resolution.

The Commission considered all of the input on training and experience that was provided during the development of this rulemaking. On the basis of the public input, the Commission is proposing the following training and experience criteria for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers:

- (1) The requirements for training and experience should be risk-based and focused on radiation safety;

(2) Individuals should complete a structured educational program that consists of didactic training and practical experience;

(3) Specific reference to speciality boards, by name, should be deleted;

(4) Speciality boards will be approved by the Commission or an Agreement State if the board certification process includes all the training and experience requirements associated with the equivalent training pathway;

(5) Preceptors, when required, should certify that individuals have achieved a level of competency sufficient to function independently as an authorized user for the requested use, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer; and

(6) Individuals should demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission or an Agreement State.

The Commission believes that training and experience criteria should be risk-based and focused on radiation safety. In addition, the Commission believes that, by requiring a combination of a structured education program, preceptorship, and examination focused on radiation safety, individuals will be able to safely handle byproduct material. It is important to note, however, that an individual's status as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer means that an individual is qualified to handle byproduct material safety and is not an assessment of the individual's clinical or professional competency.

The Commission believes that individuals should complete a structured educational program that consists of didactic training and practical experience. The number of hours and type of training were extensively discussed with the medical societies and speciality boards and have been the primary issue in the public input received on the rulemaking. However, the Commission recognizes that radiation safety training and clinical competency may be intertwined, especially for uses of therapeutic medical devices. Because of the high risk associated with use of sealed sources in therapeutic medical devices, the Commission has not proposed significant changes in the current training requirements for authorized users in this area, with the exception of the training required for the use of strontium-90 eye applicators. Under the proposed rule, authorized users of strontium-90 eye applicators will need to meet the training requirements for authorized users of therapeutic medical devices. The Commission believes this change is warranted in light of the similarity between the use of strontium-90 eye applicators and the use of sealed byproduct material in medical devices and the recent misadministrations involving strontium-90 eye applicators. It is important that the didactic training include courses in radiation physics, dosimetry, and radiation biology so that the authorized users have a clear understanding of what a dose means in terms of radiation damage to the exposed tissue.

The Commission has focused the training requirements for use of unsealed material for diagnostic administrations when a written directive is not required on radiation safety because of the low risk posed by the radionuclides. In doing so, the didactic and practical requirements for authorized users of unsealed byproduct material for diagnostic procedures were significantly reduced.

The didactic and practical requirements for use of unsealed byproduct material when a written directive is required were also reduced because of similarities between the use of unsealed material in a diagnostic setting and use in a therapeutic setting. However, the Commission recognized that the use of both therapeutic unsealed sources and sealed sources involve higher risks and, therefore, retained the requirement for clinical experience. The proposed rule would delete the specific training and experience sections that pertained to treatment of hyperthyroidism and thyroid carcinoma. Under the proposed revision of Part 35, individuals wishing to become authorized users of byproduct material for these medical uses would be required to meet the training requirements that apply to the use of unsealed material for therapeutic uses. The Commission believes that this change will not significantly affect authorized users in this area.

The Commission believes that any reference, by name, to specialty boards should be deleted from the regulation for two reasons. First, under the current Part 35, in which specialty boards are listed by name, a rulemaking is needed to add new boards or to delete existing boards. This has been a problem with the current Part 35 because on several occasions individuals requesting authorized user or medical physicist status have been certified by a specialty board that is not listed in the regulations. In these cases, NRC has had to evaluate the training of individuals, with the help of the ACMUI, on a case-by-case basis. Secondly, the current rule does not provide for periodic review of certifying boards to determine if any changes have been made in their certifying programs.

The proposed rule would require that specialty boards be approved by the NRC or an Agreement State. A specialty board will be approved by NRC if the certification process

includes all of the requirements listed in the equivalent training pathway, i.e., completion of a structured educational program of specific duration that covers specific topics; obtaining a signed preceptor certification; completion of patient casework, if required; and successful completion of an examination on radiation safety. The Commission plans to discuss proposed board approvals with the ACMUI prior to approving the boards. The NRC staff also plans to conduct periodic reviews of approved speciality boards to assure that they continue to meet commitments to NRC. If a board does not meet its previous training and experience commitments, it will be removed from NRC's list of approved boards. A list of approved boards will be maintained on the NRC external website. In addition, the Commission is contemplating noticing the approval of a speciality board in the Federal Register.

The Commission is proposing that preceptors, when required, should certify that individuals have achieved a level of competency sufficient to independently function as an authorized user for the use that they are requesting: a medical physicist, an authorized nuclear pharmacist; or a Radiation Safety Officer. In the current Part 35, a preceptorship is only required for authorized nuclear pharmacists. The current preceptors for authorized nuclear pharmacists are only required to attest to the fact that the individual has performed a specified number of cases/treatments. Preceptor forms will be revised to add a warning that 18 U.S.C. Section 1001 Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

The Commission believes that individuals should demonstrate sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an

organization or entity approved by the Commission or an Agreement State. Appendix A of the proposed rule provides the requirements for an examining organization or entity, examination programs, and written examinations. Of particular note is the requirement that procedures be established to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area. This proposed requirement is consistent with current practices of medical specialty boards and was suggested for inclusion by ACMUI members. The Commission is soliciting specific public comment on whether this proposed requirement is too prescriptive in light of current industry practice.

It is expected that examinations will be specific to the risk associated with the medical use of the byproduct material. For example, it is reasonable to expect that one exam could be used to address an authorized user's competency for the medical use of material pursuant to §§ 35.100, 35.200, and 35.300, and that another examination would be needed to assess competency for use pursuant to §§ 35.400 and 35.600. The Commission plans to discuss the examination process with stakeholders at the facilitated public meetings scheduled to be held during the comment period of this rulemaking. In addition, the Commission solicits written comment on issues associated with the examination process.

NRC expects that it will take approximately 2 years for the industry to submit required information, to NRC or an Agreement State, for approval of specialty boards or organizations providing the exam and for NRC to approve the boards or examining organizations. This expectation is based on written and verbal support, received from professional organizations, for training and experience requirements that would require written examinations to assess competency and, on statements made by members of specialty boards indicating that only

minor changes would need to be made to their current certification process to address the changes proposed by the Commission. The Commission anticipates that specialty boards and examining organizations will be prepared to submit requests for approval immediately following publication of the final rule. Nevertheless, the Commission is soliciting specific public comment on the amount of time that specialty boards and examining organizations will need to prepare and submit an application for approval of the Commission or an Agreement State.

Since NRC expects that it will take approximately 2 years to complete approval of most specialty boards and examining organizations, NRC has maintained the current training requirements in subpart J of the proposed rule. As discussed under the Supplementary Information section of this document, for a 2-year period after publication of the final rule, licensees will have the option of meeting either the requirements in subpart J or the requirements in subparts B and D-H. After the 2-year period, the requirements in subpart J will be deleted, and the licensee will need to comply with the requirements in subparts B and D-H.

B. Quality Management Program.

I. Facilitated Workshops.

Workshop participants expressed both support for the quality management program and opposition to it. Those who support it described several benefits of the program, including the requirement for licensees to have a quality management program and related requirements for "recordable events" and written directives. Opponents of the quality management program rule described it as overly prescriptive, burdensome on licensees, and ineffective in reducing the

number of misadministrations. According to certain participants, the current quality management program rule interferes with quality medical care. Many believed that the current quality management rule did little to reduce the number of misadministrations.

Some participants who did not support the quality management program expressed support for a performance-based rule that would not require licensees to submit the quality management program for regulatory approval. In their opinion, a performance-based rule would also provide a licensee with the flexibility to custom-tailor a quality management program to meet that facility's quality management needs, including patient verification, ensuring that physician's directions are written, and verifying doses to patients. Some participants proposed that NRC work with other organizations or agencies to ensure quality assurance through other mechanisms in place. Another recommendation was that the proper way to reduce misadministrations is through better training and ensuring, during the licensing process, that personnel are qualified.

2. Agreement States Workshop.

Some Agreement States and members of the public agreed that the current quality management rule has not addressed the problem of misadministrations. In addition, they do not believe that the quality management rule goes beyond what would typically be considered "quality management." They believe that modifying the quality management program will not solve that problem.

Agreement States supported an option that would state the objectives of a quality management program (without being prescriptive), but would not require a written quality management program. Other States believed that the responsibility for quality management should lie exclusively with the medical facility, not with a regulatory agency.

A member of the public advocated, in lieu of a quality management program, a training requirement for technicians and a requirement that a physician be present whenever a therapeutic dose is administered. The individual stated that the latter requirement has significantly reduced the number of misadministrations in her State. Another member of the public suggested that a proposed rulemaking by the Health Care Financing Administration (HCFA) was expected to define three levels of supervision for imaging modalities. He explained that physicians would be required to be in the facility, if not in the room, when a dose was being administered in diagnostic nuclear medicine.

3. ACMUI.

Requirements for a quality management program have been discussed on numerous occasions with the ACMUI. At the September 1997 meeting, the Committee recommended that the Commission pursue development of a rule that would state only the objectives for a quality management program. At the March 1998 meeting, the ACMUI discussed the NRC staff's proposed revisions to the quality management program. The ACMUI agreed with the NRC staff's proposal to delete the requirements for a quality management program. Although the ACMUI would have preferred deletion of the requirement for written directives and the reference to assuring high confidence that the patient's or human research subject's identity is verified

and that each administration is in accordance with the written directive, it recognized that the Commission finds these objectives to be fundamental.

4. Written Comments.

Approximately 10 written comments were submitted to the Commission on the quality management program. The majority of the comments favored deletion of any requirements in this area. Most believed that there were industry standards in place that adequately addressed administration of byproduct material; the rule intruded into medical practice; and regulation in this area was onerous. One professional society recommended that the title be changed to "Quality Assurance and Patient Safety Regulations" and believed that the regulations should be limited to requiring written prescriptions for therapy; requiring licensees to develop quality assurance programs for treatment planning and delivery devices; and requiring that independent checks be made against the written prescription before completion of a treatment. A limited number of commenters believed that the current requirements should be maintained because the quality management program provides a mechanism for reporting events and because licensees have already developed quality management plans that meet the intent of the rule.

5. Resolution.

The Commission has deleted the requirement for a quality management program. However, the Commission believes there are three elements of the current quality management program that should be addressed in the proposed rule: confirming patient identity, requiring

written directives, and verifying dose. The Commission believes that some elements of the current quality management program requirements will continue to be implemented as part of the "standard of care" in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those previously specified in the rule.

C. Reportable Events.

1. Facilitated Workshops.

The participants generally agreed that current threshold levels for reporting are too low and supported raising threshold levels. However, some participants supported the option of maintaining the current thresholds, arguing that they were familiar with the levels and reports and records of misadministrations are necessary. Participants agreed that threshold levels for recording and reporting events should be based on risk. Several participants argued that threshold levels for reportable events and Abnormal Occurrences should be the same. The NRC was commended for suggesting that the term "misadministration" be replaced with the term "reportable event."

2. Agreement State Workshop.

Discussion focused on the topic of precursor events, rather than on the threshold for reportable events. There was, however, a very brief discussion on reporting of misadministrations. Various statements made during the discussion included: regulatory

agencies did not need to be informed of misadministrations, unless an event exceeded certain levels or occurred more than once; licensee management, rather than a regulatory agency, should be informed of misadministrations; and regulatory agencies should confirm, during periodic inspections, that licensee management is informed in cases of misadministrations, and that proper corrective actions are taken.

3. ACMUI.

The ACMUI discussed the threshold for reportable events at the September 1997 and March 1998 meeting. At the September 1997 meeting, the Committee reached a consensus, recommending that the current criteria for radiopharmaceutical misadministrations be reduced from three categories to two. The two categories would be "radiopharmaceuticals not requiring a written directive" and "radiopharmaceuticals requiring a written directive." The Committee pointed out that there is a major deficiency in the current misadministration definition, i.e., there is no threshold dose for wrong treatment site. They also stated that the reporting mechanism should be decoupled from patient notification. Finally, they agreed that an underdosage, if corrected in a clinically timely manner, should not have to be reported.

At the March 1998 ACMUI meeting, the NRC staff presented a proposed revision of the current reporting criteria. The proposed reporting requirement contained a dose threshold and modality-based criteria. The ACMUI discussed the proposed criteria and offered suggestions for minor technical corrections, but did not make a formal recommendation in this area. The Committee recognized that the NRC staff was still making changes in the proposed text to address the wrong treatment site and patient intervention.

4. Written Comments.

Sixteen comments were received in this area. Two of the commenters recommended raising the reporting threshold to the NRC's Abnormal Occurrence criteria for misadministrations. Several commenters provided general comments on the reporting criteria, including a name change from "misadministration" to "medical event." The remainder of the commenters provided specific recommendations for changes to the current reporting criteria, including recommendations for addressing patient intervention and wrong treatment site.

5. Resolution.

The Commission has a statutory responsibility to keep Congress and the public informed of incidents or events which the Commission considers significant from the standpoint of public health and safety. These criteria are specified in NRC's Abnormal Occurrence Policy Statement, dated April 17, 1997 (62 FR 18820). Licensees must provide NRC with information on events meeting these criteria, in order for NRC to make needed reports to Congress.

The term "misadministration" has been deleted. The proposed rule would require licensees to report "medical events." The criteria for a medical event is based on the current requirements in § 35.33, Notifications, reports, and records of misadministrations. Minor changes were made to make the reporting threshold dose-based, where possible, and to address two areas that have caused problems in implementing the current requirements in § 35.33, Patient intervention and wrong treatment site.

D. Precursor Events.

1. Facilitated Workshops.

Participants in the facilitated public workshops, as well as members of the public, believe that:

- (1) There are already adequate mechanisms in place for identifying precursor events;
- (2) Additional requirements for notifying NRC about precursor events could result in a significant financial burden for both NRC and licensees without an associated incremental increase in safety;
- (3) Because of the nature of precursor events, it will be hard to precisely define a precursor event in rule language; and
- (4) Inclusion of a requirement for reporting precursor events could lead to an additional basis for enforcement action.

2. Agreement State Workshop.

The discussion on this subject focused on how to identify "precursor events." Many of the participants opposed adding additional requirements for reporting precursor events. According to some Agreement States, mechanisms are already in place to provide information to licensees about incidents which may be "precursors" to reportable events. Most States were in favor of identifying precursors, but believe notification should be limited to facility management (especially the radiation safety organization). Some participants noted that reporting those events to a regulatory agency could actually inhibit their identification. They did,

however, support internal programs for identifying precursor events. Finally, they stated that reporting to NRC or to the Agreement States would not be helpful unless a mechanism existed to share the information with the industry.

A member of the public noted that there are numerous event reporting requirements under which medical institutions document problem areas and conduct audits of potential problem areas. The individual encouraged NRC to avoid duplicating already existing programs.

3. ACMUI.

The ACMUI discussed the best way to capture precursor events at its September 1997 and March 1998 meetings. At the September 1997 meeting, most Committee members supported voluntary reporting of precursor events, provided there would be no punitive action taken by NRC against a licensee as a result of a report. One member recommended against reporting of precursors, whether mandatory or not, if it was going to have significant resource implications for NRC or the licensee.

At the March 1998 meeting, the ACMUI considered three alternatives proposed by NRC staff:

(1) Require reporting of conditions or incidents related to the use of radionuclides in medicine that caused or could cause serious injury to a patient, human research subject, worker, or the public;

(2) Require reporting deficiencies in equipment or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer, could lead to a

medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility; and

(3) Rely on current NRC reporting requirements in 10 CFR parts 20, 21, and 30 and the Memorandum of Understanding with the U.S. Food and Drug Administration and monitor/establish a system with U.S. Pharmacopeia to review its database on event reports.

The ACMUI acknowledged that the Commission wanted to capture precursor events. The ACMUI believed that it was appropriate to clearly define and limit the type of events that would be required to be reported in order to minimize the resource burden on licensees and the NRC. The ACMUI recommended that the NRC staff pursue the second alternative, with minor adjustments.

4. Written Comments.

Approximately five written comments were received on capturing precursor events. One commenter indicated that NRC should develop a nonpunitive method of capturing information while minimizing the burden on licensees, citing the FDA device malfunction reporting system as a model. Three other commenters felt that precursor events were not specifically enough defined (in an earlier draft of the proposed rule) and recommended that they not be included in the proposed rule. Of the remaining two commenters, one commenter did not support reporting precursor events under any condition, while the other supported voluntary reporting.

5. Resolution.

The Commission believes that identification and reporting of precursor events at some level is warranted. The Commission's objectives in capturing precursor events are to identify and analyze incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities.

The proposed rule contains a requirement for licensees to report, no later than the next calendar day, after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event.

E. Radiation Safety Committee.

1. Facilitated Workshops.

Workshop participants expressed different opinions about the benefits of radiation safety committees. Some participants stated that although radiation safety committees may be beneficial, the time and resources that must be devoted to managing the committees are excessive and the specific requirements in the regulation are overly prescriptive and not risk-based. Many participants believed that licensees should be given more flexibility in how they administer radiation safety programs. Some participants also expressed concern that the

radiation safety committee may not be necessary for effective radiation safety management at small medical institutions.

Some participants believed that a single committee, focused on radiation safety, was an important element of a radiation safety program and, therefore, recommended that the requirement for a committee be maintained. They believed that the committee enhanced communication between disciplines and departments. They were concerned that, without a requirement for a radiation safety committee, administrative support for the committee would decline and there would be decreased management involvement in the radiation safety program.

2. Agreement States.

Discussions at the workshop centered around two issues:

- (1) Whether the radiation safety committee plays a valuable role in all medical institutions, regardless of size and use of byproduct material; and
- (2) Whether the current radiation safety committee requirements in Part 35 are too prescriptive and should be relaxed.

The majority of the participants in the workshop argued that the radiation safety committee requirements should recognize the differences between large and small institutions and between low- and high-risk procedures. Participants asserted that a radiation safety committee is unnecessary at smaller, diagnostic facilities. They generally supported the lessening of prescriptive requirements for smaller, diagnostic facilities. They argued that

regulations place an unnecessary burden on facilities that conduct few procedures per year but still are required to conduct quarterly meetings. Another participant opposed a prescriptive rule, but acknowledged that it would be simpler to enforce than a performance-based rule.

3. ACMUI.

Requirements for a radiation safety committee were discussed with the ACMUI at its September 1997 and March 1998 meetings. At the September 1997 meeting, the ACMUI recommended that the NRC staff pursue developing a requirement for radiation safety committees at institutions that perform high-risk procedures. Facilities that use diagnostic, low-dose, sealed and unsealed byproduct material would not be required to have a radiation safety committee.

At the March 1998 meeting, the ACMUI agreed with the Commission's proposed deletion of the requirement for a radiation safety committee. ACMUI supported the addition of requirements for licensee management to approve licensing actions and minor revisions to the radiation safety program; and for a licensee to implement procedures for interdepartmental/ interdisciplinary coordination of the licensee's radiation protection program. They believed that the proposed language would not prohibit a large organization from utilizing a radiation safety committee, but would, at the same time, reduce regulatory burden on small rural hospitals which have small staffs and where a committee may not be needed to manage the radiation protection program.

4. Written Comments.

Approximately 10 written comments were submitted regarding the requirement for a radiation safety committee. The majority of the comments favored retention of the requirement for a radiation safety committee at larger facilities. These commenters believed that a committee was an effective way to ensure that management is involved in the operation of the radiation safety program. They recommended that a "graded" approach could be used in determining if a committee was needed, e.g., small facilities or facilities with limited use of material would not be required to have a committee. However, two commenters believed that the requirement for a radiation safety committee should be deleted in its entirety. Two others believed that the requirements should not be revised.

The Commission recognizes that medical facilities normally have a number of committees examining various areas, including safety issues, in response to accreditation requirements, etc. Specification of the objectives to be met by the radiation protection program (in the proposed § 35.24), rather than the particular mechanism to be used in meeting those objectives, is an effort to provide licensees flexibility in carrying out the responsibilities for radiation safety.

5. Resolution.

The Commission is proposing deletion of the requirement for a radiation safety committee. The Commission believes that key functions of the radiation safety committee could be transferred to licensee management and that the prescriptive requirements in the current

rule should be deleted. The Commission believes that many institutions will continue to use a radiation safety committee to oversee use of radioactive material. However, it recognizes that radiation protection program oversight may be accomplished by other means. In particular, the Commission recognizes that medical facilities normally have a number of committees examining various areas such as environmental safety. These committees are typically formed in response to hospital accreditation requirements.

In an effort to afford licensees flexibility in achieving the objectives of radiation safety, the proposed rule specifies objectives that must be achieved rather than specifying the mechanism to meet the objective. The proposed rule would require that the licensee approve licensing actions; individuals prior to allowing them to work as a Radiation Safety Officer, authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require a license amendment. The proposed rule also contains a requirement for the licensee to develop, implement, and maintain administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

F. Notification Following a Misadministration or Medical Event.

I. Facilitated Workshops.

Many participants believed that the current requirements for licensees to notify the NRC, the referring physician, and the patient of a misadministration is an intrusion into both the practice of medicine and the confidential patient-physician relationship. They stated that the

decision whether to notify the patient should be left solely to the physician. Those participants asserted that medical "standards of practice," "risk management" practices of medical institutions, and tort law are the mechanisms that should address notification of patients.

Therefore, according to these participants, Federal or State legal requirements for such notifications are unnecessary and inappropriate. Some participants believed that an authorized user would never withhold information from a referring physician because to do so would destroy the relationship between the authorized user and the referring physician.

Workshop participants did not believe that the requirement for a licensee to provide a written report to the individual was appropriate. They believed that a report that was submitted to NRC may greatly magnify, in the patient's mind, the significance of the event, when in fact, a medical event could be of minimal safety significance. However, other participants stated that without the NRC requirement for patient and referring physician notification, the physician's ethical obligation to make these notifications must be strong. Some commenters believed that the exchange of information between physicians should extend to patients as well. The participants espousing this viewpoint believe that such requirements may be necessary to protect patients and their right to know of misadministrations.

2. Agreement State Workshop.

Some participants noted that legal requirements for protecting the privacy of patients vary from State to State and may differ from Federal requirements. Other participants stated that medical standards of practice, tort law, and medical institution risk management are

mechanisms to address fundamental patient notification and, therefore, State or Federal requirements for such notification are unnecessary.

3. ACMUI.

Notification requirements have been discussed on numerous occasions with the ACMUI. The ACMUI most recently discussed the requirements in this area at its March 1998 meeting. The ACMUI continues to affirm its position that it does not support any Federal regulation requiring notification of physicians and patients. The committee strongly believes that patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which the "standard of care" for a physician is to provide the patient with complete and accurate information.

4. Written Comments.

Three written comments directly addressed notification following a medical event. Two professional organizations recommended that the requirement be deleted. One State recommended that the requirement be maintained.

5. Resolution.

The Commission believes that the current requirements for notifying individuals following a misadministration should remain unchanged with the exception of substituting the term "medical event" for "misadministration." Changing terminology in this way responds to

objections that the term "misadministration" has possible connotations of carelessness and harm, which is not always the case. Furthermore, the term "medical event" used in the proposed rule is consistent with the terms used to characterize events in other activities regulated by the NRC. The proposed rule requires that the licensee notify the NRC, referring physician, and the individual who are the subject of a medical event, unless the referring physician personally informs the licensee that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. In the latter case, or if for example, the patient is a minor, or is unconscious and incapable of comprehending the information, it is expected that the licensee would report to the patient's responsible relative or guardian rather than to the patient. This position reaffirms statements made by the Commission, at the time the misadministration rule was proposed and/or promulgated (and later modified), that patient notification "... recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector." "Human Uses of Byproduct Material, Misadministration Reporting Requirements," 43 FR 2927; May 7, 1978; "Misadministration Reporting Requirements," 45 FR 31701-31702; May 16, 1980; and "Basic Quality Assurance Program, Records, and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 FR 1439-1444; January 16, 1990. The Commission also believes that patient notification enables patients, in consultation with their personal physicians to make timely decisions regarding any remedial and prospective medical care. This approach would also codify existing industry standards [American Medical Association Principles of Medical Ethics] obligating physicians to provide complete and accurate information to their patients.

This approach is consistent with the U.S. Food and Drug Administration (FDA) regulation and with how Congress is addressing similar issues in the mammography area. In October 1992, Congress passed the "The Mammography Quality Standards Act" (Public Law 102-539) to establish national quality standards for mammography. In December 1993, the FDA promulgated interim regulations setting forth quality standards for mammography facilities. In October 1997, the FDA issued a final rule that becomes effective in April 1999. The final rule requires that, in cases where "FDA determines that the mammography program at a facility may present a serious risk to human health, a facility must notify the patients or their designees, their physicians or the public of action that may be taken to minimize the effects of the risk." Currently, the Senate has passed and the House is considering bills (S. 537 and H.R. 1289) to amend the Mammography Quality Standards Act to, inter alia, add a new section to the Act on patient notification. The bills will provide FDA with the authority to require a facility to notify patients (and their referring physicians) of, among other things, the potential harm resulting from mammograms that may have been of poor quality because of deficiencies in the mammography program at that facility.

G. General Comments.

In addition to the comments on the crosscutting issues discussed above, NRC received comments on specific sections of the rule and on several general topical areas. These comments are available for review in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Comments on specific sections of the rule were taken into consideration in preparing the proposed rule. General comments are summarized below.

1. Process for Developing the Risk-Informed, Performance-based Rule.

- a. Comments.

Workshop participants and written commenters discussed development of a risk-informed, performance-based rule. Some commenters recommended that NRC not proceed with any revision of Part 35 until it had performed an adequate and comprehensive evaluation of the risks associated with medical use. They recommended that the assessment should be performed by an "independent scientific organization" and completed in advance of any rulemaking. The risk analysis should follow the guidelines outlined by the Presidential Commission on Risk Assessment and Risk Management.

Some commenters did not believe that the current regulatory system makes optimal use of either NRC or licensee resources. They believed that NRC regulations and their associated paperwork burden inevitably contribute to the cost of providing clinically necessary procedures and may compromise the availability of the benefits of medical use of byproduct material. They recommended that NRC be guided by the following basic principles: rules should emphasize training and credentialing of professional staff deemed essential to safe operations, quality assurance and technical regulations should be based on available practice standards, and regulations should not be promulgated in the absence of a demonstrated risk to the public or patients.

Some commenters believe that Part 35 is duplicative of the Food and Drug Administration (FDA) statutes and implementing regulations and does not provide any added

overall benefits to the regulatory framework. They believed that the FDA regulatory scheme is comprehensive, requiring documentation of adverse effects relating to the use of all drug products, including radionuclides; regulations under 10 CFR Part 20 are adequate to protect health and safety; high-risk medical use can be regulated on a case-by-case basis through licensing conditions; and some prescriptive license conditions can be offset by performance-based flexibility, which is preferable to prescriptive regulations of medical users.

Finally, some commenters questioned the schedule for completion of the rulemaking. They believe that sufficient time must be provided to undertake a thorough effort to change the rule and for public comment on draft documents, including regulatory guides. They also believe that reorganization of Part 35 based on "similar subject areas" is appropriate, but the rule should include references to requirements in Part 20.

b. Resolution.

The Commission did not perform a formal risk assessment as part of this rulemaking effort. The Commission considered input from a 1993 internal senior management review report; external review report by the National Academy of Sciences, Institute of Medicine; and information presented in the Strategic Assessment Direction-Setting Issue Paper Number 7 (DSI-7) prior to determining the role of NRC regulation in the medical use area. On the basis of these reviews, the Commission believes that Part 35 should be restructured into a risk-informed, more performance-based regulation. In developing the regulation, the Commission considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC.

2. Agreement State Compatibility.

a. Comments.

Commenters recommended that NRC follow its Strategic Plan to work with Agreement States to assure protection of the public health and safety nationwide, especially where constraints due to inconsistent regulation result in barriers to accessibility of medical use involving radionuclides. One commenter suggested that Agreement States should not be required to adopt any of the revised rule or accompanying guidance documents.

b. Resolution.

The Working Group and Steering Group established to revise Part 35 are comprised of NRC staff, as well as representatives of two Agreement States and a non-Agreement State. One of the Agreement State representatives on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested state medical use regulations. The Working and Steering Groups received input from the Agreement States at several times during the rulemaking process. NRC representatives met with representatives of the Agreement States during the October 1997 All Agreement States Meeting. Agreement State representatives were invited participants at the facilitated public meetings. One Agreement State representative provided written comment during the early input stages of the proposed rule development.

The Commission has reviewed the proposed rule for issues of compatibility for Agreement States. Specific designations for the proposed rule are discussed under Section IX of the Supplementary Information section of this document.

3. Licensing and Enforcement Actions.

a. Comments.

Some commenters believed that NRC must change to a performance-based compliance system in order to have a significant impact on the entire medical use program. They believed that no change would occur if the NRC deleted regulatory requirements but had license reviewers demand that licensees make equivalent commitments in license applications or add equivalent conditions to the license. Some commenters stated that licensees should be allowed to operate their radiation safety programs without "procedure-by-procedure" approval by NRC and that regulations should cover all necessary requirements. Commenters recommended that NRC abandon an adversarial enforcement strategy based on punishment for infractions.

Commenters also believed that no change would occur if inspectors continued to apply regulatory and license requirements without regard to fault, and if inspectors continue the practice of issuing citations for minor regulatory requirements which can be attributed to normal human error and which have no safety significance. They stated that NRC must develop an enforcement system that allows for exercising clinical judgment, evaluating quality assurance

policy deviations in terms of safety rather than legal significance, and accepting voluntary practice standards and measures of practice quality as the regulatory endpoints.

b. Resolution.

The proposed rule provides for an overall change in regulatory philosophy. Consistent with a risk-informed, performance-based approach to medical use licensing, the amount of information needed from an applicant to possess and use byproduct material would be reduced. An applicant for an NRC medical use license would have to submit a signed application, documentation of the training and experience of the individuals named on the license, and the facility diagram and list of instrumentation. While licensees would be required to develop, implement, and maintain procedures required by the regulations, they would no longer be required to submit these procedures as part of the license application. Furthermore, licensees will be provided maximum flexibility in developing their procedures because most of the requirements for procedures provide performance-based objectives to be achieved, rather than a list of prescriptive details that need to be addressed in the procedures.

The NRC plans to review the enforcement policy as part of its overall revision of Part 35. This review will take into account written comments as well as those comments received during the facilitated public meetings that are scheduled to occur during the formal comment period.

IV. Discussion of Text of Proposed Rule

10 CFR PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

Section 20.1301, Dose limits for individual members of the public, would be revised.

The proposed rule responds to the petition from the University of Cincinnati by amending § 20.1301 to allow a licensee the discretion to permit visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to individuals who are not releasable pursuant to § 35.75. Currently, visitors are limited to 1 mSv (0.1 rem).

The Commission has used 5 mSv (0.5 rem) as a threshold for action in multiple locations in Parts 20 and 35. This threshold is used as both a dose limit and a reporting level. For example, § 35.75 uses the 5 mSv (0.5 rem) as a dose limit. The proposed change to § 20.1301 would also use 5 mSv (0.5 rem) as a dose limit. In contrast, however, the proposed changes to § 35.3047, Report of a dose to an embryo/fetus or a nursing child, would establish a 5 mSv (0.5 rem) reporting threshold (reference § 35.3047 for a more detailed discussion of the proposed change).

In accordance with § 35.75, patients containing radioactive material can be released from licensee control if the total dose to other individuals from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). The Commission recognizes that the provisions of § 35.75 and the proposed revision to § 20.1301(a) could result in rare instances in which certain individuals could receive a 10 mSv (1.0 rem) dose. For example, an individual could receive a 5 mSv (0.5 rem) dose while visiting a patient who can not be released pursuant to § 35.75, and

then later receive a 5 mSv (0.5 rem) because of exposure from the released patient. The Commission believes that the authorized user is the appropriate individual to evaluate, on a case-by-case basis, the merits of allowing a visitor to potentially receive this additional dose and would do so only when it is warranted by the situation.

A potential consequence of this rulemaking is that pregnant visitors would not be excluded automatically from visiting individuals who could not be released pursuant to § 35.75. The pregnant visitor is subject to the same exposure limits that are applied to any other adult member of the public. The reasons for not excluding pregnant visitors under this rulemaking are two-fold. First, as noted in NCRP Commentary No. 11, members of a radionuclide therapy patient's family are likely to perceive that visitors will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Second, declaration of pregnancy by a prospective visitor is strictly voluntary. If a prospective visitor does not voluntarily declare her pregnant status, the authorized user is not expected to demand confirmation of the visitor's nonpregnant status.

As stated earlier, the proposed revision to § 20.1301 differs from the proposed revision to § 35.3047. The revision to § 20.1301 would revise the dose limit for a small population of individuals, namely visitors to individuals who can not be released pursuant to § 35.75. In contrast, the proposed revision to § 35.3047 would establish a reporting threshold for doses to an embryo/fetus or nursing child. For example, under the proposed § 20.1301, a pregnant visitor could receive 5 mSv (0.5 rem) as a result of a visit to a patient who has not been

released. Under the proposed revision to § 35.3047, if the dose to an embryo/fetus exceeds 5 mSv (0.5 rem), as a result of an unintended administration, a report must be submitted to NRC. Finally, in the course of diagnosis and treatment, an authorized user may approve, in advance, an administration of byproduct material to a pregnant woman that may result in an absorbed dose to an embryo/fetus that exceeds 5 mSv (0.5 rem).

The Commission does not intend to require monitoring and recording of individual doses. The NRC evaluated the costs associated with monitoring individuals versus the benefits derived and determined that, at these low doses, monitoring is not justified. However, this does not preclude the licensee from monitoring and recording individual doses.

10 CFR PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Section 32.72, Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35, would be revised as a result of the proposed revision of Part 35. Paragraph (b)(1) would be revised to reference the proposed § 35.27 rather than the current § 35.25 which would be deleted. This change was necessitated because of the proposed renumbering of some Part 35 sections. Paragraph (b)(2)(ii) would be revised to include both the proposed and current training and experience requirements for authorized nuclear pharmacists and to reference the proposed § 35.59 rather than the current § 35.972 which would be deleted. As discussed in subpart J, the current training and experience requirements would be deleted 2 years after the effective date of the final rule.

Section 32.74, Manufacture and distribution of sources or devices containing byproduct material for medical use, would be revised as a result of the proposed revision of Part 35. Paragraphs (a) and (a)(3) would be revised to add a reference to the proposed § 35.600. The current section does not include a reference to medical use of sealed sources in therapeutic devices. This oversight would be corrected by the proposed rule.

10 CFR PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, would be revised to specify that the requirements and provisions in Part 35 provide for the radiation safety of workers, the general public, patients, and human research subjects. Inclusion of the phrase "patients, and human research subjects" makes it clear that the provisions of this rule would apply to the radiation safety of those individuals. This addition is consistent with the proposed revision of the Medical Use Policy Statement that will be published separately in the Federal Register. The section would also be revised to add a reference to Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licensed, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC." This revision would make it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, would be amended by deleting the definitions of "ALARA," "dental use," "ministerial change," "misadministration," "podiatric use," and "recordable event" because they do not appear in the proposed rule.

The definitions for authorized nuclear pharmacist and authorized user would be revised to eliminate the specific board certifications by name and to refer to the specific section containing the requirements that the individual must meet to be considered an authorized nuclear pharmacist or an authorized user. Reference to the specific board certifications would be deleted because the proposed rule contains provisions for NRC to approve boards. The definition of "authorized nuclear pharmacist" was also revised to recognize nuclear pharmacists that have been approved by a nuclear pharmacy that has been authorized by the Commission to approve authorized nuclear pharmacists.

The definition of "Radiation Safety Officer" would be revised to include a reference to the specific requirements that an individual must meet in order to be authorized as a Radiation Safety Officer. This change was done to make the definition of Radiation Safety Officer consistent with the definitions of authorized nuclear pharmacist, authorized user, and authorized medical physicist.

The definition of "written directive" would be revised to delete the provision for the date the directive was signed, and the signature of the authorized user before administration of any byproduct material or radiation from byproduct material to a specific patient or human research subject. These specific requirements have been moved to § 35.40.

The definition of “teletherapy physicist” would be deleted and replaced with a definition for “authorized medical physicist” because it is a broader term that includes physicists that work with all types of therapeutic units.

The definition of “mobile nuclear medicine” would be deleted and replaced with a definition for “mobile service” because it is a broader term that would encompass all modalities that could be performed by a mobile service. A new definition would be added for “temporary jobsite.” This is needed since it is used in defining “mobile service.” The definition of “temporary jobsite” is based, in part, on the definition of “temporary jobsite” as used in 10 CFR Part 34, “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations.”

Definitions would be added for “high dose-rate remote afterloader,” “low dose-rate remote afterloader,” “pulsed dose-rate remote afterloader,” and “stereotactic radiosurgery” because use of these units would be addressed in Part 35. The definitions of “high dose-rate remote afterloader” and “low dose-rate remote afterloader” contain dose rates specific to each type of afterloader. The Commission is not proposing to define the term “medium dose-rate remote afterloader” since it is not used in the proposed rule. The Commission noted that there was very little difference between the regulatory requirements for a medium dose-rate remote afterloader and high dose-rate remote afterloader and, therefore, has chosen to group the units. The Commission is soliciting public comment on whether the rule should specifically reference medium dose-rate remote afterloaders.

A definition for “medical event” would be added and refers to the criteria listed in § 35.3045(a), Reports of medical events. A new definition, “precursor event,” would be added and refers to the criteria listed in § 35.3046(a). (Reference Section III, C, of the Supplemental Information section of this document for more detailed discussion.)

A new definition, “treatment site,” would be added because it is used in § 35.2045 of the proposed rule. A new definition, “unit dosage,” was added because it is used in §§ 35.60 and 35.63 of the proposed rule.

Section 35.5, Maintenance of records, would be revised to insert “and” in the current phrase “drawings and specifications.”

Section 35.6, Provisions for research involving human subjects, would be unchanged.

Section 35.7, FDA, other Federal, and State requirements, would be unchanged.

Section 35.8, Information collection requirements; OMB approval, would be revised to reflect the renumbering of some sections within the rule and the additional recordkeeping and reporting sections in the proposed rule.

Section 35.10, Implementation, would be a new section that discusses the proposed provisions for implementing the final rule. A detailed discussion of the implementation provisions can be found in Section VIII of the Supplementary Information section of this

document. This section would replace the current § 35.999, Resolution of conflicting requirements during transition period.

Section 35.11, License required, would be revised to reflect that the requirements for supervision in the current § 35.25 would be replaced by the proposed requirements in § 35.27.

Section 35.12, Application of license, amendment, or renewal, would be revised.

Paragraph (a) would be revised to state that any application for a license, amendment, or renewal must be signed by the management of the facility. The current rule indicates that any person may apply if the application is for medical use not sited in a medical institution and that only management may apply for a license if the application is for use in a medical institution. The Commission believes it is important that facility management apply for a license, regardless of where the material is used, because NRC holds the licensee responsible for any actions of its employees. Paragraphs (b) and (c) would be revised to more clearly state that separate applications must be submitted for medical uses listed in § 35.600, other than remote afterloaders. Paragraphs (b) and (c) would also be revised to delete the reference to the Regulatory Guides. Guidance for completing an application may be found in draft NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance about Medical Use Licenses." Draft NUREG-1556, Vol 9, is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft NUREG are available as indicated in the For Further Information Contact section of this document.

Paragraph (d) would be added to address applications for medical use of byproduct material that are not specifically included in subparts D through H of the proposed rule, henceforth referred to as “emerging technologies” (e.g., intravascular brachytherapy). The current rule does not provide for efficient licensing of emerging technologies. Paragraph (d) would provide a list of the information needed by NRC to approve a use that is not specifically addressed in subparts D through H of the proposed rule.

Section 35.13, License amendments, would be revised to reflect the new numbering as a result of the overall revision of Part 35. Paragraph (b) would be revised to indicate that a licensee does not need to amend its license before allowing anyone to work as an authorized medical physicist if that individual meets the training and experience requirements in § 35.51 or § 35.961, and the requirements were met within the 7 years preceding the date of the application. Paragraph (c) would be revised to delete the requirement for licensees to amend a license if the teletherapy physicist changes provided the individual meets the requirements in §§ 35.51(a) and 35.59 or §§ 35.961 and 35.59. This change is consistent with licensing requirements for authorized users and authorized nuclear pharmacists.

The Commission recognizes that unusual conditions may arise when the Radiation Safety Officer leaves a facility with little to no advance warning. In this event, the licensee may want to consider using an authorized user to fill the position, pending appointment of a new Radiation Safety Officer. Under these conditions, the licensee must move expeditiously to permanently fill the position of Radiation Safety Officer. In these situations, the licensee should contact the appropriate NRC regional office and explain the situation.

In order to reduce regulatory burden, paragraph (e) would be revised to delete the requirement for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used pursuant to §§ 35.100 and 35.200. However, this provision does not apply to storage or waste areas because of the potential for large quantities of materials to accumulate in these areas and the possibility of commingling of radioactive material that is used pursuant to other sections of the rule.

Section 35.14, Notifications, would be revised. Paragraph (a) would be revised to include a requirement for the licensee to notify NRC no later than 30 days after the date the licensee permits an individual to work as an authorized medical physicist pursuant to § 35.13(b). Paragraph (b) would be revised to require that the licensee notify NRC when an authorized medical physicist permanently discontinues performance of duties under the license. Paragraph (b) would also be revised to require that a licensee notify NRC when the licensee changes its name. This provision applies only if there is no change in ownership, as described in § 30.34 of this chapter. Otherwise, the licensee must take appropriate action to have its license amended. A licensee must also notify NRC of any changes in areas where materials are used pursuant to §§ 35.100 and 35.200. These revisions were warranted because of requirements in the proposed § 35.13.

Section 35.15, Exemptions regarding Type A specific licenses of broad scope, would be revised to add the term “authorized medical physicist” to paragraph (d). This revision is needed because of the requirements in the proposed § 35.13. Under this proposed section, broad scope licensees would have authority to appoint authorized users, authorized nuclear

pharmacists, or authorized medical physicists without notifying NRC, provided the individuals meet approved criteria in subparts B, D-H, and J.

A new paragraph (e) would be added to also exempt these licensees from § 35.49(a). This change would codify in the regulations an exemption that is currently provided to these licensees through a standard condition. NRC's medical use licensees with a Type A specific license of broad scope currently receive a standard license condition that exempts the licensee from receiving sealed sources or devices manufactured only from licensees with medical distribution licenses issued pursuant to § 32.74. This change would replace the license condition.

Section 35.18, License issuance, would be revised. Requirements for a mobile service license would be added as paragraph (b). The NRC will issue a license for mobile service if the applicant meets the requirements specified in paragraph (a) of the section and if the individual or human research subject to whom the applicant administers byproduct material, or radiation from byproduct material, may be released following treatment in accordance with § 35.75. The later condition is necessary because mobile service licensees will not have the capability of controlling individuals that cannot be released pursuant to § 35.75.

Section 35.19, Specific exemptions, would be revised to delete the statement that the Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes. This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains general administrative requirements regarding medical use of byproduct material.

Section 35.20, ALARA program, would be deleted in its entirety from Part 35. ALARA is discussed in 10 CFR 20.1101, "Radiation protection programs," and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. The Commission does not believe that § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing and implementing a radiation protection program that meets the requirements of Part 20.

Section 35.21, Radiation Safety Officer, would be deleted in its entirety from Part 35. The requirements of paragraph (a) would be moved to the proposed § 35.24. Paragraph (b) would be deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. The Commission believes that the licensee should have the flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the Radiation Safety Officer's duties.

Section 35.22, Radiation safety committee, would be deleted in its entirety. The issue of whether NRC should require a Radiation Safety Committee was identified as a cross-cutting issue and, therefore, was discussed at the public meetings and workshops held in Fall 1997. Comments received on this topic are discussed in Section III of the Supplementary Information

section of this document. Based on the comments received prior to March 1, 1998, the Commission believes that key functions of the Radiation Safety Committee could be transferred to licensee management (reference proposed § 35.24) and that the prescriptive requirements in the current § 35.22 should be deleted. The Commission believes that many institutions will continue to use a Radiation Safety Committee to oversee use of radioactive material. However, it recognizes that radiation program oversight may be accomplished by other means. In particular, medical facilities normally have a number of committees examining various areas, such as environmental safety. These committees are typically formed in response to hospital accreditation requirements. Specifying responsibilities and functions to be accomplished, rather than the particular mechanism to be used, is an effort to afford licensees flexibility in achieving the objective of radiation safety (reference § 35.24).

Section 35.23, Statements of authority and responsibilities, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.24.

Section 35.24, Authority and responsibilities for the radiation protection program, would appear as a new section. This requirement specifies objectives that must be achieved, rather than specifying how the objective is to be met, in an effort to afford licensees flexibility in achieving the objective of radiation safety.

Paragraphs (a) and (b) would replace the current requirements for the Radiation Safety Committee. The licensee is responsible for approving licensing actions; individuals before allowing them to work as a Radiation Safety Officer, authorized user, authorized nuclear

pharmacist, or authorized medical physicist; and radiation protection program changes that do not require a license amendment.

The licensee must develop, implement, and maintain administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Interdepartmental/interdisciplinary coordination is believed to be a major component of an effective radiation protection program. The Commission recognizes that there are many ways to meet this objective and believes that the licensee should have flexibility in identifying and implementing the most appropriate modes of coordination at its facility. Identified alternatives include, but are not limited to, meetings, electronic transfer of information, or verbal communication. This requirement applies to all medical use licensees and it is expected that the extent of the coordination will be dependent on the complexity of the licensee's program.

The requirement in paragraph (c) to appoint a Radiation Safety Officer is currently required by § 35.21. The proposed paragraph would require that the Radiation Safety Officer agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (d) and (e) are similar to the requirements in the current § 35.23. A record of management's approval of actions in paragraph (a); written acceptance of Radiation Safety Officer duties as specified in paragraph (c); and the duties, responsibilities, and authority of the Radiation Safety Officer specified in paragraph (d) would have to be maintained in accordance with § 35.2024, Records of authority and responsibility for radiation protection programs.

Section 35.25, Supervision, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.27.

Section 35.26, Radiation protection program changes, would appear as a new section. The requirements in this section are similar to the requirements in the current § 35.31, which would be deleted. The proposed section states that a licensee may revise its radiation protection program without Commission approval if the revision does not require an amendment in accordance with § 35.13; the change will not reduce radiation protection; the change has been reviewed and approved in writing by the Radiation Safety Officer and licensee management; and the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides the licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require an amendment. The Commission believes that many licensees were reluctant to make changes to their current program because the term "ministerial changes," as defined in the current § 35.2 and as used in the current § 35.31, was not clearly understood. This change is intended to provide clear guidance to a licensee on when it can revise its radiation protection program without Commission approval.

The Commission believes that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction could be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this training has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this training was provided.

Section 35.27, Supervision, would appear as a new section. The requirements in this section are similar to the requirements in the current § 35.25, which would be deleted.

Paragraph (a)(1) and (b)(1) would be revised to delete the requirement to instruct individuals in the principles of radiation safety. This type of instruction is adequately addressed by § 19.12, Instructions to workers, of this chapter. Paragraph (a)(1) would also be revised to require that the licensee instruct supervised individuals in the written radiation protection procedures, written directives procedures, regulations of this chapter, and license conditions. Paragraph (a)(2) would require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, regulations, and license conditions with respect to the medical use of byproduct material.

Paragraphs (a)(3) and (b)(3) of the current § 35.25 would be deleted because the licensee should have flexibility in evaluating employee performance. Paragraph (b)(2) would be revised to require supervised individuals to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures, and the regulations of this chapter and license conditions. Paragraph (c) would require that the licensee develop, implement, and maintain a policy for supervised individuals to request clarification, as needed, from the authorized user about instructions and requirements in a written directive prior to administering the byproduct material, or radiation from the byproduct material, and from the authorized user or authorized nuclear pharmacist about instructions and requirements provided in accordance with paragraphs (a) and (b) of the section. This change would be added so that a licensee's work environment would encourage supervised individuals to ask questions if they do not understand the instructions or requirements provided to them by an authorized nuclear pharmacist or an authorized user, especially when they have questions regarding administrations of byproduct

material to patients or human research subjects. In the past, failure by licensee staff to ask questions has been identified as one of the key contributors to misadministrations.

Section 35.29, Administrative requirements that apply to the provision of mobile service, would be deleted. The conditions for the Commission to issue a mobile service license would be moved to § 35.18. The requirements in paragraphs (b) and (d) would be moved to the proposed § 35.80. Paragraph (c) would be deleted because this requirement was viewed as overly prescriptive. Individuals are required to comply with all provisions of the license that authorizes use, possession and transfer of material.

Section 35.31, Radiation safety program changes, would be deleted. The requirements, with minor changes, would be moved to § 35.26. This change is proposed so that all requirements that pertain to the management of the licensee's program appear in one area.

Section 35.32, Quality management program, would be deleted. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at the public meetings and workshops held in Fall 1997. Comments received on this topic are discussed in Section III of the Supplementary Information section of this document. Based on these comments, the Commission has deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management program that should be addressed in the proposed rule: confirming patient identity, requiring written directives, and verifying dose. Requirements for these three elements are found in proposed §§ 35.40 and 35.41. However, the Commission believes that some

elements of the current quality management program requirements will continue to be implemented as a part of the “standard of care” in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions to adopting programs similar to those previously specified in the rule.

Section 35.33, Notifications, reports, and records of misadministrations, would be deleted. In this proposed revision, recordkeeping and reporting requirements contained in Part 35 would be moved to subparts L and M, respectively.

Section 35.40, Written directives, would appear as a new section. This section contains requirements for preparation of written directives. These requirements are similar to the requirements in the current §§ 35.2 and 35.32. Minor changes would be made in the information that must be placed in a written directive for gamma stereotactic radiosurgery, remote afterloaders, and brachytherapy. These changes were based on comments received during public meetings of the Part 35 Working Group.

Section 35.41, Procedures for administrations requiring a written directive, would appear as a new section. It would require the licensee to develop, implement, and maintain written procedures to assure that, before each administration, the patient’s or human research subject’s identity is verified and that each administration is in accordance with the written directive, including verification of dose. It would also specify the objectives that should be addressed in the procedures. The specific details to be included in the written directives are in § 35.40. The topics identified in § 35.41 are viewed by the Commission as key elements of a program that will provide high confidence that byproduct material will be administered as

directed by the authorized user. However, the regulations are not prescriptive as to how these objectives are met, allowing licensees the flexibility to develop procedures to meet their needs. There is no requirement for submittal or approval of the procedures as was previously required by the quality management rule.

Section 35.49, Suppliers for sealed sources or devices for medical use, would be unchanged.

Section 35.50, Training for Radiation Safety Officer, would appear as a new section that would revise the current requirements of § 35.900, Radiation Safety Officer. Section III of the Supplementary Information of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after the final rule is published in the Federal Register, this section would replace the current requirements in § 35.900, Radiation Safety Officer.

Requirements in the current § 35.50, with minor modifications, would be moved to the proposed § 35.60.

Section 35.51, Training for an authorized medical physicist, would appear as a new section that would revise the training and experience requirements found in § 35.961, Training for an authorized medical physicist. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after the final rule is published in the

Federal Register, this section would replace the requirements in § 35.961, Training for authorized medical physicist.

Requirements in the current § 35.51, with minor modifications, would be moved to the proposed § 35.61.

Section 35.52, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.63.

Section 35.53, Measurements of dosages of unsealed byproduct material for medical use, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to the proposed § 35.63.

Section 35.55, Training for an authorized nuclear pharmacist, would appear as a new section that would revise the training and experience requirements found in § 35.980, Training for an authorized nuclear pharmacist. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication in the Federal Register, this section would replace the current requirements in § 35.980, Training for an authorized nuclear pharmacist.

Section 35.57, Training for an experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist, would appear as a new section that

would replace the current requirements in §§ 35.901, 35.970, and 35.981, which would be deleted. Changes would be made in the regulatory text of this section to reflect the effective date of the rule.

Requirements in the current § 35.57, with minor modifications, would be moved to the proposed § 35.65.

Section 35.59, Recentness of training, would appear as a new section that would replace the current requirements in § 35.972. Although this is not a new requirement, questions have recently been raised regarding whether all elements of the requirements must have been obtained in the last 7 years. It is expected that either the individual has been board certified or has completed the training specified in the alternative pathway within the 7 years preceding the date of the application or must have had related continuing education and experience since completing the required training and experience requirements. Continuing education is reviewed on a case-by-case basis. The text has been revised to reference subparts B, D, E, F, G, H and J since training and experience requirements appear in multiple subparts.

Requirements in the current § 35.59, with minor modifications, would be moved to the proposed § 35.67.

Subpart C, General Technical Requirements, contains general technical requirements regarding medical use of byproduct material.

Section 35.60, Possession, use, calibration, and check of instruments to measure activity of photon-emitting radionuclides, would appear as a new section that would replace the current § 35.50. This section addresses calibration of all instruments used to measure the activity of photon-emitting radionuclides, rather than only dose calibrators. The change recognizes that there are various types of instruments that can be used to measure the activity of photon-emitting radionuclides.

The proposed rule would require that licensees develop, implement, and maintain procedures for use of the instrumentation. Licensees would be required to calibrate all instruments used to measure the activity of photon-emitting radionuclides.

Licensees would be required by § 35.63 to determine the activity of each dosage before medical use. If a licensee uses only unit dosages of radiopharmaceuticals, § 35.63 would allow the licensee to determine the dosage by a decay correction based on the measurement by a manufacturer or preparer licensed pursuant to § 32.72 or equivalent Agreement State. If a licensee chooses to determine the dosage using this method, it would not be necessary for the licensee to possess instrumentation to measure the activity of the photon-emitter. In this case, the licensee would not be required to comply with this section. If, however, a licensee chooses to re-assay a unit dosage to either confirm the activity or for the purpose of adjusting the dosage, the licensee must comply with this section. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be made based on properly-calibrated equipment.

Many of the prescriptive requirements for calibration would be deleted from the current requirements in § 35.50. The requirements that would remain are viewed by the Commission

as essential elements of a calibration program and are generally consistent with the recommendations of ANSI N42.13-1986 (R 1993), "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Licensees would be required to perform accuracy, linearity, and geometry dependence tests before initial use and following repair; perform accuracy tests annually; perform linearity tests annually over the range of medical use; and check constancy and proper operation at the beginning of each day of use. Note, it would not be necessary to test for linearity for all activities that might be measured, e.g., the first elution from a fresh generator or a multidose vial, because this would subject the worker to an unnecessary radiation dose. Paragraph (c) would require that accuracy tests be performed using a source with a principle photon energy of between 100 and 500 keV whose activity is traceable to the National Institutes of Standards and Technology (NIST). The allowance for a licensee to mathematically correct dosage has been revised to raise the level for correction to 30 μ Ci to make the level consistent with § 35.63. The allowance for a licensee to mathematically correct dosage readings remains, but has been re-numbered § 35.60(d). The recordkeeping requirements for this section would appear in § 35.2060, Records of instrument calibrations.

Requirements in the current § 35.60, with minor modifications, would be moved to the proposed § 35.69.

Section 35.61, Calibration and check of survey instruments, would appear as a new section that would replace the current § 35.51. The requirement in the current § 35.51(a)(3) to note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the daily check source requirement in paragraph (c) would be deleted. These

changes would give the licensee greater flexibility in instrument calibrations. Paragraph (b) would require that the licensee attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent. Paragraph (c) would require that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent. Previously, there was no threshold for attaching a correction chart or for removing instruments from use. The requirements in this section are generally consistent with ANSI N323-1978 (R 1993), "Radiation Protection Instrumentation Test and Calibration." The recordkeeping requirements for this section would appear in § 35.2061, Records of radiation survey instrument calibrations.

Requirements in the current § 35.61, with minor modifications, would be moved to the proposed § 35.69.

Section 35.62, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides, would appear as a new section that would replace the current § 35.52. This section addresses calibration of all instruments used to measure the activity of alpha- or beta-emitting radionuclides. Paragraph (a) from the current § 35.52 would be deleted. This text is no longer needed since the term "unit dosage" has been defined in § 35.2. The new paragraph (b) would require that a licensee develop, implement, and maintain written procedures for use of the instrumentation. The Commission recognizes that it may not be possible to test linearity and geometry dependency on all instrumentation. However, the Commission believes that all instruments used to measure alpha- or beta-emitting radionuclides can be tested for accuracy or constancy. The new paragraph (c) would require that accuracy tests be performed using sources whose activity is traceable to NIST. The

recordkeeping requirements for this section would appear in § 35.2060, Records of instrument calibrations.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, would appear as a new section that would replace the current § 35.53. This section would require licensees to determine and record the activity of each dosage before medical use. For unit dosages of an alpha-, beta-, or photon-emitting radionuclides, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to § 32.72 or equivalent Agreement State requirements. For other than unit doses, a licensee may determine the dosage by direct measurement or by combination of measurements and calculations. Previously, photon measurements could only be made by direct measurement. This action allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made. Paragraph (d) would not permit a licensee to use a dosage if it differed from the prescribed dosage by more than 20 percent. This change would codify requirements that are currently imposed on licensees by license conditions. This does not prevent an authorized user from revising the prescribed dosage at any time prior to the administration. The recordkeeping requirements for this section would appear in § 35.2063, Records of dosage measurements.

Section 35.65, Authorization for calibration and reference sources, would appear as a new section that would replace the current § 35.57. The references in the current § 35.57, to §§ 35.100 and 35.200, would be deleted because specific radionuclides were not listed in these sections. Paragraph (b) in the current § 35.57 would be revised to extend the half-life from 100

days to 120 days to be consistent with the financial assurance regulations in 10 CFR Part 30. The limit of 10^{-3} would be added to the regulation to allow receipt, possession, and use of radionuclides in quantities that do not exceed the limits requiring financial assurance. The possession limit for Tc-99m would be deleted. The Commission believes that it is not necessary to limit the possession of Tc-99m for calibration and reference sources because there are no possession limits for Tc-99m associated with use of Tc-99m pursuant to §§ 35.100 or 35.200.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources, would appear as a new section that would replace the current § 35.59. Paragraph (b) would require that a source be tested for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months, and the source is tested for leakage at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR).¹ The SSDR certificates, in most cases, will include a requirement for leak-testing. Approved intervals for testing are based on information regarding source design construction that is provided by the manufacturer.

Prescriptive requirements in the current § 35.59(c) would be deleted to reflect the risk-informed, performance-based nature of this proposed rule. Paragraph (d) would require that leak test records be maintained in accordance with § 35.2067, Records of possession of sealed sources and brachytherapy sources. Paragraph (e) would be revised to give the licensee two

¹ A national registry that contains all the registration certificates generated by both NRC and the Agreement States. Registration certificates summarize the radiation safety information submitted by the applicant, and describe the licensing and use conditions approved for the product.

additional alternatives for action after a leaking source has been identified. The proposed rule would allow the licensee the added flexibility of repairing or disposing of the source, in accordance with 10 CFR parts 20 and 30, if the leakage test reveals the presence of 185 Becquerels(Bq) (0.005 microcuries) or more of removable contamination. The current rule only allows the licensee to withdraw the sealed source from use and store it in accordance with the requirements in 10 CFR parts 20 and 30. The licensee would still be required to report to NRC if a leakage test reveals the presence of 0.005 microcuries or more of removable contamination. Reporting requirements for this section would appear in § 35.3059, Reports of leaking sources.

Paragraph (g) of the current rule would be revised to change the frequency for source inventories from quarterly to semi-annually, to reduce the regulatory burden on licensees. It does not, however, preclude the licensee from conducting an inventory on a more frequent basis. Paragraph (h) of the current rule would be deleted because radiation surveys are addressed under 10 CFR Part 20. The recordkeeping requirements for this section would appear in § 35.2067, Records of possession of sealed sources and brachytherapy sources.

Section 35.69, Labeling and shielding of vials and syringes, would appear as a new section that would replace the current §§ 35.60 and 35.61. It would require licensees to develop, implement, and maintain procedures for labeling and shielding radiopharmaceuticals and instruct individuals in those procedures. Procedures must ensure that a syringe, syringe shield, or vial shield is conspicuously labeled as containing radioactive material and is labeled with the radiopharmaceutical name. These requirements were needed because the Commission does not believe that the labeling and shielding requirements in Part 20 are

sufficient to ensure that syringes, syringe shields, or vial shields are properly labeled to identify radioactive contents. In addition, the Commission believes that labeling helps to reduce administration errors. The proposed rule would require that licensees instruct individuals, commensurate with that individual's assigned duties, on the labeling and shielding procedures. It is expected that technologists preparing radiopharmaceuticals and nuclear pharmacists will be given instruction in the licensee's procedures. Records of instructions would not be required to be maintained.

Section 35.70, Surveys for ambient radiation exposure rate, would be revised and retitled. The proposed rule would require that licensees survey, at the end of each day of use, all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered with an appropriate radiation detection survey instrument unless the material was prepared for use or administered in an area where patients or human research subjects could not be released pursuant to § 35.75. All other requirements in this section would be deleted. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (10 CFR 20.1101). In situations where radioactive material was used at levels that would not have required a survey pursuant to this section, the licensee should be aware that a survey may be required by § 20.1501, General. Maintaining the requirement for surveys in areas where radiopharmaceuticals requiring a written directive are used is consistent with the Commission direction for a risk-informed rule. The Commission believes that licensees will continue to perform radiation surveys as dictated by "good health physics" practices. Recordkeeping

requirements for this section would appear in § 35.2070, Records of surveys for ambient radiation exposure rate.

Section 35.75, Release of individuals containing radiopharmaceuticals or implants, would be retitled and revised. The title of the section and paragraph (a) would be revised to delete the term "permanent." This was done to clarify that this section applies to all individuals released from licensee control. Paragraph (b) would be revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term "dose" with the term "total effective dose equivalent." The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later term was changed to clarify what was intended by "dose."

Paragraph (b)(2) would be modified to state "potential consequences, if any," of failure to follow the guidance. The Commission recognizes that, at low doses, there may be no consequences to continued breast-feeding. A patient may be unnecessarily alarmed if he/she is provided with information on consequences. Therefore, if consequences are not anticipated, the licensee would not be required to provide information to the individual. The Commission has recently received comments from the public on the provisions in § 35.75 at the public workshops and in writing. Professional societies and representatives of the Agreement States have expressed concerns about the release criteria in § 35.75. It is believed that the new criteria permit the release of patients with a body burden of as much as several hundred millicuries of I-131. Commenters believed that the released individual is a "leaking-source" that creates a contamination and exposure problem that extends beyond the control of the licensee.

There is concern that pressure from those paying for such medical procedures will undermine the Radiation Safety Officer's ability to protect the public health and safety and to control contamination within the medical facility. In addition, there is concern about the recent increase of radiation alarms going off at landfills caused by household trash from a released patient. As a result of these concerns, the Commission is specifically soliciting public comment on whether any changes need to be made to the release criteria in this rule. The recordkeeping requirements for this section would appear in § 35.3075, Records of the release of individuals containing radiopharmaceuticals or implants.

Section 35.80, Provision of mobile service, would be retitled and revised. The title would be changed to make it clear that the provisions in this part apply to all mobile services and not just to mobile nuclear medicine services. Current paragraphs (a), (b), and (c) would be deleted because radiopharmaceutical usage is limited by the requirements in §§ 35.100 and 35.200, and control and security of material are addressed in 10 CFR Part 20.

Proposed paragraph (a) would require the mobile service provider to obtain a letter from its client, which permits the use of byproduct material at the client's address of use and that clearly delineates the authority and responsibility of each entity. Paragraph (c) would require that the mobile service provider check instruments for proper function, as described in §§ 35.60 and 35.62, before use at each address of use or on each day of use, whichever is more frequent. For example, if a mobile service licensee provides service to more than one client in a day, the instruments would need to be checked at each client's address of use. The Commission recognizes that the standard of practice is to check other types of equipment, such as gamma cameras, for proper operation at each place of use. Therefore, the Commission has

not included any requirements to check this type of equipment in the proposed rule. Currently, mobile nuclear medicine services may be required by license conditions to check gamma camera operation.

Based on discussions with the States, this section is designated as a Category D item of compatibility since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity. NRC specifically requests comment on this issue relative to whether mobile medical licensees operate under reciprocity in other regulatory jurisdictions.

Paragraph (d) would require that the licensee check survey instruments for proper operation with a dedicated check source, before use, at each address of use. The NRC staff believes this is appropriate, because extensive movement in a transport vehicle may cause the instruments to become damaged or uncalibrated. Paragraph (e) would be revised to require a licensee to survey all areas of use to comply with the dose limits in 10 CFR Part 20 before leaving each client's address of use. This is necessary to assure that all radioactive material is removed from a client's facility. Recordkeeping requirements for this section would appear in § 35.2080, Records of administration and technical requirements that apply to the provision of mobile services.

Section 35.90, Storage of volatiles and gases, would be deleted in its entirety. Licensees are required to comply with the public and occupational public dose limits in 10 CFR Part 20 and to maintain exposures ALARA. The Commission believes that licensees should have flexibility in complying with 10 CFR Part 20, and, therefore, a prescriptive requirement in Part 35 is not needed.

Section 35.92, Decay-in-storage, would be revised to allow decay in storage for byproduct material with a physical half-life of less than 120 days. If a licensee would like to decay material with a physical half life greater than 120 days, it would have to apply for and receive an amendment that would permit the decay-in-storage.

The current Part 35 only permits decay-in-storage for materials with a half-life of less than 65 days. This change provides licensees with greater flexibility in handling radioactive waste. NRC has received multiple requests to amend licenses to allow for decay-in-storage for materials greater than 65 days, and NRC has amended licenses to allow for decay-in-storage for materials with half-lives up to 120 days. This revision to § 35.92 would codify current licensing practice.

The requirement in the current paragraph (a)(1) to hold byproduct material for 10 half-lives would be deleted. This requirement is not needed in light of the requirement in paragraph (a) that precludes disposal of radioactive material as ordinary trash until radiation levels adjacent to the material do not exceed background levels. The Commission is soliciting specific public comment on whether this provision should be deleted. Concerns have been raised regarding licensees' ability to detect low levels of some beta-emitters such as sulfur-35. In this case, the requirement to hold material for 10 half-lives provides added assurance that material has decayed to background levels prior to release.

The requirement in paragraph (a)(4) to separate and monitor each generator column would be deleted. This level of prescriptiveness is not warranted in light of the requirements in

paragraph (a)(1). The recordkeeping requirements for this section would appear in § 35.2092, Records of waste disposal.

Subpart D would be retitled Unsealed Byproduct Material - Low Dose. This subpart would combine the requirements in the current subpart D, Uptake, dilution, and excretion and subpart E, Imaging and localization. This change is consistent with the Commission's intent to make Part 35 modality specific where appropriate.

Section 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required, would be retitled and revised. The title would be changed to clearly state that the provisions in this subpart do not apply to the medical use of byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.120, Possession of survey instruments, would be deleted because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.200, Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required, would be retitled and revised. The title would be

changed to clearly state that the provisions in this part do not apply to the medical use of byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.204, Permissible molybdenum-99 concentration, would be revised. Paragraph (b) would be revised to require that a licensee measure the molybdenum-99 concentration of the first eluate from a generator. The Commission recognizes that the industry standard for molybdenum breakthrough is specified in the United States Pharmacopia (USP) 23 U.S. Pharmacopial Convention, Inc., 1994, page 486-487. The Commission believes that the licensee should measure the molybdenum-99 concentration in the first elution of a generator after the generator is received at the licensee's facility. Although the frequency of molybdenum breakthrough is exceedingly rare, an initial check may detect generators that have been damaged in transport. The term "extract" was deleted because the term is no longer needed. NRC is not aware of any licensees that prepare technetium-99m by the solvent extraction method. The recordkeeping requirements for this section would appear in § 35.2204, Records of molybdenum-99 concentration.

Section 35.205, Control of aerosols and gases, would be deleted in its entirety. Part 35 licensees must comply with the occupational and public dose limits of 10 CFR Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not warranted in Part 35.

Section 35.220, Possession of survey instruments, would be deleted in its entirety because specific requirements are not needed in Part 35. Section 20.1501 of this chapter

requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.290, Training for uptake, dilution, and excretion studies, would appear as a new section that would revise the training and experience requirements found in § 35.910, Training for uptake, dilution, and excretion studies. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for uptake, dilution, and excretion studies.

Section 35.292, Training for imaging and localization studies, would appear as a new section that would revise the training and experience requirements found in § 35.920, Training for imaging and localization studies. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for imaging and localization studies.

Subpart E would be retitled, Unsealed byproduct material - high dose. The subpart contains the requirements for any medical use of unsealed byproduct material for which a

written directive is required. This subpart would replace the requirements in the current subpart F, Radiopharmaceuticals for therapy.

Section 35.300, Use of unsealed byproduct material for which a written directive is required, would be retitled and revised. The title would be changed to clearly state that the provisions in this subpart apply to the medical use of unsealed byproduct material that would require a written directive. Changes would be made to paragraph (b) to reflect the renumbering of sections in the proposed rule.

Section 35.310, Safety instruction, would be revised to explicitly state that the instruction requirements of this section are in addition to, and not in lieu of, the training requirements in 10 CFR 19.12. The Commission believes that it is important that personnel caring for patients or human research subjects that have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75) receive instruction in limiting radiation exposure to the public or occupational workers and the actions to be taken in the case of a death or medical emergency. The proposed rule would require that safety instruction be provided initially and at least annually. Instruction topics are specific to medical use of unsealed radiopharmaceuticals. It is not expected that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. For example, the instruction provided to the registered nurse will not necessarily be the same as the instruction provided to a nursing assistant.

Paragraph (a) would be revised to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in § 20.1301(a)(1), as well as visitation that is authorized under the proposed provisions of § 20.1301(a)(3). Paragraph (a) would also be revised to state that personnel should notify the authorized user and Radiation Safety Officer, or his/her designee, if the patient or human research subject dies or has a medical emergency. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.315, Safety precautions, would be revised. Paragraph (a) would be revised to clarify that the requirements in this section only apply if a patient has been confined pursuant to § 35.75. Paragraph (a)(2) would be revised to require that the patient's room, rather than the door, be visibly posted to give the licensee some flexibility in determining where to place the posting. These requirements are in addition to the posting requirements in 10 CFR Part 20. The Commission believes that posting requirements in 10 CFR Part 20 are not adequate to ensure that individuals entering the room would be aware of the presence of radioactive materials in the room. The current requirements in paragraphs (a)(3), (4), (6), (7), and (8) would be deleted because they are radiation protection requirements that are covered under 10 CFR Part 20. Paragraph (b) would be revised to state that personnel should notify the authorized user and the Radiation Safety Officer, or his/her designee, as soon as possible, if the patient or human research subject dies or has a medical emergency. This change was made to recognize that the licensee's primary responsibility is the care of the patient and to provide the Radiation Safety Officer flexibility in designating who should be notified to address radiation protection issues.

The Commission is soliciting specific comments on whether the requirement for a private room with a private sanitary facility in paragraph (a)(1) should be maintained in the final rule.

Section 35.320, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make or cause to be made surveys to demonstrate compliance with 10 CFR Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, 10 CFR 30.33(a)(2) requires a licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.390, Training for therapeutic use of unsealed byproduct material, would appear as a new section that would revise the training and experience requirements found in § 35.930, Training for therapeutic use of unsealed byproduct material, and subsumes the training requirements for treatment of hyperthyroidism and treatment of thyroid carcinoma. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.930, Training for therapeutic use of unsealed byproduct material, § 35.932, Training for treatment of hyperthyroidism, and § 35.934, Training for treatment of thyroid carcinoma.

Subpart F would be retitled Manual brachytherapy. This subpart contains the requirements for medical use of sealed sources for manual brachytherapy and replaces the requirements in the current subpart G, Sources for brachytherapy.

Section 35.400, Use of sources for manual brachytherapy, would be retitled and revised to delete the specific sources and uses listed in the current paragraphs (a) through (g). This conforms with the risk-informed, performance-based nature of this proposed rule. The licensee would have the flexibility to use sealed sources for therapeutic medical uses as approved in the Sealed Source and Device Registry.

Section 35.404, Radiation surveys of patients or human research subjects treated with implants, would be retitled and revised. Paragraph (a) would be revised to delete the requirement that a licensee may not release a patient or a human research subject treated by temporary implant until all sources have been removed and would be retitled paragraph (b). Release of patients or human research subjects is addressed in § 35.75. The proposed paragraph (a) contains requirements that were previously required by § 35.406(c) with one modification. Licensees would be required to survey adjacent areas of use. This change was done to group radiation survey requirements. The recordkeeping requirements for this section would appear in § 35.2404, Records of radiation surveys of patients and human research subjects.

Section 35.406, Brachytherapy sources inventory, would be revised. Paragraph (a) requires that the licensee maintain accountability for all brachytherapy sources in storage or use. The majority of the prescriptive requirements and associated recordkeeping requirements

in the current section have been deleted to give the licensee flexibility in program management. The requirements in paragraph (c) would be moved to the proposed § 35.404. The Commission believes that the requirements that were maintained are essential to the radiation safety program. The recordkeeping requirements for this section would appear in § 35.2406, Records of brachytherapy source inventory.

Section 35.410, Safety instruction, would be revised to explicitly state that the instruction requirements in this section are in addition to, and not in lieu of, the training requirements of 10 CFR 19.12. The Commission believes that it is important that personnel caring for patients or human research subjects, that have received implant therapy and cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public and workers and the actions to be taken in the case of a death or medical emergency. The proposed rule would require that safety instruction be provided initially and at least annually. Instruction topics are specific to medical use of manual brachytherapy sources. It is not expected that the same level of training be provided to all individuals caring for the patient. The level of training should be commensurate with the type of care that the personnel may render to the patient or human research subject. Paragraph (a) would be revised to require that instruction on visitor control include instruction on routine visitation authorized under the provisions in the current § 20.1301(a)(1), as well as visitation that is authorized under the provisions of revised § 20.1301(a)(3). Paragraph (a) would also be revised to state that personnel should notify the authorized user and Radiation Safety Officer, or designee, if the patient or human research subject dies or has a medical emergency. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.415, Safety precautions, would be revised. Paragraph (a) would be revised to clarify that the requirements in this section apply only if a patient or human research subject cannot be released pursuant to § 35.75. The current requirements in paragraphs (a)(3) and (4) would be deleted because they are radiation protection requirements that are covered under 10 CFR Part 20. A new requirement would be added (paragraph b) to require the licensee to have equipment such as shields and remote handling tools available near each treatment room. This change codifies requirements that are currently imposed on licensees by license conditions. Current paragraph (b) would be relettered as paragraph (c) and would be revised to state that personnel should notify the authorized user and the Radiation Safety Officer, or his/her designee, as soon as possible if the patient or human research subject dies or has a medical emergency. This change was made to recognize that the licensee's primary responsibility is the care of the patient and to provide the Radiation Safety Officer flexibility in who should be notified to address radiation protection issues. The Commission is soliciting public comment on whether the requirement for a licensee to not quarter a patient in the same room as an individual who is not receiving radiation therapy be maintained in the final rule.

Section 35.420, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, 10 CFR 30.33(a)(2) requires licensees to have adequate equipment. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.432, Full calibration measurements of brachytherapy sources, would appear as a new section that would require a licensee authorized to use brachytherapy sources for medical use to perform full calibration measurements on brachytherapy sources before the first medical use. The requirements in this section are based on recommendations found in American Association of Physicists in Medicine (AAPM) Task Group 40 - Comprehensive QA for Radiation Oncology (1994) and 56 - Code of Practice for Brachytherapy Physics (1997), and are consistent with the calibration requirements for sealed sources and devices for therapy. The proposed rule would not allow the licensee to rely on the output measurement provided by the manufacturer or distributor. The Commission is soliciting specific comment on whether the final rule should allow licensees to rely on the output measurements provided by the manufacturer or distributor provided the dosimetry equipment used by the manufacturer or distributor met the calibration requirements in § 35.630. In addition, the Commission is soliciting specific public comment on calibration for sources where there is no standard traceable to the National Institute of Standards and Technology (e.g. palladium-103).

The Regulatory Analysis for this section of the rule assumes that the majority of licensees using long-lived radionuclides will need to calibrate the sources to show compliance with this section. It is estimated that licensees will spend approximately \$1000 to calibrate these sources resulting in a \$8M burden on NRC and Agreement State licensees. The Commission has not calculated the impact of determining the output of short-lived sealed therapy sources (e.g. iodine-125, iridium-192) because of the limited information available on the number of sources and variability in the type of dosimeter equipment available at a licensee's facility to perform the calibration. The Commission is soliciting specific public input on the number of short and long-lived sources that will need to be calibrated on an annual basis; whether

licensees will need to procure additional equipment to perform the calibrations; and the time needed to calibrate the sources.

Recordkeeping requirements for this section would appear in § 35.2432, Records of full calibrations on brachytherapy sources.

Section 35.490, Training for use of manual brachytherapy sources, would appear as a new section that would revise the training and experience requirements found in § 35.940, Training for use of brachytherapy sources, and subsumes the requirements for training for ophthalmic use of strontium-90. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section will replace the current requirements in § 35.940, Training for use of brachytherapy and in § 35.941, Training for ophthalmic use of strontium-90.

Subpart G would be retitled Sealed sources for diagnosis. This subpart would contain the requirements for diagnostic medical use of sealed sources and replace the requirements in the current subpart H, Sealed Sources for Diagnosis.

Section 35.500, Use of sealed sources for diagnosis, would be revised to delete the specific sources and uses listed in paragraphs (a) and (b). This conforms with the risk-informed, performance-based nature of this proposed rule. The licensee would have flexibility to use sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

Section 35.520, Availability of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make or cause to be made surveys to demonstrate compliance with 10 CFR Part 20 and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires the licensee to have adequate instrumentation. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.590, Training for use of sealed sources for diagnosis, would appear as a new section. This section is a revision of the training and experience requirements found in § 35.950, Training for use of sealed sources for diagnosis. Section III of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed changes to the training and experience requirements in Part 35. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.920, Training for use of sealed sources for diagnosis.

Subpart H, Therapeutic medical devices, would be retitled and revised to address all medical uses of sealed sources and devices for therapy. Devices such as teletherapy, remote afterloaders, and gamma radiosurgery units are addressed in this subpart. This section does not contain requirements for manual brachytherapy, which are in subpart F. This subpart would replace the requirements in the current subpart I, Teletherapy.

Section 35.600, Use of a sealed source in a device for therapeutic medical uses, would be retitled and revised to delete any references to specific radionuclides and devices. The licensee would have the flexibility to use sealed sources and devices for therapeutic medical uses as approved in the Sealed Source and Device Registry.

Section 35.604, Radiation surveys of patients and human research subjects treated with remote afterloaders, would appear as a new section. This section would require that a licensee make a radiation survey of a patient or human research subject to confirm that the sources have been removed from the individual and returned to a shielded position before releasing the individual from licensee control. For fractionated treatments where the patient is not releasable pursuant to § 35.75, surveys need only be performed after the last time the source is returned to the shielded position. For example, a survey of the patient is not required every time that the source is retracted into the shielded safe when nursing personnel enter the patient treatment room to provide care to patients undergoing fractionated treatments using a low- or pulsed-dose rate remote afterloader. This new requirement was previously imposed on remote afterloader licensees by license condition. Recordkeeping requirements for this section would appear in § 35.2404, Records of radiation surveys of patients and human research subjects.

Section 35.605, Installation, maintenance and repair, would be retitled and revised to clarify that only a person specifically licensed by the Commission or an Agreement State can install, maintain, adjust, or repair a device that involves work on the source shielding, source driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the sources. It would also be revised to include additional types of devices, rather than just

teletherapy units. The Commission is soliciting specific comment on whether the restrictions in paragraph (a) should apply to low dose-rate remote afterloaders.

Paragraph (b) would also specify that, except for low dose-rate remote afterloaders, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device. For a low dose-rate remote afterloader, installation, replacement, relocation, or removal of a sealed source must be done by a person specifically licensed by the Commission or an Agreement State or by an authorized medical physicist. The exception to allow an authorized medical physicist to perform these activities for low-dose rate remote afterloaders was included in the proposed rule because the Commission believes that the radiation hazards associated with installation, replacement, relocation, or removal of a sealed source in these devices are similar to that of manipulation of manual brachytherapy sources. The recordkeeping requirements for this section would appear in § 35.2605, Records of installation, maintenance, and repair.

Section 35.606, License amendments, would be deleted in its entirety. The requirements in the current paragraphs (a), (b), and (d) would be addressed in the proposed revision to § 35.13(e). Paragraph (c) would be deleted because the licensees must comply with the dose limit requirements in 10 CFR Part 20 and no further limitations are warranted. The requirement in paragraph (e) to file an amendment before allowing an individual to perform the duties of the authorized medical physicist is addressed in the proposed § 35.13(b). Paragraph (e) would be deleted because the proposed requirements in subpart H would require that the authorized medical physicist perform specific duties. Any deviations from these requirements would necessitate an exemption from Part 35.

Section 35.610, Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units, would be retitled and revised to include remote afterloaders and gamma stereotactic radiosurgery units.

Paragraph (a) would require that a licensee develop, implement, and maintain safety procedures; locate safety procedures at the unit console; post safety instructions at the device console; and train operators.

Paragraphs (a) (1) and (a)(3) would codify requirements that are currently imposed on licensees by license conditions related to use of remote afterloaders. Because of the applicability of the requirements to all therapy device uses, they were added to the rule with the intent of having the requirements apply to all such device uses. Paragraph (a)(2) would be expanded to apply to all types of therapy devices. However, the Commission recognizes that there are certain design conditions that will necessitate an individual, other than the patient, being in the treatment room during the treatment. An example of this condition is use of a low energy beta or gamma source in a therapeutic medical device where the authorized user may need to be in the room with the patient. This exception does not relieve the licensees from complying with the dose limits for occupationally-exposed individuals or the general public in 10 CFR Part 20.

Paragraph (b) would be revised to require that a copy of the licensee's procedures be located at the unit console, and paragraph (c) would be revised to require that the location of the procedures and emergency response telephone numbers be posted. Previously, all of the

above procedures were required to be posted. This was impractical with the addition of remote afterloaders because error conditions and responses are often several pages in length.

Paragraph (d) would be revised to require that, in addition to the initial instruction required in § 35.610, the licensee must provide initial instruction, annual training, and annual practice drills, in specifically identified procedures to all individuals who operate the device. The level of instruction should be commensurate with the individual's assigned duties. For example, an individual need not be instructed in equipment inspection, unless it is expected that during the normal course of the day, the individual will be required to inspect the unit. The Commission believes that due to the complexity of therapeutic treatment devices, refresher training and practice drills on emergency response are warranted. The recordkeeping requirements for this section would appear in § 35.2310, Records of instruction and training.

Section 35.615, Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units, would be retitled and revised to include remote afterloaders and gamma stereotactic radiosurgery units. Many of the prescriptive requirements (e.g., beam condition indicator light and radiation monitor) were deleted from this section because they are currently addressed in 10 CFR Part 20.

The requirement in paragraph (d) for intercom systems, and the requirements in paragraphs (e), (f) and (g) would be added to codify requirements that are currently imposed on licensees by license conditions. Current license conditions were modified when they were incorporated into the proposed rule. For example, the presence of an authorized user and medical physicist during patient treatments was clarified for each type of use. As used in this

provision, physically present means to be within ear shot of normal voice. Immediately available means that the individual is available on an on-call basis to respond to an emergency. At a minimum, this person must be available by telephone.

The Commission believes that the inherent risk of these procedures justifies the prescriptiveness of this regulation and believes that it is important that a properly trained physician be available at all times to respond to an emergency requiring source removal.

New sources, using pure beta emitters, are being considered for use in low and high dose-rate remote afterloading brachytherapy units. Because these beta sources present lower radiation risks to medical personnel and the public, the requirements for some of the safety precautions in this section may not be appropriate. The Commission is soliciting specific public comment on whether the requirements in this section should be waved for licensees that are using remote afterloaders with beta-emitting sources.

Section 35.620, Possession of survey instruments, would be deleted in its entirety because these specific requirements are not needed in Part 35. Section 20.1501 of this chapter requires that the licensee make, or cause to be made, surveys to demonstrate compliance with 10 CFR Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with 10 CFR Part 20 are periodically calibrated. In addition, § 30.33(a)(2) of this chapter requires licensees to have adequate equipment. Information on the types of instruments recommended for medical licensees is available in draft NUREG-1556, Vol. 9.

Section 35.630, Dosimetry equipment, would be revised to provide calibration requirements for instruments used in this subpart and subpart F. Paragraph (a)(1) would require that dosimetry systems be calibrated using a source whose activity is traceable to NIST and in accordance with published protocols approved by a nationally recognized body or by a calibration laboratory approved by AAPM. This change would give licensees two alternatives for direct traceability of dosimetry equipment calibration; i.e., either a source or the measurement instrument (e.g., well chamber) can be calibrated against a national standard. The Commission acknowledges that the industry standards for instrument calibration provide adequate assurance that equipment is properly calibrated. Paragraph (a)(2) would be revised to delete the reference to intercomparison meetings sanctioned by a calibration laboratory or radiologic physics centers accredited by the AAPM. This provision is no longer necessary because the AAPM does not sanction intercomparison meetings. References to cobalt-60 and cesium-137 contained within teletherapy units were deleted from the rule text to make the section applicable to dosimetry equipment for all radionuclides and therapy units. The recordkeeping requirements for this section would appear in § 35.2630, Records of dosimetry equipment.

Section 35.632, Full calibration measurements on teletherapy units, would be revised and retitled to clarify that the requirements in this section apply to teletherapy units. Paragraph (d) would be revised to delete the reference to the AAPM Task Group Reports and replace it with a requirement that full calibration measurements be done in accordance with published protocols approved by nationally recognized bodies. This allows the licensee more flexibility in choosing appropriate protocols. The Commission acknowledges that the industry standards for teletherapy unit calibration provide adequate assurance that equipment is properly calibrated.

Paragraph (f) would be revised to replace the term "teletherapy physicist" with the term "authorized medical physicist." The recordkeeping requirements for this section would appear in § 35.2632, Records of teletherapy full calibration.

Section 35.633, Full calibration measurements on remote afterloaders, would appear as a new section that would contain the requirements for the calibration of remote afterloaders. This section is similar in content to § 35.632. Requirements in this section would be based on recommendations found in AAPM Task Group Report No. 56. Recordkeeping requirements for this section would appear in § 35.2633, Records of remote afterloader full calibrations.

Section 35.634, Periodic spot-checks, would be deleted in its entirety and the requirements of this section, with minor modifications, would be moved to § 35.643.

Section 35.635, Full calibration measurements for gamma stereotactic radiosurgery units, would appear as a new section. This section would contain the requirements for the calibration of gamma stereotactic radiosurgery units and is similar in content to § 35.632. Requirements in this section are based on recommendations found in AAPM Report No. 54 - Stereotactic Radiosurgery (Task Group 42, 1995). Recordkeeping requirements for this section would appear in § 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations.

The current § 35.636, Safety checks for teletherapy facilities, would be deleted in its entirety and the requirements in this section would be incorporated into proposed §§ 35.642, 35.643, 35.644, and 35.645.

The current § 35.641, Radiation surveys for teletherapy facilities, would be deleted in its entirety. Radiation surveys at the surface of the main source safe would be addressed under proposed § 35.652. The remaining requirements in the current § 35.641 would be deleted to allow the licensee more flexibility in managing its radiation protection program.

Section 35.642, Periodic spot-checks for teletherapy units, would be retitled and revised. The phrase "teletherapy physicist" would be replaced with the term "authorized medical physicist" throughout the section. The requirement in paragraph (c) to maintain a copy of the physicist's notification of the results of spot-checks to the licensee would be deleted to reduce the recordkeeping requirements for licensees. Paragraph (d) would be modified to require that the safety spot-checks be performed monthly and after each source installation. This revision would replace the safety check requirements after each source replacement in the current § 35.634, which would be deleted in the proposed rule. Paragraph (d)(3) would be modified to replace the term "beam condition indicator" with "source exposure indicator" to clarify that indicators were needed to note whether the source was exposed and note to what degree the source was exposed. Paragraph (d)(4) would be revised to include a requirement for an intercom system that was previously imposed on licensees by license condition. An intercom is needed to assure that the licensee's staff and the patients have the ability to communicate verbally, in addition to the ability to communicate visually. Paragraph (e) would be revised to require that the licensee lock the control console in the off position, and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system, in case of any malfunction identified during a safety spot-check. This revision is intended to make § 35.642 consistent with the requirement in the current § 35.650 regarding immediate actions to be taken

when a malfunctioning system is identified. Recordkeeping requirements for this section would appear in § 35.2642, Records of periodic spot-checks for teletherapy units.

Section 35.643, Periodic spot-checks for high and pulsed dose-rate remote afterloaders, would appear as a new section that would replace the current requirements in § 35.643. The requirements in the current § 35.643 would be deleted because they were considered to be overly prescriptive. A licensee should have flexibility in designing a radiation protection program that is specific to its facility and which assures that the dose limits in 10 CFR Part 20 are not exceeded.

The revised section contains the requirements for periodic spot-checks of high and pulsed dose-rate remote afterloaders, and is similar in content to § 35.642. Requirements in this section are based on recommendations in AAPM Task Group Report No. 56. Recordkeeping requirements for this section would appear in § 35.2643, Records of periodic spot-checks for remote afterloaders.

Section 35.644, Periodic spot-checks for low-dose rate remote afterloaders, would appear as a new section. This revised section would contain the requirements for periodic spot-checks of low dose-rate remote afterloaders and would be similar in content to § 35.642. These proposed requirements are based on recommendations found in the AAPM Task Group Report No. 56. Some requirements were added to make the safety checks, and associated corrective actions, consistent with the requirements in § 35.642. The Commission is soliciting comment on whether the requirements for electrical interlocks and audiovisual systems should

apply to low-dose rate remote afterloaders. Recordkeeping requirements for this section would appear in § 35.2643, Records of periodic spot-checks for remote afterloaders.

Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units, would be retitled and revised to address gamma stereotactic radiosurgery units. This section would replace the current requirements in § 35.645, which were deleted to reduce the reporting burden on medical use licensees. The Commission believes that there is no need to submit survey results to the appropriate Regional Office because the survey results are maintained by a licensee to show compliance with 10 CFR Part 20 and, therefore, are available for review.

The revised section would contain requirements for periodic spot-checks of gamma stereotactic radiosurgery units, and is similar in content to § 35.642. Requirements in this section are based on recommendations found in AAPM Report No. 54. Some requirements were added to make the safety checks, and associated corrective actions, consistent with the requirements in § 35.642. Recordkeeping requirements for this section would appear in § 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.647, Additional technical requirements for mobile remote afterloaders, would replace the current § 35.647. Requirements in the current § 35.647 were moved to the proposed § 35.655. The new section would contain the requirements for mobile remote afterloaders which were previously listed in an internal NRC document entitled, "Supplement 1 to Policy and Guidance Directive FC 86-4; Revision 1, Mobile Remote Afterloading Brachytherapy Licensing Module." Recordkeeping requirements for this section would appear in § 35.2647, Records of additional technical requirements for mobile remote afterloaders.

Based on discussions with the States, this section is designated as a Category D item of compatibility since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity. NRC specifically requests comment on this issue relative to whether mobile medical licensees operate under reciprocity in other regulatory jurisdictions.

Section 35.652, Radiation surveys, would appear as a new section. This section would replace the current § 35.641. This section would require that, in addition to the surveys required by 10 CFR 20.1501, the licensee make surveys to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe do not exceed the levels stated in the Sealed Source and Device Registry. These surveys provide added assurance that a device has been manufactured and that source(s) have been installed properly. Recordkeeping requirements for this section would appear in § 35.2652, Records of surveys of therapeutic treatment units.

Section 35.655, Five-year inspection for teletherapy and gamma stereotactic radiosurgery units, would appear as a new section and would contain the requirements for inspections which are in the current § 35.647. Proposed § 35.655 would require that teletherapy units and gamma stereotactic radiosurgery units be inspected and serviced during source replacement, or at intervals not to exceed 5 years, to assure proper functioning of the source exposure mechanism. Most gamma stereotactic radiosurgery licensees are required, by license condition, to inspect the units every 7 years; however, professionals in the medical community have indicated that the units are inspected on a more frequent bases. The Commission believes that the risk associated with using gamma stereotactic radiosurgery units justifies a change in the inspection frequency. Recordkeeping requirements for this section

would appear in § 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Section 35.657, Therapy-related computer systems, would appear as a new section that would require licensees to verify that the computerized operating system and treatment planning system associated with a therapy device are operating appropriately and to perform acceptance testing on the treatment planning systems in accordance with published protocols approved by nationally recognized bodies. These changes are consistent with recommendations found in AAPM Task Group Report No. 40 - Comprehensive QA for Radiation Oncology (1994).

This proposed requirement is especially important in light of recent information on the inability of computers to correctly recognize dates beyond December 31, 1999. Therapy-related computer systems may misread the year 2000 and cause the systems to fail, generate faulty data, or act in an incorrect manner. In particular, computer software used to calculate dose or to account for radioactive decay may not recognize the turn of the century, which could lead to incorrectly calculated doses or exposure times for treatment planning. The potential for system failures, such as this, would be identified when determining compliance with this proposed section.

Section 35.690, Training for use of therapeutic medical devices, would appear as a new section. This section would revise the training and experience requirements found in § 35.960, Training for teletherapy, and would be expanded to include training for authorized uses of teletherapy, remote afterloaders, and gamma stereotactic radiosurgery units. Section III of the

Supplementary Information section of this document contains a detailed discussion of training and experience. Note, 2 years after publication of the final rule, this section would replace the current requirements in § 35.960, Training for teletherapy.

Subpart J, Training and Experience Requirements, is in the current Part 35. Licensees would have the option to comply with the training and experience requirements in this subpart or in subparts B, and D-H until 2 years after the final rule is published in the Federal Register. At that time this subpart will be deleted. A more detailed discussion of the Commission's proposed changes to the training and experience requirements is in Section III of the Supplementary Information section of this document. The proposed schedule for implementation of the training and experience requirements is in Section VIII of the Supplementary Information section of this document.

Section 35.900, Radiation Safety Officer, is in the current Part 35. Two changes would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist; and § 35.24, Authority and responsibilities for the radiation protection program. This section would be deleted 2 years after the final rule is published in the Federal Register at which time licensees would be required to comply with the training and experience requirements in the new § 35.50, Training for Radiation Safety Officer. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.901, Training for experienced Radiation Safety Officer, would be deleted in its entirety and the requirements of this section would be moved to the proposed § 35.57.

Section 35.910, Training for uptake, dilution, and excretion studies, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.290, Training for uptake, dilution, and excretion studies. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.920, Training for imaging and localization studies, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.292, Training for imaging and localization studies. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.930, Training for therapeutic use of unsealed byproduct material, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.932, Training for treatment of hyperthyroidism, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.934, Training for treatment of thyroid carcinoma, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system:

§ 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.390, Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.940, Training for use of brachytherapy sources, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.941, Training for ophthalmic use of strontium-90, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply

with the training and experience requirements in the new § 35.490, Training for use of manual brachytherapy sources. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.950, Training for use of sealed sources for diagnosis, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.590, Training for use of sealed sources for diagnosis. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.960, Training for use of therapeutic medical devices, is in the current Part 35. One change would be made in this section to correspond to the revised numbering system: § 35.57, Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.690, Training for use of therapeutic medical devices. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.961, Training for an authorized medical physicist, is in the current Part 35. The title of this section would be revised to reflect that the training and experience requirements in this section apply to authorized medical physicists rather than just teletherapy physicists. In addition, the list of tasks in paragraph (c) has been changed to reflect the new numbering system. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.51, Training for an authorized medical physicist. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.971, Physicians training in a three month program, would be deleted in its entirety. Three month nuclear medicine programs are no longer available. Criteria for authorized users are now specified in other areas of the rule.

Section 35.970, Training for an authorized nuclear pharmacist, would be deleted in its entirety and the requirements would be moved to the proposed § 35.57.

Section 35.980, Training for an authorized nuclear pharmacist, would not be changed. This section would be deleted 2 years after the final rule is published in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.981, Training for experienced nuclear pharmacists, has not been changed. This section would be deleted 2 years after the publication of the final rule in the Federal Register, at which time licensees would be required to comply with the training and experience requirements in the new § 35.55, Training for an authorized nuclear pharmacist. The Commission solicits specific comment on the impact of deleting this section. Section VIII of the Supplementary Information section of this document contains a detailed discussion of the Commission's proposed implementation of the training and experience requirements.

Section 35.990, Violations, would be deleted in its entirety, and the requirements of this section, with minor modifications, would be moved to the proposed § 35.4001

Section 35.991, Criminal penalties, would be deleted in its entirety, and the requirements of this section, with minor modifications, would be moved to the proposed § 35.4002.

Section 35.999, Resolution of conflicting requirements during transition period, would be deleted in its entirety; and the requirements of this section, with modifications, would be moved to the proposed § 35.10.

Subpart K, Other Medical Uses of Byproduct Material or Radiation from Byproduct Material, would be a new subpart. This subpart was developed to accommodate use of radioactive material in an emerging technology.

Section 35.1000, Other medical uses of byproduct material or radiation from byproduct material, is new. It would be added to accommodate emerging technologies. Specific information that must be provided to the Commission in support of an application for use under § 35.1000 is provided in § 35.12(d).

Subpart L, Records, is a new subpart. This subpart would contain all the specific recordkeeping requirements necessary to implement the proposed requirements in Part 35. General requirements for record maintenance, such as electronic storage, are provided in § 35.5. Grouping of records into one subpart was done to facilitate use by the licensees. A licensee may reference this section when determining whether something must be recorded, rather than having to review the entire regulation to find out if there is a particular recordkeeping requirement. Many of the recordkeeping requirements remain unchanged. However, some new sections have been added as a result of new requirements, especially in subpart H. The Commission is soliciting public comment on whether all recordkeeping requirements should be grouped into one subpart or whether all recordkeeping requirements should be included in the section requiring the record.

Section 35.2024, Records of authority and responsibility for radiation protection programs, would require the licensee to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The 5-year retention period is a reduction from current requirements to maintain records of the approval of licensing actions, individuals, and radiation protection program changes. Currently, similar records are required to be maintained for the duration of the license (reference current § 35.22 and § 35.31). This period would allow sufficient time for NRC to review records of licensee actions.

It would also require the licensee to retain the copy of the authorities, duties, and responsibilities of the Radiation Safety Officer for the duration of the license. In many cases, these records would take the place of the Radiation Safety Committee meeting minutes. The Commission believes that it is important to document licensees' management review and approval of licensing actions, changes to the radiation protection program, and the authorities, duties, and responsibilities of the Radiation Safety Officer. The record of licensing actions and radiation protection program changes must include a summary of actions and a signature of licensee management.

In addition, this section would require the licensee to retain a copy of the authorities, duties and responsibilities of the Radiation Safety Officer that includes the signatures of the radiation safety officer and licensee management for the duration of the license. This extended period is warranted in light of the importance of the functions performed by the Radiation Safety Officer.

Section 35.2026, Records of radiation protection program safety changes, would require the licensee to retain a record of each radiation protection program change, as required by § 35.26 for 5 years. The record must include a copy of the old and new procedure, the effective date of the change, and the signature of the Radiation Safety Officer and licensee management that reviewed and approved the change. The Commission recognizes that this requirement for management's signature is redundant to the requirement in § 35.2024; however, it believes this approach is warranted in light of the importance of these actions and the intent to keep requirements that are closely related in one subject area. Currently, licensees must retain a record of each "radiation safety program" change until the license has

been renewed or terminated; therefore, this proposed change represents a reduction in burden. This record is needed to document what radiation changes were made in the program. This record facilitates the Commission's evaluation of minor radiation safety program changes and provides licensees with a record of the changes.

Section 35.2040, Records of written directives, would require the licensee to retain a copy of written directives required by § 35.40 for 3 years. These records will help to ensure that administrations were in accordance with the written directives. The 3-year recordkeeping retention period corresponds with the current retention period for written directives. Only minor changes were made to the specific items that must currently be recorded in the written directive. These changes were discussed under § 35.40.

Section 35.2045, Records of medical events and precursor events, would require that the licensee maintain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for 3 years. This section, in part, is intended to replace the current recordkeeping requirements in § 35.33 and to establish recordkeeping requirements for precursor events. The records made pursuant to §§ 35.3045 and 35.3046 must contain the licensee's name; the name of the prescribing physician; the affected or potentially affected individual's social security number or other identification number if one has been assigned; a brief description of the medical event or precursor event; why it occurred; the effect on the individual; and the actions taken to prevent recurrence. This record is needed to document medical events and precursor events for licensee and Commission review. The requirement to maintain records of medical events is similar to the current requirement for maintaining records of misadministrations. This proposed requirement would provide for a reduction in licensee

burden since medical events records would be required to be maintained for 3 years rather than 5 years.

Section 35.2060, Records of instrument calibrations, would require the licensee to maintain a record of dose calibrator calibrations performed in accordance with §§ 35.60 and 35.62 for 3 years. These records are required to document that the instruments are functioning correctly. The name, rather than the signature, of the individual who performed the calibration would be required so that licensees would have the flexibility of using paper records or computer-generated records. This requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

Section 35.2061, Records of radiation survey instrument calibrations, would require the licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. No changes have been made from the current recordkeeping requirements for radiation survey instrument calibrations. These records are required to document that the instruments are functioning correctly. The 3-year recordkeeping retention period is consistent with the current retention period for instrument calibrations.

Section 35.2063, Records of dosage of unsealed byproduct material for medical use, would require the licensee to maintain a record of dosage determinations required by § 35.63 for 3 years. Minor changes have been made from the current recordkeeping requirements for dosage measurement to delete the requirement to record the expiration date of the radiopharmaceutical. This was done because the expiration date is primarily related to drug

stability and sterility. The term “dosage measurement” has been replaced by the term “dosage determination” to be consistent with the change proposed in § 35.63. Finally, a change would be made to require that the name of the individual who determined the dosage be documented. The licensee will be required to record dosages administered to patients or human research subjects. This record is required for licensees to show that they are maintaining control of radioactive material. The 3-year recordkeeping retention period corresponds with the current retention period for dosage records.

Section 35.2067, Records of possession of sealed sources and brachytherapy sources, would require the licensee to retain records of the leak tests and inventory required by § 35.67 (b) and (g) for 3 years. The record retention period was reduced from 5 years to 3 years to reduce regulatory burden. The Commission does not believe the extra period is warranted. One change has been made from the current recordkeeping requirements for leak tests and inventories. The name of the individual performing the leak test and inventory would be recorded rather than the signature of the Radiation Safety Officer. Leak test records are required to show that the leak test was done at the appropriate time interval and that sealed sources are not leaking. Inventory records are necessary to show that the possession of sealed sources did not exceed the amount authorized by the license.

Section 35.2070, Records of surveys for ambient radiation exposure rate, would require the licensee to maintain records of radiation surveys for 3 years. One change has been made from the current recordkeeping requirements for radiation surveys. The name of the individual performing the survey rather than the initials of the individual would be required to be recorded. These records are needed to document that surveys were performed. The 3-year

recordkeeping retention period is consistent with the current retention period for radiation surveys.

Section 35.2075, Records of the release of individuals containing radiopharmaceuticals or implants, would require the licensee to maintain records of patient release required by § 35.75 for 3 years. No changes have been made from the current recordkeeping requirements in § 35.75. This record is needed to show compliance with the requirements in § 35.75.

Section 35.2080, Records of administrative and technical requirements that apply to the provision of mobile services, would require the licensees to maintain a copy of the letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and to retain the records of the surveys for 3 years. One change has been made in these records that are required by § 35.80. The name of the individual performing the survey rather than the initials of the individuals would be required to be recorded. The records are needed to show compliance with the requirements in § 35.80.

Section 35.2092, Records of waste disposal, would require the licensee to maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. Minor changes have been made in the recordkeeping requirements in the current Part 35. The licensee would no longer be required to record the date that the material was placed in storage because the requirement to store material for 10 half-lives would be deleted in the proposed rule. The record must include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. This record is

needed to document that radioactive material is not disposed of as ordinary waste. The 3-year recordkeeping retention period is consistent with the current retention period for waste disposal records.

Section 35.2204, Records of molybdenum-99 concentration, would require the licensee to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. The licensee would no longer be required to record the measured activity of the technetium expressed in millicuries, and the measured activity of the molybdenum expressed in microcuries. The record must include, for each measured elution of technetium-99m, the ratio for the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measure, and the name of the individual who performed the disposal. This record is needed to document that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded. The 3-year recordkeeping retention period is consistent with the current retention period for records of molybdenum-99 concentration.

Section 35.2310, Records of instruction and training, would require the licensee to maintain a record of radiation safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s) and the name of the individual who gave the instruction. This record is needed to document that the instruction and training was given. The 3-year recordkeeping retention period is consistent with the current retention period for training records.

Section 35.2404, Records of radiation surveys of patients and human research subjects, would require the licensee to maintain a record of the radiation surveys required by § 35.404 for 3 years. The licensee would no longer be required to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or human research subject. Each record must include the date, location, results of the survey, an identification of the patient or the human research subject, survey instrument used, and the name of the individual who made the survey. These records are used to show that sources have not been misplaced and that all sources have been removed from the patient. The 3-year recordkeeping retention period is consistent with the current retention period for surveys.

Section 35.2406, Records of brachytherapy source inventory, would require the licensee to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. Changes have been made in the recordkeeping requirements that are in the current rule. The licensee would no longer be required to record the following items since they would be deleted from discussion in § 35.406: the names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return.

The proposed rule would require that, for temporary implants, the record must include the number and activity of sources removed from and returned to storage; the time and date they were removed from and returned to storage; the location of use; and the name of the individual who removed and returned the sources to storage. For permanent implants, the

record must include the number and activity of sources removed from and returned to storage; the date they were removed from and returned to storage; the number and activity of sources removed from and returned to storage; the number and activity of sources permanently implanted in the patient or human research subject; and the name of the individual who removed and returned the sources to storage. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action. The 3-year recordkeeping retention period is consistent with the current retention period for inventory records.

Section 35.2432, Records of full calibrations on brachytherapy sources, would require the licensee to retain a record of the results of brachytherapy source calibrations for 3 years after the last use of the source. This is a new recordkeeping section. The record must contain the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

Section 35.2605, Records of installation, maintenance, and repair, would require the licensee to retain a record of the installation, maintenance, and repair of therapeutic medical devices, as required by § 35.605, for 3 years. This is a new recordkeeping section. Previously, licensees were not required to keep records of installation, maintenance, and repair. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work. This record is necessary to document that the devices are properly installed, maintained, and repaired; to establish trends

in device performance; and to establish a service history that may be used in evaluation of generic equipment problems.

Section 35.2630, Records of dosimetry equipment, would require the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. No changes have been made in the recordkeeping requirements from the current rule. These records are needed to show that calibrations of medical devices were made with properly calibrated instruments.

Section 35.2632, Records of teletherapy full calibrations, would requires the licensee to maintain a record of the teletherapy full calibrations required by § 35.632 for 3 years. The record retention period was decreased from the duration of the use of the teletherapy unit source to 3 years to reduce regulatory burden. The term "teletherapy physicist" was replaced with the term "authorized medical physicist." No other changes were made to the current recordkeeping requirements for this section. These records are needed to document that calibrations were performed in accordance with § 35.632.

Section 35.2633, Records of remote afterloader full calibrations, would require the licensee to maintain a record of the remote afterloader full calibrations required by § 35.633 for 3 years. This is a new recordkeeping section. The recordkeeping requirements in this section are similar to the recordkeeping requirements for teletherapy units in § 35.2632. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the remote afterloader, source, and instruments used to calibrate the unit; the source output; an assessment of timer accuracy and linearity, source positioning accuracy,

source guide tube and connector lengths, source retraction functionality; and the signature of the authorized medical physicist who performed the full calibration. These records are needed to document that calibrations were performed in accordance with § 35.633.

Section 35.2635, Records of gamma stereotactic radiosurgery unit full calibrations, would require the licensee to maintain a record of the calibrations required by § 35.635 for 3 years. This is a new recordkeeping section. The recordkeeping requirements in this section are similar to the recordkeeping requirements for teletherapy units in § 35.2632. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit; the unit output; an assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and the signature of the authorized medical physicist who performed the full calibration. These records are needed to document that calibrations were performed in accordance with § 35.635. This change reflects corresponding changes made in § 35.642.

Section 35.2642, Records of periodic spot-checks for teletherapy units, would require the licensee to retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. Minor changes have been made in the recordkeeping requirements from the current rule. The licensee would no longer be required to record the operability of the beam condition indicator light, but would be required to record the operability of the source exposure indicator light. This change reflects corresponding changes made in § 35.642. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the teletherapy unit source, and instrument used to measure the output of the

teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; name of the individual who performed the test and the signature of the authorized medical physicist who reviewed the periodic spot-check. These records are needed to document that spot-checks were performed in accordance with § 35.642. The 3-year recordkeeping retention period is consistent with the current retention period for periodic spot-checks.

Section 35.2643, Records of periodic spot-checks for remote afterloaders, would require the licensee to retain a record of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the remote afterloader, source, and instrument used to measure the output of the remote afterloader; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; the name of the individual who performed the periodic spot-check; and signature of the authorized medical physicist who reviewed the periodic spot-check. These records are needed to document that spot-checks were performed in accordance with §§ 35.643 and 35.644.

Section 35.2645, Records of periodic spot-checks for gamma stereotactic radiosurgery units, would require the licensee to retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. This is a new recordkeeping section. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, and the instrument used to measure the output of the unit; the measured source output and source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff mechanism, and stereotactic frames and localizing devices (trunnions); and the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the periodic spot-check. This record is needed to show that spot-checks were performed in accordance with § 35.645.

Section 35.2647, Records of additional technical requirements for mobile remote afterloaders, would require the licensee to retain a record of each check for mobile remote afterloaders required by § 35.647 for 3 years. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader; notations accounting for all sources before departing from a client's facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the check. This record is needed to show that required spot-checks were performed in accordance with § 35.647 and

that the unit is operable. The 3-year recordkeeping retention period is consistent with the current retention period for checks on mobile remote afterloaders.

Section 35.2652, Records of surveys of therapeutic treatment units, would require the licensee to maintain a record of radiation surveys made in accordance with § 35.652 for the duration of use of the unit. This recordkeeping section has been changed to require that the records of radiation surveys of the treatment unit must be maintained for the duration of use of the unit, rather than for the duration of the license, to reduce regulatory burden. In addition, the licensee is no longer required by this section to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area. This change reflects corresponding changes made in § 35.652. The record must include the date of the measurements; the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; and each dose rate measured around the source while the unit is in the off position and the average of all measurements and the signature of the individual who performed the surveys. This record is needed to document radiation levels in areas surrounding therapeutic devices.

Section 35.2655, Records of 5-year inspection for teletherapy and gamma stereotactic surgery units, would require the licensee to maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the unit. This recordkeeping section has been changed to require that the records of inspections of the treatment units must be maintained for the duration of use of the unit, rather

than for the duration of the license, to reduce regulatory burden. A minor change was made to delete the requirement to maintain a record of the components replaced to also reduce regulatory burden. The record must contain the inspector's name; the inspector's radioactive materials license number; the date of inspection; the manufacturer's name and model number and serial number for both the treatment unit and source; a list of components inspected and serviced; the type of service; and the signature of the inspector. This record is needed to document the type of service that was performed.

Subpart M, Reports, is a new subpart in Part 35. This subpart would contain all the reporting requirements necessary to implement the proposed requirements in Part 35. Grouping of reporting requirements into one subpart was done to facilitate use by the licensee. A licensee may reference this section when determining whether something must be reported, rather than having to review the entire regulation to find out if there is a particular reporting requirement. Many of the reporting requirements remain unchanged. The Commission is soliciting public comments on whether the reporting requirements should be included in the section requiring the report.

Section 35.3045, Reports of medical events, would provide criteria for reporting medical events. The criteria are based on the current requirements in § 35.33. Changes would be made to make the reporting threshold dose-based where possible to add a dose threshold of 0.5 Sv (50 rem) shallow dose equivalent to the skin; and to address two areas that have caused problems in implementing the current requirements in § 35.33 -- patient intervention and wrong treatment site. With respect to patient intervention, the licensee is expected to act reasonably, in accordance with prevailing standards of care, to prevent a medical event. Generally

speaking, patient intervention involves actions by the patient such as dislodging or removing treatment devices or prematurely terminating treatment. In cases where patient intervention is probable, the licensee should take reasonable actions (e.g., extra sutures, taping, or more frequent checks by the nursing staff) to avoid a medical event. Factors which may be considered in determining whether a licensee's actions are reasonable include whether the licensee monitors the patient routinely and whether the licensee responds properly once it becomes aware of the disruption of treatment. The Commission is soliciting input from the public on whether the proposed changes adequately address patient intervention and wrong treatment site.

The proposed rule would require that licensees notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee would be required to submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event. In addition, the licensee would be required to notify the referring physician and the individual affected by the medical event, or the responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. This reporting requirement is needed to ensure that NRC is aware of medical events. Section III of the Supplementary Information of this document contains a detailed discussion of the Commission's views on the notification requirements.

Section 35.3046, Reports of precursor events, would require that the licensee notify NRC of precursor events. The section would require the licensee to report, no later than the

next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event. The licensee would be required to submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of the event. The written report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence.

This requirement was added to the rule in response to Commission direction to staff to determine the best way to "capture precursor events." Issues associated with capturing precursor events and associated public comment are presented in Section III of the Supplementary Information section of this document. The Commission has attempted to estimate the burden on licensees associated with this requirement. The Regulatory Analysis for this rule contains a detailed discussion of this issue. The Commission estimates that approximately 50 reports would be received from NRC and Agreement State licensees on an annual basis and that it will take approximately 5 hours of licensee effort to prepare the report required by this section. This results in an annual burden on NRC and Agreement State licensees of approximately \$14,000. The Commission is soliciting input from the public on whether the estimated number of reports and number of hours to prepare the written report is reasonable in light of current practice.

Section 35.3047, Report of a dose to an embryo/fetus or a nursing child, is a new section. Paragraph (a) would require that a licensee report to NRC any administration of

byproduct material, or radiation from byproduct material, to a pregnant woman that results in a dose to an embryo/fetus that is greater than 5 mSv (500 mrem) absorbed dose unless specifically approved, in advance, by the authorized user. It should be emphasized that only unintended exposures would be reported to NRC. This report does not include exposure of individuals in excess of the public dose limits in Part 20. Paragraph (b) would require a licensee to report to NRC any administration of byproduct material to a breast feeding woman that results in a dose to the nursing child that is greater than 5 mSv (500 mrem) total effective dose equivalent unless the administration was specifically approved, in advance, by the authorized user. Oral reports must be made to the NRC Operations Center within 5 days of discovery and followed with a written report no later than 30 days.

Information required by this section is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438), as amended, to annually submit to Congress a report of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences.

NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that was published in the Federal Register on April 17, 1997 (62 FR 18820). Section II of the policy statement defines unintended radiation exposure as "any occupational exposure, exposure to the general public or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations." This section also states that "All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or

embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.” Appendix A, Section I. A, of the policy statement, states that NRC will provide information on “any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.”

At the present time, NRC has no regulatory requirements that would require reporting of those types of events. The Commission considered two alternatives that could be pursued: revise the current Abnormal Occurrence Criteria to delete the requirement to inform Congress of this type of event; or develop a reporting requirement that would provide information needed by the Commission to comply with Section 208. The Commission did not pursue the first option because the Abnormal Occurrence reporting criteria were recently revised.

Only two comments were received on the proposed criteria in this area. One commenter believed that the threshold for reporting a dose to any minor or embryo/fetus should be reduced to less than 0.350 rem instead of the proposed 5 rem. The second commenter recommended that the criteria related to a nursing infant, fetus or embryo as a result of an exposure to a nursing mother or a pregnant woman should be deleted from the criteria until the issue can be resolved through consultation with the ACMUI and a separate public comment period on that issue.

The Commission is not inclined to revise the criteria without public comments indicating that it is not appropriate for NRC to report this type of event to Congress and that the proposed

reporting requirement in § 35.3047 is overly burdensome or unwarranted. As a result, the Commission has decided to pursue the second alternative. However, the Commission does solicit specific comments in this area regarding whether modification of the Abnormal Occurrence Policy Statement criteria is needed.

The proposed rule would require that licensees report to NRC any unintended exposures to an embryo/fetus or nursing child that exceeds the dose threshold, as specified in the proposed § 35.3047. The Commission recognizes that the proposed reporting threshold is less than the Abnormal Occurrence reporting level. This was done to make the Part 35 reporting threshold consistent with the reporting thresholds in 10 CFR Part 20. The time period for reporting is similar for the reporting requirements in 10 CFR parts 20 and 35. The period for initial notification to NRC is longer than the period for reporting medical events. The Commission believes it appropriate to provide for a longer reporting period because the threshold for reporting and the risk associated with this threshold are lower than those for a medical event.

The Commission recognizes that the standard of practice for authorized users is to assess the pregnancy or nursing status of their patients (reference American College of Radiology "Standard for the Performance of Therapy with Unsealed Radio nuclide Sources," 1996, and "Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides," 1997). As a result, NRC does not believe that it is appropriate to propose a rule that would require a licensee to assess the pregnancy or nursing status of patients. It does, however, believe that it is appropriate to propose a rule that would require the licensee to inform NRC when it learns of an unintended dose to an embryo/fetus or a nursing child that

exceeds the thresholds discussed above. Reporting under § 35.3047 would not necessarily be subject to enforcement action if the licensee had complied with § 35.75. Although the regulation requires that the licensee provide information on the cause of the incident and corrective actions to prevent recurrence, NRC acknowledges that in many, and if not all, incidents, the licensee might not have been able to prevent the incident because the individual may have opted not to disclose her pregnancy or nursing status. NRC is soliciting specific public comment on the impacts of this reporting requirement on licensee procedures, activities, or medical practices.

Section 35.3067, Reports of leaking sources, would require the licensee to file a report with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 5 days if a leakage test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. This reporting requirement is similar to the current requirements for leaking sources. The report must contain the model number and serial number if assigned, of the leaking source; Radio nuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the action taken.

Subpart N, Enforcement, contains statements regarding enforcement. This subpart would replace the statements in the current Subpart K, Enforcement.

Section 35.4001, Violations, would appear as a new section and replace the current § 35.990 which would be deleted in the proposed rule. This section reflects the new numbering system for the revised Part 35.

Section 35.4002, Criminal penalties, would appear as a new section and replace the current § 35.991 which would be deleted in the proposed rule. This section reflects the new numbering system for the revised Part 35.

Appendix A to Part 35, Examining Organization or Entity, would appear as a new appendix. This appendix would provide the requirements for an examining organization or entity; examination programs; and written examinations. This appendix is needed because of the proposed revision to the training and experience criteria for an authorized user, medical physicist, authorized nuclear pharmacist, and radiation safety officer that would require an individual to pass an examination given by an organization or entity approved by NRC or an Agreement State. All criteria in Appendix A are considered by the Commission as necessary to assure that an individual's competency is adequately assessed.

NRC is proposing that an independent examining organization be an organization that would make its examination process available to the general public nationwide and not restrict access because of race, color, religion, sex, age, national origin or disability. The independent examining organization or entity would need to:

- (1) Have adequate staff;
- (2) Have a viable system of financing its operations;
- (3) Have a policy and decision making review board;

- (4) Be governed by written organizational by-laws and policies;
- (5) Provide NRC or an Agreement State with a description of its procedures for choosing examination sites and for providing an appropriate examination environment;
- (6) Submit its request for approval to the Director, Office of Nuclear Materials Safety and Safeguards.

An independent examining organization or entity would also need to have:

- (1) A committee to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program;
- (2) A committee to review complaints from examined individuals;
- (3) Written procedures describing all aspects of its examination program;
- (4) An agreement to exchange information about examined individuals with the Commission and the Agreement States;
- (5) Procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area;
- (6) Procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program;
- (7) Procedures for proctoring examinations; and
- (8) Procedures to ensure that all examination questions are protected from disclosure.

NRC is proposing in Section II of Appendix A that all examination programs must

- (1) require applicants for examination to receive training in the topics set forth in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(3), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1)

and satisfactorily complete a written examination covering these topics. NRC is proposing in Section III that:

(1) The written examination must be designed to test an individual's knowledge and understanding of the topics listed in the above sections;

(2) The written examination must have test items drawn from a question bank containing psychometrically valid questions based on the material in the above listed questions; and

(3) A sample examination must be submitted to the Commission for review initially and every 5 years.

A 5-year review cycle is consistent with the review of residency programs by the Accreditation Council for Graduate Medical Education.

Summary of Specific Issues Identified for Public Comment

The Commission is soliciting specific public comment on various issues associated with this rulemaking action. These issues are discussed in detail in the noted sections.

1. Training and Experience -- Is the proposed requirement for examining organizations to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area too prescriptive in light of current industry practice? What is the projected amount of time needed for specialty boards and examining organizations to prepare and submit an application to NRC or Agreement States.

2. Section 35.2 -- Should the term "medium dose-rate remote afterloader" be defined since it not used in the rule? (Requirements for medium dose-rate remote afterloaders have been grouped with high dose-rate remote afterloaders in this rulemaking.)
3. Section 35.75 -- Should any changes be made to the release criteria specified in this section?
4. Section 35.92 -- Is it appropriate to delete the requirement to hold byproduct material for a minimum of ten half-lives?
5. Section 35.315 -- Should the requirement for a private room with a private sanitary facility be maintained in the final rule?
6. Section 35.415 -- Should the requirement for a licensee to not quarter a patient in the same room as an individual who is not receiving radiation therapy be maintained in the final rule?
7. Section 35.432 -- Should the final rule allow licensees to rely on the brachytherapy source output provided by the manufacturer or distributor if the dosimetry equipment used by the manufacturer or distributor met the calibration requirements in § 35.630? How should sources be calibrated if there is no standard traceable to the National Institute of Standards and Technology? What is the estimated number of short- and long-lived brachytherapy sources that will need to be calibrated on an annual basis and how long will it take to perform the calibration? Will licensees need to procure additional equipment to perform the calibrations?
8. Section 35.605 -- Should the restrictions in paragraph (a) of the proposed rule apply to low dose-rate remote afterloaders?
9. Section 35.615 -- Should the requirements in this section be waived for licensees that are using remote afterloaders with beta-emitting sources?

10. Section 35.644 -- Should the restrictions for electrical interlocks and audiovisual systems apply to low dose-rate remote afterloaders?
11. Section 35.981 -- What is the impact of deleting this section?
12. Subpart L -- Should all recordkeeping requirements be grouped into one subpart or should they be incorporated into the section requiring the record?
13. Subpart M -- Should all reporting requirements be grouped into one subpart or should they be incorporated into the section requiring the report?
14. Section 35.3045 -- Do the proposed rule changes adequately address patient intervention and wrong treatment site?
15. Section 35.3046 -- Are the estimated number of reports that would be submitted to NRC and the number of hours needed to prepare the written report reasonable in light of current practice?
16. Section 35.3047 -- Should the Abnormal Occurrence Policy Statement criteria for reporting of exposures to an embryo/fetus or nursing child be modified? What is the impact of the proposed reporting requirement on licensee procedures, activities, or medical practices?

V. Coordination With The Advisory Committee on the Medical Uses of Isotopes

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) is an advisory body established to advise the NRC staff on matters that involve the administration of radioactive material and radiation from radioactive material. At the public ACMUI meetings on September 25-26, 1997, and March 1-2, 1998, held in Rockville, MD., the NRC staff presented

alternatives for major cross-cutting issues related to revising Part 35, recommendations for revising the NRC's Medical Use Policy Statement, and draft proposed rule text.

These meetings were transcribed. The ACMUI's comments at the September 1997 meeting are summarized in "Summary of Discussion: Meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Held in Rockville, Maryland on September 25-26, 1997" (date of document to be inserted). The summary document is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary document are available as indicated in the For Further Information Contact section of this document. A brief summary of the ACMUI positions on the major crosscutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

Working group members also met with separate ACMUI subcommittees for diagnostic and therapeutic medical uses on February 9-10, 1998 (Rockville, MD.) and February 12-13, 1998 (Freeport, IL.), respectively. The subcommittee meetings provided the Working Group with an opportunity to discuss in depth the specific provisions of the draft proposed rule with ACMUI members.

VI. Coordination With NRC Agreement States

NRC staff discussed the proposed revision of Part 35 with representatives of the Agreement States at a workshop on October 18, 1997. The workshop commentary was transcribed, and the participant's comments are summarized in "Summary of Discussion:

Facilitated Public Workshop on NRC's Medical Rulemaking Initiative Held at All Agreement States Meeting, Los Angeles, California, October 18, 1997" (date of document to be inserted). The summary document is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the summary document are available as indicated in the For Further Information Contact section of this document. A brief summary of the workshop participants' positions on the major cross-cutting issues associated with this rulemaking is provided in Section III of the Supplementary Information section of this document.

Both the Working Group and Steering Group that developed the draft proposed rule included representatives of Agreement States. The Agreement State representative on the Working Group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested state medical regulations. State participation in the process has provided an early opportunity for State input and should enhance development of corresponding rules in State regulations. In addition, it will allow the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States.

VII. Consistency with Medical Policy Statement

The Commission is proposing a revision to its General Policy on the Regulation of the Medical Uses of Radioisotopes that was issued on February 9, 1979 (44 FR 8424), as part of the efforts undertaken to revise 10 CFR Part 35. The proposed revision and detailed

discussion on the need for the revision is being published for comment in the Federal Register concurrently with the proposed revision to Part 35. Because of the nature of the proposed revision to the policy, consistency with each policy will be discussed separately.

Consistency with the proposed revision to the Medical Use Policy Statement

The proposed revision to Part 35 is consistent with the Commission's proposed revision to the Medical Use Policy Statement.

The first statement of the proposed policy reads "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with the statement because one of its purposes is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate to "protect health and minimize danger to life."

The second statement of the proposed policy reads "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." The proposed rule would also be consistent with this statement because its focus is on protecting the public and workers from patients who have been administered byproduct material or radiation from byproduct material for medical use.

The third statement of the proposed policy reads "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is

in accordance with the physician's directions." The proposed rule is consistent with this statement because it includes provisions, where warranted by the risk, to provide high confidence that the authorized user's directions for the administration of byproduct material are followed.

The fourth statement of the proposed policy reads "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." The proposed rule is consistent with this statement because the rulemaking process included examining relevant industry and professional standards to determine if specific areas of concern were included in the standards, or whether regulatory requirements needed to be included in Part 35.

Consistency with the 1979 Medical Use Policy Statement

The proposed revision to Part 35 is generally consistent with the Commission's General Policy on the Regulation of the Medical Uses of Radioisotopes issued on February 9, 1979 (44 FR 8242).

The first statement of the policy reads "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The proposed rule is consistent with this statement because its purpose is to provide for the radiation safety of workers and individual members of the public, which is central to fulfillment of the Commission's statutory mandate to "protect health and minimize danger to life."

The second statement of the policy is “The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.” The proposed rule is generally consistent with this statement. The proposed rule includes requirements to ensure the radiation safety of patients in areas where justified by the risk to patients. The rulemaking process included examining relevant industry and professional standards to determine if specific areas of concern were included in the standards, or whether additional regulatory requirements needed to be developed for inclusion in Part 35. The process did not include an assessment of licensee compliance with these standards. Where appropriate, the proposed revision includes references to published protocols approved by nationally recognized bodies. Where warranted by risk, key elements of the standards were included as performance objectives. Prescriptive compliance requirements for these performance objectives were not included in the rule because it is expected that licensees will use voluntary standards to achieve the objective. This approach is consistent with a performance-based, risk-informed rule.

The third statement of the policy reads, “The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.” The proposed rule is consistent with this statement because it includes no requirements associated with the diagnosis and treatment of patients.

VIII. Implementation

The Commission intends to have different implementation dates for particular requirements of this proposed rule. With one exception (discussed below), the proposed

requirements would be effective 6 months after publication of the final rule in the Federal Register. Because the consolidated guidance document for medical use licensees is being developed in parallel with the revised regulatory requirements in Part 35, the Commission believes that a longer implementation period will not be necessary. The 6-month implementation period would allow the NRC time to train licensing and inspecting staff so that the revised Part 35 will be uniformly implemented; and provide licensees the time to understand the specific features of the revised Part 35, and to develop and implement any changes in their radiation safety programs or procedures that are required to comply with the revised requirements. NRC workshops might be offered for the benefit of licensees, Regional Offices, States, and others who are affected by the revision.

The Commission proposes that licensees would have up to 2 years after the effective date of the final rule to comply with the proposed training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees will have the option of complying with either the existing training requirements, which will be retained in subpart J, or the training requirements in subparts B and D-H of the proposed rule.

The 2-year implementation period will allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; and for NRC to review and approve the applications submitted in accordance with Appendix A, and to review and approve certification of the specialty boards in §§ 35.50(a), 35.51(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). The 2-year time period will also allow individuals from Agreement States time to satisfy the proposed training

requirements in order to work in NRC jurisdiction. After the 2-year implementation period, the requirements in subpart J will be deleted.

Section 35.10 of the proposed rule addresses how a licensee can determine if it must comply with the requirements of its license conditions or the requirements of the revised Part 35, when it becomes effective.

The Commission invites comments and suggestions on the effective date of implementation, including specific information on time and economic considerations, and on additional guidance or documents that would be needed or useful in implementing the proposed revision.

IX. Issues of Compatibility for Agreement States

10 CFR PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Part 35. A Category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. Category "A" designated Agreement

State requirements should be essentially identical to those of the NRC. A Category "B" designation means the requirement has significant direct transboundary implications. Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A Category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Health and Safety (H&S) Category identifies requirements which are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

The following discussion identifies the compatibility designations for each section:

Subpart A, "General Information," § 35.2, "Definitions," is assigned to Compatibility Category "D," with the exception of the terms "Agreement State", "authorized user," "medical event," "medical use," "precursor event," "prescribed dosage," "prescribed dose," "sealed source," "treatment site" and "written directive." The terms "Agreement State" and "sealed source" are assigned to Compatibility Category "B" because they have significant direct transboundary implications. The terms "authorized user," "medical event," "medical use," "precursor event," "prescribed dosage," "prescribed dose," "treatment site" and "written directive" have been assigned to Compatibility Category "C." Section 35.11, "License required," is assigned to Compatibility Category "C."

Subpart B, "General Administrative Requirements," is assigned to Compatibility Category "D," with the exception of four sections. Section 35.24, "Authority and responsibilities for the radiation protection program"; § 35.27, "Supervision"; § 35.40, "Written directives"; and § 35.41(a), "Procedures for administrations requiring a written directive" are all assigned to the Health and Safety Category. Section 35.50, "Training for radiation safety officer"; § 35.51, "Training for authorized medical physicist"; § 35.55 "Training for an authorized nuclear pharmacist"; and § 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist" are assigned to Compatibility Category "C."

Subpart C, "General Technical Requirements," is assigned to Compatibility Category "D," with the exception of four sections. Section 35.61, "Calibration and check of survey instruments"; § 35.63(a), "Determination of dosages of unsealed byproduct material for medical use"; § 35.67, "Requirements for possession of sealed sources and brachytherapy sources"; and § 35.70, "Surveys of ambient radiation exposure rate" are assigned to the Health and Safety Category. Section 35.75, "Release of individuals containing radiopharmaceuticals or implants," paragraph (a), is assigned to Compatibility Category "C."

Subpart D, "Unsealed Byproduct Material - Low Dose"; and Subpart E, "Unsealed Byproduct Material - High Dose" are assigned to Compatibility Category "D," except for § 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required"; § 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required"; § 35.204, "Permissible molybdenum-99 concentration"; and § 35.300, "Use of unsealed byproduct

material for which a written directive is required," which are assigned to the Health and Safety Category. Section 35.290, "Training for uptake, dilution, and excretion studies"; and § 35.292, "Training for imaging and localization studies"; and § 35.390, "Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive," are assigned to Compatibility Category "C."

Subpart F, "Manual Brachytherapy" is assigned to Compatibility Category "D," with the exception of five sections. Section 35.400, "Use of sources for manual brachytherapy"; § 35.404(a) and (b), "Radiation surveys of patients or human research subjects treated with implants"; § 35.406(a) and (b), "Brachytherapy sources inventory"; and § 35.432(a-e), "Full calibration measurements of brachytherapy sources" are assigned to the Health and Safety Category. Section 35.490, "Training for use of manual brachytherapy sources," is assigned to Compatibility Category "C."

Subpart G, "Sealed Sources for Diagnosis," is assigned to Compatibility Category "D," with the exception of Section 35.590, "Training for use of sealed sources for diagnosis" which is assigned to Compatibility Category "C."

Subpart H, "Therapeutic Medical Devices," is assigned to Compatibility Category "D," with the exception of 16 sections. The following sections are assigned to the Health and Safety Category: §§ 35.600; 35.604(a); 35.605; 35.610(a)(1), (a)(2), and (a)(4); 35.615(a), (b)(1), (b)(2), (d), and (e); 35.630; 35.632; 35.633; 35.635; 35.642; 35.643; 35.644; 35.645; 35.655; and 35.657. Section 35.690, "Training for use of therapeutic medical devices" is assigned to Compatibility Category "C."

Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," and Subpart L, "Records," are assigned to Compatibility Category "D."

Subpart M, "Reports," is assigned to Compatibility Category "C." Section 35.3045, "Reports of medical events"; § 35.3046, "Reports of precursor events"; § 35.3047, "Reports of a dose to an embryo/fetus or a nursing child," and § 35.3069, "Reports of leaking sources" are assigned to Compatibility Category "C."

Subpart N, "Enforcement," is assigned to Compatibility Category "D."

Appendix A, "Examining Organization or Entity," is assigned to Compatibility Category "B."

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

Section 20.1301(a)(3) is assigned to Compatibility Category "A."

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Section 32.72 (b)(1) and (b)(2)(ii) and § 32.74 (a) and (a)(3) are assigned to Compatibility Category "B."

As discussed under Section VIII of this document, the Commission proposes that licensees would have up to 2 years after the effective date of the final rule to comply with the proposed training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2-year period, licensees would have the option of complying with either the existing training requirements in subpart J, or the proposed training requirements in subparts B and D through H. At the end of the 2 years, subpart J would be deleted and licensees would have to comply with the proposed training and experience criteria. The training and experience requirements in the proposed subpart J are assigned to Compatibility Category "D," as they are in the current rule. Subparts B and D through H of the proposed rule have been assigned to Compatibility Category "C" for Agreement States. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," approved by the Commission on June 30, 1997, the Agreement States are required to adopt NRC program elements (or promulgate regulations) required for compatibility within 3 years of the effective date of the NRC rulemaking. Therefore, the Commission recognizes that if an Agreement State does not revise its regulations until 2 years after the effective date of the NRC rule, it may choose not to include subpart J training and experience requirements in the newly promulgated rules, since the subpart J requirements are assigned to Compatibility Category "D" (not required for compatibility). In this case, the Agreement States would only be expected to adopt the proposed training and experience requirements in subparts B and D through H.

X. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR Part 51, that the proposed amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these proposed amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. The proposed amendments to Part 35, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material. The proposed amendment to 10 CFR 20.1301 is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiation Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

The draft environmental assessment on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment are available as indicated in the For Further Information Contact section of this document.

XI. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by [hours to be inserted when OMB package is completed] hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by

Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010 and 3150-0120), Office of Management and Budget, Washington, DC, 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

XII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis for the proposed rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the regulatory analysis are available as indicated in the For Further Information Contact section of this document.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft regulatory analysis may be submitted to the NRC as indicated under the Addresses section of this document.

XIII. Regulatory Flexibility Analysis

The NRC has prepared an initial regulatory flexibility analysis of the impact of this proposed rule on small entities. The preliminary regulatory flexibility analysis indicates that the proposed rule will have an economic impact of approximately \$8,000 annually on medical licensees, of which 36 percent are small entities. However, the NRC notes that this would be a substantial reduction in the cost to the average licensee under the current regulations. The NRC estimates that the proposed requirements would reduce the annual cost to an average medical licensee by approximately \$ 900. The NRC believes that the proposed alternative is the least costly alternative that provides adequate protection from radiation exposure for patients and workers. The regulatory flexibility analysis appears as Appendix A to this document.

Because of the widely differing conditions under which small medical licensees operate, the NRC is seeking comments on the impact of the rule and any suggested modifications that may affect its economic impact. Any small medical licensee that would be subject to this regulation that determines, because of its size, that it is likely to bear a disproportionate adverse economic impact, should notify the Commission of this in a comment that indicates-

(a) The licensee's size and how this proposed regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee;

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested under paragraph (b) above;

(d) How the proposed regulation, as modified, would more closely equalize its impact as opposed to providing special advantages to any individual licensee or groups of licenses; and

(e) How the proposed regulations, as modified, would still adequately protect the public health and safety.

The comments should be sent to the NRC as indicated under the Addresses section of this document.

XIV. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule because these amendments would not involve any provision that would impose backfits as defined in 10 CFR Chapter I.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation Protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposed to adopt the following amendments to 10 CFR parts 20, 32 and 35.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1301, paragraph (a)(3) is added to read as follows:

§ 20.1301 Dose limits for individual members of the public.

(a) * * *

(3) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to individuals who are not released in accordance with § 35.75 to receive a radiation dose greater than (1 mSv) 0.1 rem, but not to exceed (5 mSv) 0.5 rem, if the authorized user, as defined in 10 CFR Part 35, determines that it is appropriate.

* * * * *

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

3. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Secs. 81, 82, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.72 [Amended]

4. In § 32.72, in paragraph (b)(1), the reference to "10 CFR 35.25" is revised to read "10 CFR 35.27" and in paragraph (b)(2)(ii), the reference to "10 CFR 35.980(b) and 35.972" is revised to read "10 CFR 35.55(b) and 35.59 or 10 CFR 35.980(b) and 35.972."

§ 32.74 [Amended]

5. In § 32.74, in paragraph (a), the reference to "§§ 35.400 and 35.500" is revised to read "§§ 35.400, 35.500, and 35.600" and in paragraph (a)(3), the reference to "§§ 35.58, 35.400, or 35.500" is revised to read "§§ 35.400, 35.500, and 35.600."

6. 10 CFR Part 35 is revised to read as follows:

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A--General Information

Sec.

- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.
- 35.6 Provisions for research involving human subjects.
- 35.7 FDA, other Federal, and State requirements.
- 35.8 Information collection requirements: OMB approval.

- 35.10 Implementation.
- 35.11 License required.
- 35.12 Application for license, amendment, or renewal.
- 35.13 License amendments.
- 35.14 Notifications.
- 35.15 Exemptions regarding Type A specific licenses of broad scope.
- 35.18 License issuance.
- 35.19 Specific exemptions.

Subpart B--General Administrative Requirements

- 35.24 Authority and responsibilities for the radiation protection program.
- 35.26 Radiation protection program changes.
- 35.27 Supervision.
- 35.40 Written directives.
- 35.41 Procedures for administrations requiring a written directive.
- 35.49 Suppliers for sealed sources or devices for medical use.
- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
- 35.59 Recentness of training.

Subpart C--General Technical Requirements

35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.

35.61 Calibration and check of survey instruments.

35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

35.63 Determination of dosages of unsealed byproduct material for medical use.

35.65 Authorization for calibration and reference sources.

35.67 Requirements for possession of sealed sources and brachytherapy sources.

35.69 Labeling and shielding of vials and syringes.

35.70 Surveys for ambient radiation exposure rate.

35.75 Release of individuals containing radiopharmaceuticals or implants.

35.80 Provision of mobile service.

35.92 Decay-in-storage.

Subpart D--Unsealed Byproduct Material - Low Dose

35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

35.204 Permissible molybdenum-99 concentration.

35.290 Training for uptake, dilution, and excretion studies.

35.292 Training for imaging and localization studies.

Subpart E -- Unsealed Byproduct Material - High Dose

- 35.300 Use of unsealed byproduct material for which a written directive is required.
- 35.310 Safety instruction.
- 35.315 Safety precautions.
- 35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

Subpart F-Manual Brachytherapy

- 35.400 Use of sources for manual brachytherapy.
- 35.404 Radiation surveys of patients or human research subjects treated with implants.
- 35.406 Brachytherapy sources inventory.
- 35.410 Safety instruction.
- 35.415 Safety precautions.
- 35.432 Full calibration measurements of brachytherapy sources.
- 35.490 Training for use of manual brachytherapy sources.

Subpart G --Sealed Sources for Diagnosis

- 35.500 Use of sealed sources for diagnosis.
- 35.590 Training for use of sealed sources for diagnosis.

Subpart H--Therapeutic Medical Devices

- 35.600 Use of a sealed source in a device for therapeutic medical uses.
- 35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.

- 35.605 Installation, maintenance, and repair .
- 35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.615 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.
- 35.630 Dosimetry equipment.
- 35.632 Full calibration measurements on teletherapy units.
- 35.633 Full calibration measurements on remote afterloaders.
- 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
- 35.642 Periodic spot-checks for teletherapy units.
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Subpart I -- Reserved

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35.2067 Records for possession of sealed sources and brachytherapy sources.

35.2070 Records of surveys for ambient radiation exposure rate.

35.2075 Records of the release of individuals containing radiopharmaceuticals or implants.

35.2080 Records of administrative and technical requirements that apply to the provision of mobile services.

35.2092 Records of waste disposal.

35.2204 Records of molybdenum-99 concentration.

35.2310 Records of instruction and training.

35.2404 Records of radiation surveys of patients and human research subjects.

35.2406 Records of brachytherapy source inventory.

35.2432 Records of full calibrations on brachytherapy sources.

35.2605 Records of installation, maintenance, and repair.

35.2630 Records of dosimetry equipment.

35.2632 Records of teletherapy full calibrations.

35.2633 Records of remote afterloader full calibrations.

35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.

35.2642 Records of periodic spot-checks for teletherapy units.

35.2643 Records of periodic spot-checks for remote afterloaders.

35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

35.2647 Records of additional technical requirements for mobile remote afterloaders.

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Subpart M --Reports

35.3045 Reports of medical events.

35.3046 Reports of precursor events.

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Subpart N -- Enforcement

35.4001 Violations.

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Appendix A to 10 CFR Part 35 - Examining Organization or Entity

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A--General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized medical physicist means a physicist who --

- (1) Meets the requirements in §§ 35.51(a) and 35.59 or §§ 35.961 and 35.59; or
- (2) Is identified as a medical physicist on a Commission or Agreement State license; or
- (3) Is identified as a medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material.

Authorized nuclear pharmacist means a pharmacist who --

- (1) Meets the requirements in §§ 35.55(a) and 35.59 or §§ 35.980(a) and 35.59; or
- (2) Is identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

- (3) Is identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy; or

(4) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy authorized by the Commission to approve authorized nuclear pharmacists.

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59, or §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.59; or

(2) Is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(3) Is identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

Brachytherapy source means a radioactive sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

High dose-rate remote afterloader, as used in this part, means a device that remotely delivers a dose rate in excess of 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader as used in this part, means a device that remotely delivers a dose rate of less than 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or that person's delegate or delegates.

Medical event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Mobile service means the transportation and medical use of byproduct material by the same licensee at temporary jobsites.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented --

- (1) In a written directive; or
- (2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means --

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive;
- (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
- (4) For remote afterloaders, the total dose as documented in the written directive.

Precursor event means an event that meets the criteria in § 35.3046(a).

Pulsed dose-rate remote afterloader means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license who --

- (1) Meets the requirements in §§ 35.50 and 35.59 or §§ 35.900 and 35.59; or
- (2) Is identified as a Radiation Safety Officer on a Commission or Agreement State license.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Temporary jobsite means a location where mobile services are conducted other than those location(s) of use authorized on the license.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Unit dosage means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel

and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the

Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.57, 35.60, 35.61, 35.62, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.204, 35.290, 35.292, 35.310, 35.315, 35.390, 35.404, 35.406, 35.410, 35.415, 35.432, 35.490, 35.590, 35.604, 35.605, 35.610, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.2024, 35.2026, 35.2040, 35.2045, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2605, 35.2630, 35.2632, 35.2633, 35.2635, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3046, 35.3047, 35.3067, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, NRC Form 313, including NRC Forms 313A, and 313B which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before [insert date 6 months from publication of the Final Rule], with the exception of the requirements listed in paragraph (b) of this section.

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a) on or before [insert date-- 2 years from publication of the Final Rule].

(c) Prior to [insert date-- 2 years from publication of the Final Rule], a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

- (1) The appropriate training requirements in subpart J; or
- (2) The appropriate training requirements in subpart B or subparts D-H.

(d) If the requirements of this part are more restrictive than the existing license condition, the licensee shall comply with this part unless exempted by paragraph (f) of this section.

(e) Any existing license condition that is more restrictive than a requirement in this part remains in effect until there is a license amendment or license renewal.

(f) If a license condition exempted a licensee from a provision of Part 35 on [insert date-- 6 months from publication of the Final Rule], it will continue to exempt a licensee from the corresponding provision in this part.

(g) If a license condition cites provisions in Part 35 that will be deleted on [insert date-- 6 months from publication of the Final Rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

§ 35.11 License required.

(a) A person may not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition.

(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the management of the facility.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500, and for medical use of remote afterloaders in § 35.600, must be made by filing an original and one copy of NRC Form 313, "Application for Material License." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) Except for medical use of remote afterloaders, a separate license application must be filed for each medical use of byproduct material as described in § 35.600 of this part by filing an original and one copy of NRC Form 313. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) An application for a license for medical use of byproduct material as described in § 35.1000 of this part must be made by filing an original and one copy of NRC Form 313.

(1) In addition to the information required in NRC Form 313, the application must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part, as well as any specific information necessary for --

- (i) Radiation safety precautions and instructions;
- (ii) Training and experience of proposed users;
- (iii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
- (iv) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment --

- (a) Before it receives or uses byproduct material for a clinical procedure that is permitted under this part, but that is not authorized on the licensee's current license issued pursuant to this part;
- (b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is --

(1) An authorized user who meets the requirements §§ 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and § 35.59, or §§ 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and § 35.59;

(2) An authorized nuclear pharmacist who meets the requirements in § 35.55(a) and § 35.59; or §§ 35.980 and 35.59;

(3) An authorized medical physicist who meets the requirements in § 35.51(a) and § 35.59; or §§ 35.961 and 35.59;

(4) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(5) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

(c) Before it changes Radiation Safety Officers;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form that is different than the radionuclide or form authorized on the license;

(e) Before it adds to or changes the areas identified in the application or on the license, except for areas where byproduct material is used in accordance with §§ 35.100 and 35.200; and

(f) Before it changes the address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, pursuant to § 35.13 (b)(1) through (b)(5).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas where byproduct material is used in accordance with §§ 35.100 and 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from --

(a) The provisions of § 35.13(b);

(b) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

- (c) The provisions of § 35.14(a);
- (d) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist; and
- (e) The provisions of § 35.49(a).

§ 35.18 License issuance.

- (a) The Commission shall issue a license for the medical use of byproduct material if --
 - (1) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;
 - (2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;
 - (3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and
 - (4) The applicant meets the requirements of Part 30 of this chapter.
- (b) The Commission shall issue a license for mobile services if the applicant:
 - (1) Meets the requirements in paragraph (a) of this section; and
 - (2) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized

by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management must approve in writing --

(1) Requests for license application, renewal, or amendments before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee with multiple modalities or multiple users shall also develop, implement, and maintain written administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

(c) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements in the daily operation of the licensee's radiation protection program

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective actions;
- (3) Stop unsafe operations; and,
- (4) Verify implementation of corrective actions.

(f) A licensee shall retain a record of actions taken pursuant to paragraphs (a), (c), and (d) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if --

- (1) The revisions do not require an amendment under § 35.13;
- (2) The revisions do not reduce radiation safety;
- (3) The revisions have been reviewed and approved by the Radiation Safety Officer and licensee management; and
- (4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by § 35.11(b) of this part shall --

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, regulations of this chapter; and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(c), shall --

(1) Instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions.

(c) A licensee shall establish, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from --

(i) The authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done; and

(ii) The authorized user or authorized nuclear pharmacist about the instructions and requirements provided to the supervised individual in accordance with paragraphs (a) and (b) of this section.

(d) A licensee that permits supervised activities under paragraph (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be prepared, dated, and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from byproduct material.¹

(b) The written directive must contain the patient or human research subject's name and the following:

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

¹ If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

(5) For remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(c) The licensee shall retain the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) The procedures required by paragraph (a) of this section must, at a minimum, address --

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the specific details of the administration are in accordance with the written directive and treatment plan;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by § 35.600.

§ 35.49 Suppliers for sealed sources or devices for medical use.

A licensee may use for medical use only --

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and § 32.74 of this chapter or the equivalent requirements of an Agreement State; or

(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.

§ 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in § 35.24 to be an individual who --

(a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or;

(b)(1) Has completed a structured educational program consisting of both:

(I) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following;

- (A) Shipping, receiving, and performing related radiation surveys;
- (B) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
- (C) Securing and controlling byproduct material;
- (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
- (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (F) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor RSO, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an RSO for medical uses of byproduct material; and

(3) Following completion of the requirements in paragraph (b) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

§ 35.51 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by a speciality board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the NRC, and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.634, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652 of this part; and

(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the requirements in paragraph (b)(1) in this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist; and,

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(I) Didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the requirements in paragraph (b)(1) have been satisfactorily completed and

that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license before [insert date--6 months from publication of the Final Rule] need not comply with the training requirements of §§ 35.50 and 35.51, respectively.

(b) Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before [insert date--6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts C-H.

§ 35.59 Recentness of training.

The training and experience specified in subparts B, D, E, F, G, H, and J must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C--General Technical Requirements

§ 35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.

(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the activity of photon-emitting radionuclides prior to administration to each patient or human research subject.

(b) If a licensee uses instrumentation to measure the activity of dosages of photon-emitting radionuclides, including unit dosages, it shall develop, implement, and maintain written procedures for proper operation of the instrumentation. At a minimum, a licensee shall --

- (1) Perform tests, before initial use and following repair, on each instrument for accuracy, linearity, and geometry dependence;
- (2) Perform an accuracy test annually;
- (3) Perform a linearity test annually over the range of medical use; and
- (4) Check each instrument for constancy and proper operation at the beginning of each day of use.

(c) Accuracy tests must be performed with source(s) with a principal photon energy of between 100 and 500 keV whose activity is traceable to the National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.11 MBq (30 μ Ci) and shall repair or replace the instrumentation if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section in accordance with § 35.2060.

§ 35.61 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following repair. A licensee shall —

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale that will be used to show compliance with this part; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and conspicuously attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent.

(c) Survey instruments must be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent.

(d) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee shall measure, by

direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject.

(b) A licensee shall develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee shall --

(1) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary;

(2) Perform accuracy annually;

(3) Perform linearity tests annually over the range of medical use; and

(4) Check each instrument for constancy and proper operation at the beginning of each day of use.

(c) Accuracy tests must be performed with source(s) that are traceable to NIST or by a supplier who has compared the source to a source that was calibrated by NIST.

(d) A licensee shall retain a record of each check and test required by this section in accordance with § 35.2060.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage prior to medical use.

(b) For a unit dosage of an alpha-, beta-, or photon-emitting radionuclide, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements.

(c) For a dosage of a alpha-, beta-, or photon-emitting radionuclide prepared by the licensee, this determination must be made by direct measurement or by combination of measurements and calculations.

(d) A licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

§ 35.65 Authorization for calibration and reference sources.

Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 1.11 kBq (30 mCi) each;

(b) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 MBq (15 mCi);

(c) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 µCi) each and not to exceed 1000 times the quantities in Appendix B of Part 30 whichever is more limiting; and

(d) Technetium-99m in amounts as needed.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall --

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 μ Ci) of radioactive material on the sample.

(d) A licensee shall retain leakage test records in accordance with § 35.2067.

(e) If the leakage test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the licensee shall --

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leakage test in accordance with § 35.3067.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) or less of alpha-emitting material;

(4) Sources stored for less than a 10-year period and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within 6 months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067.

§ 35.69 Labeling and shielding of vials and syringes.

(a) A licensee shall develop, implement, and maintain written procedures for --

(1) Labeling each syringe, syringe shield, or vial shield that contains a radiopharmaceutical to identify the radiopharmaceutical name, or its abbreviation, and to ensure that the contents are conspicuously identified as containing radioactive material; and

(2) Shielding vials and syringes containing radiopharmaceuticals.

(b) A licensee shall instruct individuals, commensurate with the individual's assigned duties, in the procedures required by paragraph (a) of this section.

§ 35.70 Surveys for ambient radiation exposure rate.

(a) Except as provided in paragraph (b) of this section, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects can not be released pursuant to § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing radiopharmaceuticals or implants.

(a) A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).²

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include --

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with § 35.2075(c).

² Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

§ 35.80 Provision of mobile service.

(a) A licensee providing mobile service shall --

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address of use and clearly delineates the authority and responsibility of each entity;

(2) Check instruments as described in §§ 35.60 and 35.62 for proper function before medical use at each address of use or on each day of use, whichever is more frequent;

(3) Check survey instruments for proper operation with a dedicated check source before use at each address of use;

(4) Before leaving a client's address of use, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter; and

(b) A mobile nuclear medicine service may not have byproduct material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material. Radioactive material delivered to the client's address of use must be received and handled in conformance with the client's license.

(c) Retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash if it --

(1) Monitors byproduct material at the surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level

with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels;

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D--Unsealed Byproduct Material - Low Dose

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material, except in quantities that require a written directive pursuant to § 35.40, prepared for medical use that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

A licensee may use for imaging and localization studies any unsealed byproduct material, except in quantities that require a written directive pursuant to § 35.40, prepared for medical use that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 5.55 kBq (0.15 µCi) of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.57, the licensee shall require the authorized user of a radiopharmaceutical for the uses listed in § 35.100 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or --

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals, consisting of both --

- (I) 40 hours of didactic training in the following areas --
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Mathematics pertaining to the use and measurement of radioactivity;
 - (D) Chemistry of byproduct material for medical use; and
 - (E) Radiation biology; and
- (ii) 20 hours of supervised practical experience under the supervision of an authorized user involving --
 - (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (C) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (D) Using administrative controls to prevent a medical event involving the use of byproduct material;
 - (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
 - (F) Administering dosages to patients or human research subjects; and
- (2) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of a diagnostic radiopharmaceutical for the uses listed in § 35.100; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

§ 35.292 Training for imaging and localization studies.

Except as provided in §§ 35.57, the licensee shall require the authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in § 35.200 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals and generators, consisting of both --

(I) 80 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) 40 hours of supervised practical experience under the supervision of an authorized user involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(G) Administering dosages to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in § 35.200; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart E--Unsealed Byproduct Material - High Dose

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is either --

(a) Obtained from a manufacturer or preparer licensed pursuant to § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.292, or an individual under the supervision of either as specified in § 35.27.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received radiopharmaceutical therapy and can not be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1); and

(ii) Visitation authorized in accordance with § 20.1301(a)(3);

(3) Contamination control;

(4) Waste control; and

(5) Notification of the authorized user and the Radiation Safety Officer, or his designee, if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject that cannot be released in accordance with § 35.75, a licensee shall --

(1) Provide a private room with a private sanitary facility;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(3) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) A licensee shall notify the authorized user and the Radiation Safety Officer, or his or her designee, as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

§ 35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical for the uses listed in § 35.300 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of unsealed byproduct material consisting of both --

(i) 80 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 40 hours of supervised practical experience under the supervision of an authorized user at a medical institution involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating dose calibrators, as appropriate, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(2) Has had experience, obtained under the direct supervision of an authorized user, involving at least five cases for each procedure with radiation safety hazards similar to that use for which the individual is requesting authorized user status;

(3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b)(1) and (2) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of unsealed byproduct material for the uses listed in § 35.300; and

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart F-- Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses as approved in the Sealed Source and Device Registry.

§ 35.404 Radiation surveys of patients or human research subjects treated with implants.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject and the adjacent area of use to confirm that no sources have been misplaced.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of patient or human research subject surveys in accordance with § 35.2404.

§ 35.406 Brachytherapy sources inventory.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions;
- (3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1); and

(ii) Visitation authorized in accordance with § 20.1301(a)(3); and

(5) Notification of the authorized user and Radiation Safety Officer, or his or her designee, if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving brachytherapy and confined pursuant to § 35.75 of this part, a licensee shall --

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have available, near each treatment room, emergency response equipment. The emergency response equipment must include, as applicable --

(1) A device to assist in placing the source(s) in the shielded position;

(2) A shielded source/applicator storage container;

(3) Remote handling tools; and

(4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources.

(c) A licensee shall notify the authorized user and the Radiation Safety Officer, or his designee, as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

§ 35.432 Full calibration measurements of brachytherapy sources.

(a) A licensee authorized to use brachytherapy sources for medical use shall perform full calibration measurements on brachytherapy sources before the first medical use of the source or source/applicator configuration.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output or activity within +/- 5 percent; and

(2) Source positioning accuracy within applicators.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output or activity of the brachytherapy source.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs or activities determined in paragraph (b) of this section for physical decay at intervals consistent with 1 percent physical decay.

(f) A licensee shall retain a record of each calibration in accordance with § 35.2432.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a manual brachytherapy source for the uses listed in § 35.400 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources consisting of both --

(I) 200 hours of didactic training in the following areas;

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology;

(ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing sealed sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC,

and an additional two years of clinical experience under the supervision of an authorized user;
and

(3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b)(1) and (2) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the uses listed in § 35.400; and,

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart G--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for the use in a device listed in § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes --

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Radiation biology; and
- (5) Training in the use of the device for the uses requested.

Subpart H--Therapeutic Medical Devices

§ 35.600 Use of a sealed source in a device for therapeutic medical uses.

A licensee shall use sealed sources and devices for therapy as approved in the Sealed Source and Device Registry for medical use.

§ 35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the afterloader device with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of patient or human research subject surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

(b) Except for low dose-rate remote afterloader devices, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device,

(c) For a low dose-rate remote afterloader device, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall perform the functions listed in paragraph (b) of this section.

(d) A licensee shall retain a record of the installation, maintenance, and repair done on therapeutic medical devices in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall develop, implement, and maintain written procedures for --

(1) Securing the device, the console, the console keys, and the treatment room when not in use or unattended;

(2) Except for low dose-rate remote afterloaders, ensuring that only the patient or the human research subject is in the treatment room before initiating treatment with the source(s), unless contraindicated, or after a door interlock interruption;

(3) Preventing dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include --

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) Process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(b) A copy of the procedures required by § 35.610(a) must be physically located at the unit console.

(c) A licensee shall post instructions at the device console to inform the operator of --

(1) The location of the procedures required by § 35.610(a); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console unit or console operates abnormally.

(d) A licensee shall provide instruction and practice drills, initially and at least annually, in the procedures identified in paragraph (a) of this section and the operating procedures to all individuals who operate the device, as appropriate to the individual's assigned duties. A licensee shall ensure that operators receive refresher training in the operation of the unit and

that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures.

(e) A licensee shall retain a record of individuals receiving instruction required by paragraph (b) of this section, in accordance with § 35.2310.

§ 35.615 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the sources to be shielded immediately when an entrance door is opened;
and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloaders, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For low dose-rate remote afterloader devices, require --

(i) An authorized user or an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device.

(2) For high dose-rate remote afterloader devices, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has been trained in emergency response for the device, to be physically present during continuation of all patient treatments involving the device.

(3) For pulsed dose-rate remote afterloader devices, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has

been trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device.

(4) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(g) The licensee shall have available, near each treatment room, emergency response equipment. The emergency response equipment must include, as applicable --

- (1) A device to assist in placing the source(s) in the shielded position;
- (2) A shielded source/applicator storage container;
- (3) Remote handling tools; and
- (4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a source traceable to the National Institute of Standards and Technology and published protocols approved by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and

Technology or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic devices, the licensee shall use a comparable device with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit --

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(I) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloaders.

(a) A licensee authorized to use a remote afterloader for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(iii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 120 days for high dose-rate and pulsed dose-rate remote afterloaders; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloaders.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

- (1) The output within ± 5 percent;
- (2) Source positioning accuracy to within ± 1 millimeter;
- (3) Source retraction with backup battery upon power failure; and
- (4) The operability of the electrically assisted treatment room doors with the high-dose rate remote afterloader unit electrical power turned off.

(c) In addition to the requirements for full calibrations for all remote afterloaders in paragraph (b) of this section, a licensee shall:

- (1) For high dose-rate and pulsed dose-rate remote afterloaders, calibrate --
 - (i) At intervals not exceeding one quarter:
 - (A) The source guide tubes;
 - (B) Timer accuracy and linearity over the typical range of use; and
 - (C) Length of the connectors; and
 - (ii) Annually, the function of the source tube guides and connectors.
- (2) For low dose-rate remote afterloaders, perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement and a spot check of the absolute timer accuracy at intervals not exceeding one quarter.

(d) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(e) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(f) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(g) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (f) of this section must be performed by the authorized medical physicist.

(h) A licensee shall retain a record of each calibration in accordance with § 35.2633.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions --

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) Trunnion centricity.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2635.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of --

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of --

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

- (4) Viewing and intercom systems;
- (5) Treatment room doors from inside and outside the treatment room; and
- (6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d), in accordance with § 35.2642

§ 35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.

(a) A licensee authorized to use high dose-rate or pulsed dose-rate remote afterloaders for medical use shall perform spot-checks on each unit:

- (1) At the beginning of each week of use;
- (2) At the beginning of each day of use; and.
- (3) After each source installation.

(b) The licensee shall have the authorized medical physicist:

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of paragraphs (a)(1) of this section, spot-checks must, at a minimum --

- (1) Verify source positioning accuracy;
- (2) Determine output with the dosimetry system described in § 35.630(b); and
- (3) Calculate the difference between the measurement made in paragraph (c)(2) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration mathematically corrected for physical decay).

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must, at a minimum, assure proper operation of --

- (1) Electrical interlocks at each remote afterloader room entrance;
- (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- (3) Viewing and intercom systems;
- (4) Emergency response equipment;
- (5) Radiation monitors used to indicate the source position;
- (6) Timer constancy; and
- (7) Clock (date and time) in the unit's computer.

(e) In addition to the requirements for spot checks in paragraph (d), a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(f) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating.

(g) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not

use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(h) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with § 35.2643.

§ 35.644 Periodic spot-checks for low dose-rate remote afterloaders.

(a) A licensee authorized to use low dose-rate remote afterloaders for medical use shall perform spot-checks on each unit prior to each patient treatment and after each source installation that include proper operation of --

- (1) Electrical interlocks at each remote afterloader room entrance;
- (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
- (3) Viewing and intercom systems;
- (4) Emergency response equipment;
- (5) Radiation monitors used to indicate the source position;
- (6) Timer constancy; and
- (7) Clock (date and time) in the unit's computer.

(b) In addition to the requirements for spot checks in paragraph (a), a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(c) The licensee shall have the authorized medical physicist --

- (1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(d) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (a) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use gamma stereotactic radiosurgery units for medical use shall perform spot-checks on each unit --

- (1) Monthly,
- (2) At the beginning of each day of use, and
- (3) After each source installation.

(b) The licensee shall have the authorized medical physicist --

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --

- (1) Assure proper operation of --
 - (i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - (ii) Helmet microswitches;
 - (iii) Emergency timing circuits;
 - (iv) Emergency off buttons; and
 - (v) Stereotactic frames and localizing devices (trunnions).
- (2) Determine --
 - (i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);
 - (ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
 - (iii) Source output against computer calculation;
 - (iv) Timer accuracy and linearity over the range of use;
 - (v) On-off error; and
 - (vi) Trunnion centricity.
- (d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of --
 - (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - (3) Viewing and intercom systems;
 - (4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Hydraulic cutoff mechanism (if applicable).

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating properly.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloaders.

(a) A licensee providing mobile remote afterloader service shall --

(1) Check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader before each address of use. At a minimum, checks must be made to verify the operation of --

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators and connectors;

- (5) Radiation monitors used to indicate room exposures;
- (6) Source positioning (accuracy); and
- (7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) A licensee shall arrange for prompt repair of any system identified in paragraph (b) of this section that is not operating properly.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a licensee shall make such surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall:

(a) Verify that the computerized operating system and treatment planning system associated with the therapy device are operating appropriately; and

(b) Perform acceptance testing on the treatment planning system in accordance with published protocols approved by nationally recognized bodies.

§ 35.690 Training for use of therapeutic medical devices.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source for a use listed in § 35.600 to be a physician who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or;

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical device consisting of both --

(I) 200 hours of didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving --

(A) Review of the full calibration measurements and periodic spot checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC and an additional two years of clinical experience under the supervision of an authorized user; and

(3) Has obtained written certification, signed by a preceptor authorized user, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical device for which the individual is requesting authorized user status; and

(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A of this part.

Subpart I- -Reserved

Subpart J--Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by the --

- (1) American Board of Health Physics in Comprehensive Health Physics;
- (2) American Board of Radiology;
- (3) American Board of Nuclear Medicine;
- (4) American Board of Science in Nuclear Medicine;
- (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;
- (6) American Board of Medical Physics in radiation oncology physics;
- (7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

- (8) American Osteopathic Board of Radiology; or
- (9) American Osteopathic Board of Nuclear Medicine; or
- (b) Has had classroom and laboratory training and experience as follows --
 - (1) 200 hours of classroom and laboratory training that includes --
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry; and
 - (2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material;
- or
- (c) Be an authorized user identified on the licensee's license.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who --

- (a) Is certified in --
 - (1) Nuclear medicine by the American Board of Nuclear Medicine;
 - (2) Diagnostic radiology by the American Board of Radiology;
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
 - (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows --

(1) 40 hours of classroom and laboratory training that includes --

- (I) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiation biology; and
- (v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes --

(I) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject follow up; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who --

(a) Is certified in --

- (1) Nuclear medicine by the American Board of Nuclear Medicine;
- (2) Diagnostic radiology by the American Board of Radiology;
- (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
- (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiopharmaceutical chemistry; and
- (v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

- (iii) Calculating and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent the medical event of byproduct material;
 - (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
 - (vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and
- (3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes --
- (I) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 - (iii) Administering dosages to patients or human research subjects and using syringe radiation shields;
 - (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (v) Patient or human research subject follow up; or
- (c) Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in § 35.57, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who --

(a) Is certified by --

(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

(4) The American Osteopathic Board of Radiology after 1984; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows --

(1) 80 hours of classroom and laboratory training that includes --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes --

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows --

(a) 80 hours of classroom and laboratory training that includes --

- (1) Radiation physics and instrumentation;
- (2) Radiation protection,
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows --

(a) 80 hours of classroom and laboratory training that includes --

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;

- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology; and
- (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.57, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who --

- (a) Is certified in --
 - (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;
 - (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;
- or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows --

- (1) 200 hours of classroom and laboratory training that includes --
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent a medical event involving byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration follow up and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows --

(a) 24 hours of classroom and laboratory training that includes --

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity; and
- (4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes --

- (1) Examination of each individual to be treated;
- (2) Calculation of the dose to be administered;
- (3) Administration of the dose; and
- (4) Follow up and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified in --

(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes --

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

§ 35.960 Training for use of therapeutic medical devices.

Except as provided in § 35.57, the licensee shall require the authorized user of a sealed source listed in § 35.600 to be a physician who --

(a) Is certified in --

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and supervised clinical experience as follows --

(1) 200 hours of classroom and laboratory training that includes --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized

user at a medical institution that includes --

(i) Review of the full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent medical events;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical

experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes --

- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications;
- (ii) Selecting the proper dose and how it is to be administered;
- (iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and
- (iv) Post-administration follow up and review of case histories.

§ 35.961 Training for authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --

(a) Is certified by the American Board of Radiology in --

- (1) Therapeutic radiological physics;
- (2) Roentgen ray and gamma ray physics;
- (3) X-ray and radium physics; or
- (4) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics;

or

(c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed 1 year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a medical physicist

at a medical institution that includes the tasks listed in §§ 35.67, 35.632, 35.633, 35.634, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652.

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who - -

- (a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
- (b)(1) Has completed 700 hours in a structured educational program consisting of both --
 - (i) Didactic training in the following areas:
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Mathematics pertaining to the use and measurement of radioactivity;
 - (D) Chemistry of byproduct material for medical use; and
 - (E) Radiation biology; and
 - (ii) Supervised experience in a nuclear pharmacy involving the following --
 - (A) Shipping, receiving, and performing related radiation surveys;
 - (B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
 - (C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - (D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) and recency of training (§ 35.59) to qualify as an authorized nuclear pharmacist.

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if --

(a) The applicant or licensee has submitted the information required by § 35.12(d); and

(b) The applicant or licensee has received written approval from the Commission in a license and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L--Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the radiation safety officer as required by § 35.24(d). The record must include the signature of the radiation safety officer and licensee management.

§ 35.2026 Records of radiation protection program safety changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the radiation safety officer and the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2045 Records of medical events and precursor events.

A licensee shall retain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for 3 years. The record must contain the licensee's name, names of all the individuals involved, the affected or potentially affected individual's social security number or other identification number if one has been assigned, a brief description of the medical event or precursor event, why it occurred, the effect on the individual, and the actions taken to prevent recurrence.

§ 35.2060 Records of instrument calibrations.

A licensee shall maintain a record of instrument calibrations required by §§ 35.60 and 35.62 for 3 years. The records must include --

(a) For constancy, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the activity measured, and the name of the individual who performed the check;

(b) For accuracy, the model and serial number of the instrument, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test, and the name of the individual who performed the test --

(c) For linearity, the model and serial number of the instrument, the calculated activities, the measured activities, and the date of the test, and the name of the individual who performed the test; and

(d) For geometric dependence, the model and serial number of the instrument, the configuration of the source measured, the activity measured for each volume measured, and the date of the test, and the name of the individual who performed the test.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include --

- (a) A description of the calibration procedure; and
- (b) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

- (b) To satisfy this requirement, the record must contain the --
 - (1) Radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical, and its lot number;
 - (2) Patient's or human research subject's name, or identification number if one has been assigned;
 - (3) Prescribed dosage and activity of the dosage at the time of determination, or a notation that the total activity is less than 1.1 MBq (30 µCi);
 - (4) Date and time of the dosage determination; and
 - (5) Name of the individual who determined the dosage.

§ 35.2067 Records of possession of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing radiopharmaceuticals or implants.

(a) A licensee shall retain records of the release of individuals containing pharmaceuticals or implants in accordance with § 35.75 for 3 years after the date of release.

(b) A licensee shall retain a record in accordance with § 35.2075(a) that describes the basis for authorizing the release of individuals if the total effective dose equivalent is calculated by --

- (1) Using the retained activity rather than the activity administered;
- (2) Using an occupancy factor less than 0.25 at 1 meter;
- (3) Using the biological or effective half-life; or
- (4) Considering the shielding by tissue.

(c) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

§ 35.2080 Records of administrative and technical requirements that apply to the provision of mobile services.

(a) A licensee shall retain a copy of the letter(s) that permits the use of byproduct material at a client's address of use, in accordance with § 35.80(a)(1). This letter must clearly delineate the authority and responsibility of each entity and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour,

the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of waste disposal.

A licensee shall maintain records of the disposal of licensed materials made in accordance with § 35.92 for 3 years. The record must include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of instruction and training.

A licensee shall maintain a record of instructions and training required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of radiation surveys of patients and human research subjects.

A licensee shall maintain a record of the radiation surveys of patients and human research subjects required by §§ 35.404 and 35.604 for 3 years. Each record must include the date, location, and results of the survey, an identifier for the patient or the human research subject, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source inventory.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include --

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them from storage.

(c) For permanent implants, the record must include --

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of full calibrations on brachytherapy sources.

A licensee shall maintain a record of the full calibrations on brachytherapy sources required by § 35.432 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

§ 35.2605 Records of installation, maintenance, and repair.

A licensee shall retain a record of the installation, maintenance, and repair of therapeutic medical devices as required by § 35.605 for 3 years. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2630 Records of dosimetry equipment.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy full calibrations.

(a) A licensee shall maintain a record of the teletherapy full calibrations required by § 35.632 for 3 years.

(b) The record must include --

- (1) The date of the calibration;
- (2) The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instruments used to calibrate the teletherapy unit;
- (3) Tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;
- (4) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (5) An assessment of timer accuracy and linearity;
- (6) The calculated on-off error;
- (7) The estimated accuracy of each distance measuring and localization device; and
- (8) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2633 Records of remote afterloader full calibrations.

(a) A licensee shall maintain a record of the remote afterloader full calibrations required by § 35.633 for 3 years.

(b) The record must include--

- (1) The date of the calibration;
- (2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instruments used to calibrate the unit; the source output;

(3) An assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, and source retraction functionality; and

(4) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.

(a) A licensee shall maintain a record of the gamma stereotactic radiosurgery full calibrations required by § 35.635 for 3 years.

(b) The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit;

(3) The unit output;

(4) An assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and

(5) The signature of the authorized medical physicist who performed the full calibration..

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

- (4) The calculated on-off error;
- (5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
- (6) The determined accuracy of each distance measuring and localization device;
- (7) The difference between the anticipated output and the measured output;
- (8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
- (9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

§ 35.2643 Records of periodic spot-checks for remote afterloaders.

(a) A licensee shall retain a record of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for 3 years.

(b) The record must include --

- (1) The date of the spot-check;
- (2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instrument used to measure the output of the remote afterloader;
- (3) The difference between the anticipated output and the measured output;
- (4) Notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; and
- (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include --

- (1) The date of the spot-check;
- (2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
- (3) The measured source output and source output against computer calculations;
- (4) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff switch and stereotactic frames and localizing devices (trunnions); and
- (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

§ 35.2647 Records of additional technical requirements for mobile remote afterloaders.

(a) A licensee shall retain a record of each check for mobile remote afterloaders required by § 35.647 for 3 years.

(b) The record must include --

- (1) The date of the check;
- (2) The manufacturer's name, model number, and serial number of the remote afterloader;
- (3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include --

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic surgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain --

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M--Reports

§ 35.3045 Reports of medical events.

(a) A licensee shall report any administration, except for administrations resulting from a direct intervention of a patient or human research subject that could not have been reasonably prevented by the licensee, that results in either --

(1) A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more; or

(ii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following --

(I) An administration of a wrong pharmaceutical;

(ii) An administration of a radiopharmaceutical by the wrong route of administration;
(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong treatment mode; or
(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 20 percent the dose expected from the administration defined in the written directive.

(b) The licensee shall notify by telephone the NRC Operations Center³ no later than the next calendar day after discovery of the medical event .

(c) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include --

(I) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect on the individual(s) who received the administration;

(vi) What improvements are needed to prevent recurrence;

(vii) Actions taken to prevent recurrence;

(viii) Whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

³ The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(ix) If there was notification, what information was provided.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(d) The licensee shall notify the referring physician and also notify the individual affected by the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this section, the notification of the individual receiving the medical event may be made instead to that individual's responsible relative or guardian, when appropriate.

(e) If the individual was notified pursuant to paragraph (d) of this section, the licensee shall also furnish, within 15 days after discovery of the medical event, a written report to the individual by sending either --

(1) A copy of the report that was submitted to the NRC; or

(2) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

§ 35.3046 Reports of precursor events.

(a) A licensee shall notify by telephone the NRC Operations Center³ no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or authorized user, could lead to a medical event.

(b) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 within 15 days after discovery of the precursor event. The written report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence.

§ 35.3047 Report of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) absorbed dose that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant woman unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is greater than 5 mSv (500 mrem) total effective dose equivalent that is a result of an administration of byproduct material to a breast feeding woman.

(c) A licensee shall notify by telephone the NRC Operations Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

³ The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(d) A licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 no later than 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include --

(i) The licensee's name;

(ii) The name of the prescribing physician ;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect on the individual(s) who received the administration;

(vi) What improvements are needed to prevent recurrence; and

(vii) Actions taken to prevent recurrence.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

§ 35.3067 Reports of leaking sources.

A licensee shall file a report within 5 days if a leakage test required by § 35.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the action taken.

Subpart N--Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended; or
- (3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

- (1) For violations of--
 - (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;
 - (ii) Section 206 of the Energy Reorganization Act;
 - (iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;
 - (iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation

issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR Part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR Part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.600, 35.4001, and 35.4002 .

Appendix A to 10 CFR Part 35--Examining Organization or Entity

I. Requirements for an examining organization or entity.

An independent organization or entity that submits an application for approval of the Commission to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.290(b)(3), 35.292(b)(3), 35.390(b)(4), 35.490(b)(4), or 35.690(b)(4) shall:

1. Make its examination process available to the general public nationwide and ensure that it is not restricted because of race, color, religion, sex, age, national origin, or disability;
2. Have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board;
3. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
4. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program;

5. Have a committee, whose members can carry out their responsibilities impartially, to review complaints by examined individuals;

6. Have written procedures describing all aspects of its examination program, maintain records of the current status of each individual's examination and the administration of its examination program;

7. Have procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area;

8. Have procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program, including the process of being examined;

9. Have procedures for proctoring examinations, including qualifications for proctors.

10. Exchange information about examined individuals with the Commission and other independent examining organizations and/or Agreement States and allow periodic review of its examination program and related records;

11. Provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment; and

12. Submit its request to the Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

II. Requirements for Examination Programs.

All examination programs must --

1. Require applicants for examination to receive training in the topics set forth in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1)

or 35.690(b)(1), or equivalent Agreement State regulations, and satisfactorily complete a written examination covering these topics; and

2. Include procedures to ensure that all examination questions are protected from improper disclosure.

III. Requirements for Written Examinations.

1. All examinations must be designed to test an individual's knowledge and understanding of the topics listed in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1), or equivalent Agreement State regulations;

2. Test questions must be drawn from a question bank containing psychometrically valid questions based on the material in §§ 35.50(b)(1), 35.51(b)(1), 35.55(b)(1), 35.290(b)(1), 35.292(b)(1), 35.390(b)(1), 35.490(b)(1) or 35.690(b)(1), or equivalent Agreement State regulations; and

3. Sample examinations must be submitted to the Commission for review initially and every 5 years.

Dated at Rockville, Maryland, this ____ day of _____, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

Preliminary Regulatory Flexibility Analysis

The NRC is required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to consider the impact of their rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. This analysis describes the assessment of the small entity impacts expected to be incurred by 10 CFR Part 35 licensees as a result of the comprehensive revisions to Part 35 being proposed.

An assessment of small entity impacts involves three major tasks: (1) defining “small entities” for the rule being analyzed, including “small businesses,” “small governments,” and “small organizations;” (2) determining what number constitutes a “substantial number” of these entities; and (3) determining if “significant impacts” will be incurred by licensees under the proposed rule.

1.1 *Defining “Small Entities” Affected by the Rule*

The NRC has established size standards that it uses to determine which NRC licensees qualify as small entities (60 FR 18344; April 11, 1995). These size standards are codified in 10 CFR 2.810. The size standards pertinent to Part 35 licensees include the following:

Under 10 CFR 2.810(a)(1), a small business is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$5 million or less over its last 3 completed fiscal years. (The Small Business Administration size standards for the "health services" category, including "offices and clinics of doctors of medicine" and all other health services subcategories also establish \$5 million as the cut off point for "small entities.")

Under 10 CFR 2.810 (b) a small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of \$5 million or less.

For purposes of this analysis, therefore, "small entity" refers to any specific licensee under 10 CFR Part 35 with annual gross receipts of \$5 million or less.

The proposed rule would affect 1902 NRC licensees. These licenses are issued principally to medical institutions, with at least 1216 of the Part 35 licensees classified as medical institutions (codes 2110, 2120, and 2121 in NRC's licensee tracking system). Review of available data indicates that at most 8 of these medical institutions had operating revenues of less than \$5 million in 1996.

First, all hospitals in States in which Part 35 licensees are regulated by NRC were screened for revenues, using data obtained from Profiles of U.S. Hospitals, 1996, HCIA Inc. HCIA collects, analyzes, and publishes data on hospitals, based on financial submissions to the Health Care Financing Administration (HCFA). Revenues were measured as operating revenue, which is the sum of net patient revenue and other operating revenue, such as revenue

from sources such as cafeterias and parking facilities, but which does not include revenue from non-operating sources such as investment income or donations. Operating revenue therefore is a less inclusive measure of revenues than gross revenues. All hospitals identified as having operating revenues less than \$5 million then were checked against the NRC License Tracking System to identify those medical institutions that both had revenues less than \$5 million and were regulated by NRC under Part 35. Of the eight institutions that were identified as meeting both criteria, three had operating revenues above \$4.4 million, and therefore may have gross revenues above \$5 million. They have, however, been included in the group of institutions with less than \$5 million in revenues for this analysis.

The balance of the licenses, approximately 686 licenses, are issued principally to physicians in private practice. Information on gross revenues for such physicians suggests that all may be "small entities."

First, data from the AMA's Socioeconomic Monitoring System, provided in Physician Marketplace Statistics 1996: Profiles for Detailed Specialties, Selected States and Practice Arrangements, Center for Health Policy Research, American Medical Association, were reviewed for physicians' revenues or income. Table 89 of that source, which reports "Total Practice Revenue per Self-Employed Nonfederal Physician (in thousands of dollars), 1995" indicates that even at the 75th percentile no physician specialty, geographic area, or practice arrangement exceeded even \$1 million in revenues. Similar data from the Physician Compensation and Production Survey: 1996 Report Based on 1995 Data, Medical Group Management Association, indicate that the median for "production," defined as gross charges, for all physicians was \$422,937 in 1995 (p. 10). Although "production" generally is larger for

specialists than all physicians, the difference is too small to place specialists above the \$5 million criterion.

In total, therefore, an upper bound estimate of 36 percent of Part 35 licensees, or approximately 686 licensees, may be "small entities."

1.2 *Determining What Number Constitutes a Substantial Number*

This analysis applied a figure corresponding to 20 percent of small entities in determining whether a "substantial number" of small entities are likely to be impacted by the rule. Therefore, based on the analysis in section 1.1, the proposed rule would affect a substantial number of small entities.

1.3 *Measuring "Significant Impacts"*

To evaluate the impact that a small entity is expected to incur as a result of the rule, the analysis should calculate the entity's ratio of annualized compliance costs as a percentage of gross receipts. Entities are classified as facing potentially "significant" impacts if this ratio exceeds one percent.

Determining annual compliance costs for the revisions to Part 35, however, is complicated by the fact that the proposed rule would comprehensively address a wide variety of uses of byproduct materials in medicine. The entities likely to be most affected by the rule are broad scope medical institutions with a large number of different modalities and conducting a

large number of medical procedures involving byproduct material or radiation from byproduct material. However, the preceding analysis indicated that such broad scope licensees are not small entities. The costs attributable to Part 35 compliance for such broad scope licensees will be substantially greater than the annual compliance costs likely to be incurred by those licensees most likely to be small entities (i.e., single private practice physicians performing diagnostic procedures).

The Part 35 rule addresses contingent actions as well as actions that must be carried out by all licensees. In particular, the lower risk posed by diagnostic procedures reduces the likelihood that private practice physicians performing diagnostic procedures will experience medical events or precursor events involving costs of reporting and follow up.

All licensees will incur annual compliance costs for general administrative and technical requirements established by Part 35, although the level of such compliance costs will vary significantly depending on certain contingencies and on the activities being performed by the licensee. Annual compliance costs for licensees are expected, in all cases, to involve compliance with requirements to establish and maintain a radiation protection program; possess, use, calibrate, and check survey instruments, and satisfy the requirements pertinent to the modality or modalities used by the licensee.

NRC estimates that annual compliance costs for a licensee carrying out any level of activities under Part 35 will in all cases exceed 80 hours annually at \$100 per hour, or \$8,000. Assuming annual revenues of \$244,000 for a single private practitioner subject to Part 35, as estimated in Socioeconomic Characteristics of Medical Practice, 1997, American Medical

Association, Center for Health Policy Research, Table 43. "Mean Physician Net Income (in thousands of dollars) after Expenses before Taxes, 1995," for the net income for "all physicians-rad," a very conservative surrogate for gross revenues, these annual compliance costs exceed both the one percent cutoff level and the three percent cutoff level under SBREFA for "significant impacts." Assuming an average "production" of \$423,000, (Section 1.1 of this analysis), however, the 1 percent but not the 3 percent cutoff is exceeded. Therefore, the proposed rule appears to have significant impacts on a significant number of licensees.

NRC has taken a number of actions in this proposed rule to ensure that the proposed alternative is the least costly alternative that adequately protects workers and patients from radiation exposure. As the Regulatory Analysis prepared for the proposed rule demonstrates, the total annual cost to licensees of compliance with the proposed rule would be approximately \$6 million less than the cost of compliance with the current rule (See XII. Regulatory Analysis of the Supplementary Information section of this document). This is equivalent to savings of approximately \$900 per licensee. Although savings to small licensees can be expected to be proportionately less than savings to licensees with more extensive operations, smaller licensees also can be expected to incur smaller compliance costs.

In order to assist small licensees, the NRC has sought in the proposed rule to eliminate prescriptive requirements wherever possible, and to allow for much greater flexibility in compliance. Such flexibility is particularly helpful to small licensees in reducing their cost of compliance, because it will enable them to avoid the costs of radiation safety measures, such as the detailed requirements for Radiation Safety Committees, that were especially oriented toward larger licensees with numerous modalities and activities in the same institution. NRC

has reduced the training and experience requirements applicable to the diagnostic use of byproduct material by focusing those requirements on radiation safety and by reducing the number of hours of training required. NRC has also sought to reduce the prescriptive nature of requirements for testing and calibration, and to reduce reporting and recordkeeping burdens, which can have an especially strong impact on small entities.

Finally, the program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public, including representatives of small licensees) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA., and Chicago, IL., held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997, and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

As indicated in the Regulatory Flexibility Analysis statement included in the proposed rule, the NRC requests comments from small medical licensees concerning the impacts of the

proposed rule and any suggested modifications that may affect the economic impact of the proposed requirements.

ATTACHMENT 4

Draft NUREG 1556, Vol. 9

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Consolidated Guidance About Materials Licenses

**Program-Specific Guidance About
Medical Use Licenses**

Draft Report for Comment

Manuscript Completed:

Date Published:

P.A. Lanzisera, A.R. Jones, R.G. Gattone, R.D. Reid,

Division of Industrial and Medical Nuclear Safety

Office of Nuclear Material Safety and Safeguards

U.S. Nuclear Regulatory Commission

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ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. Draft NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated [date to be inserted], is the ninth program-specific guidance document developed for the new process and is intended for use by applicants, licensees, and NRC staff and will also be available for use by Agreement States. This guidance document corresponds with the revision to the Code of Federal Regulations (CFR), Title 10, Part 35, concurrently published in draft in [date to be inserted]. This document combines and supersedes the guidance previously found in Regulatory Guide (RG) 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs"; Appendix X to RG 10.8, Revision 2, "Guidance on Complying With New Part 20 Requirements"; Draft RG DG-0009, "Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs"; Draft RG FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs"; Policy and Guidance Directive (P&GD) FC 87-2, "Standard Review Plan for License Applications for the Medical Use of Byproduct Material"; P&GD FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices"; Addendum to Revision 1 to P&GD FC 86-4, "Information Required for Licensing Remote Afterloading Devices-Increased Source Possession Limits"; P&GD 3-15, "Standard Review Plan for Review of Quality Management Programs"; RG 8.39, "Release of Patients Administered Radioactive Materials"; RG 8.33, "Quality Management Program"; P&GD 3-17, "Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants"; and RG 8.23, "Radiation Safety Surveys at Medical Institutions, Revision 1".

This draft report, where applicable, provides a more risk-informed, performance-based approach to medical use licensing consistent with the proposed regulations.

This draft guide has been distributed for comment to encourage public participation in its development. It represents the current position of NRC staff, which is subject to change after the review of public comments. Comments received will be considered in developing the final guide that represents the official NRC staff position. Once the final guide is published, NRC staff will use it in its review of requests for licensing actions.

FOREWORD

The NRC is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a list of volumes currently included in the NUREG-1556 series:

Volume Number	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Draft for Use and Comment
3	Applications for Sealed Source and Device Evaluation and Registration	Draft for Comment
4	Program-Specific Guidance About Fixed Gauge Licenses	Draft for Comment
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses	Draft for Comment
6	Program-Specific Guidance About Part 36 Irradiator Licenses	Draft for Comment
7	Program-Specific Guidance About Master Material Licenses	Draft for Comment
8	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	Draft for Comment

The current document, draft NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated [date to be inserted], is the ninth program-specific guidance document developed for the new process. It is

intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in RG 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs," dated August 1987, and the guidance for licensing staff previously found in P&GDs, draft RGs and Standard Review Plans. In addition, this draft report also contains pertinent information found in Information Notices (IN), as listed in Appendix A.

Since this draft report takes a risk-informed, performance-based approach to medical use licensing, it reduces the amount of information needed from an applicant seeking to possess and use relatively safe quantities of byproduct material.

A team composed of NRC and State Department of Health staff drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to medical use of byproduct material. A representative of NRC's Office of the General Counsel provided a legal perspective.

This draft report is strictly for public comment and is not for use in preparing or reviewing applications for medical use licenses until it is published in final form. It is being distributed for comment to encourage public participation in its development. NRC is requesting comments on the information provided about medical use of byproduct material, as well as comments on a risk-informed, performance-based approach to licensing. Please submit comments within 75 days of the draft report's publication. Comments received after that time will be considered if practicable.

Address comments to: Secretary, U. S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff. Hand deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Copies of comments received may be examined at: NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

Draft NUREG-1556, Vol. 9, is not a substitute for NRC regulations. The approaches and methods described in this draft report are provided for information and comment only.

Donald A. Cool, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

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The Participants

Bolling, Lloyd A.
Cool, Donald A.
DelMedico, Joseph R.
Flack, Diane S.
Haney, Catherine
Hill, Thomas E.
Howard, Marcia
Jones, Samuel Z.
Lohaus, Paul H.

Lieberman, James
Merchant, Sally L.
Paperiello, Carl A.
Rothschild, Marjorie U.
Roe, Mary Louise
Siegel, M.D., Barry
Trottier, Cheryl A.
Treby, Stuart A.
Walter, David

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Ayres, Robert
Bhalla, Neelam
Brown, Keith D.
Frazier, Cassandra F.
Fuller, Mike L.
Holahan, Patricia K.

Merchant, Sally L.
Minnick, Sheri A.
Schlueter, Janet R.
Smith, James A.
Taylor, Torre M.

ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	Business Process Redesign
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	curies
cc	centimeter cubed
cm ²	centimeter squared
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	Derived Air Concentration
DIS	decay-in-storage
DOT	United States Department of Transportation
dpm	disintegrations per minute
FDA	United States Food and Drug Administration
ft	foot
G-M	Geiger-Mueller
GPO	Government Printing Office
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
mR	milliroentgen
mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide (thallium doped)

NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
P&GD	Policy and Guidance Directive
QA	Quality Assurance
Ra-226	Radium-226
RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
Sr-90	strontium-90
SSDR	Sealed Source and Device Registration
std	standard
Sv	sievert
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
U-235	uranium-235
μCi	microcurie
WD	Written Directive

1 PURPOSE OF DRAFT REPORT

This document is strictly for public comment and is not for use in preparing or reviewing applications for medical use licenses until this document is published in final form.

This draft report provides guidance to an applicant in preparing a medical use license application as well as NRC criteria for evaluating a medical use license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of medical radionuclides or sources in devices.

Radionuclides are used for a variety of purposes in medicine. Typical uses are:

- Diagnostic studies with unsealed radionuclides
- Therapeutic administrations with unsealed radionuclides
- Diagnostic studies with sealed radionuclides
- Manual brachytherapy
- Therapeutic administrations with sealed sources in devices [i.e., teletherapy, remote afterloaders, and gamma stereotactic radiosurgery (GSR) units].

This draft report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for medical use of radionuclides. The information collection requirements in 10 CFR Part 30 and 35, and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, 3150-0010, and 3150-0120, respectively.

Information in this draft report will also help medical users understand specific regulatory requirements and licensing policies as they apply to medical licenses. Applicants are expected to address all the items on NRC Form 313 and to either follow the specific guidance that will become available in the final version of this draft report or to respond to the items in a manner that assures safe operation and compliance with the regulations that apply.

The format within this document for each item of technical information is as follows:

- **Regulations** -- references the regulations applicable to the item
- **Criteria** -- outlines the criteria used to judge the adequacy of the applicant's response
- **Discussion** -- provides additional information on the topic sufficient to meet the needs of most readers, and
- **Response from Applicant** -- provides suggested response(s) or indicates that no response is needed on that topic during the licensing process.

The regulations require the applicant/licensee to develop and implement procedures that will ensure compliance with the regulations. The appendices describe model radiation protection procedures. Each applicant should carefully read the regulations and model procedures and then decide if the model procedure appropriately addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a model procedure or they may develop their own procedures to comply with the applicable regulation. Written procedures developed by applicants do not need to be submitted as part of the license application. However, the applicant must state that applicable procedures have been developed and implemented in accordance with the regulations.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313.

Appendix C includes sample medical licenses with conditions most often found on these licenses, although not all licenses will have all conditions. Appendix C also contains a checklist to assist the applicant in determining which sections of this document and required procedures apply to the type of medical license requested. Appendices D through Y contain additional information on various radiation protection topics.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in 10 CFR Part 20. Rem, and Sievert (Sv), its SI equivalent ($1 \text{ rem} = 0.01 \text{ Sv}$), are used to describe units of radiation exposure or dose. This is because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen, and the sealed sources commonly used in therapy emit beta and gamma rays, which means that $1 \text{ roentgen} = 1 \text{ rad} = 1 \text{ rem}$.

This NUREG not only updates the information and guidance provided in Revision 2 of RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs," but also revises the format in which it is presented to assist with the preparation of a medical use license. Revision 2 was issued in August 1987 to provide guidance for the revised 10 CFR Part 35, which became effective on April 1, 1987. Since then, 10 CFR Part 35 has been revised a number of times. Technology-specific information has been revised and expanded to include technologies that are now more commonly used, for example, computerized remote afterloading brachytherapy [particularly high dose-rate (HDR)] and GSR.

Applicants and licensees should also be aware of two other documents that provide useful information for medical use licensees. The first is the October 1994 Draft RG DG-0005 (second proposed revision to RG 10.5), "Applications for Licenses of Broad Scope," which provides additional licensing guidance on medical use programs of broad scope. The second is the May 1997 NUREG-1516, "Effective Management of Radioactive Materials Safety Programs at Medical Facilities." The guidance in NUREG-1516 emphasizes a team approach to program management as a means to effectively manage radiation protection programs, and provides tools to help licensees manage these programs. Radiation protection team members should include the

management of the licensed facility, the Radiation Safety Committee (RSC), if applicable, and the Radiation Safety Officer (RSO). The document also includes discussions on the duties and responsibilities of the RSO and supervised individuals; conduct of required audits; advantages and disadvantages in using consultants or service companies to augment the radiation protection program; resources that may be needed to support the program; and NRC notification and reporting requirements. Specific tools for day-to-day operation of a radiation protection program are provided in several appendices. Additionally, an extensive annotated bibliography lists publications on radiation protection program management at medical facilities.

1.1 LICENSES

NRC regulates the intentional internal or external administration of byproduct material, or the radiation therefrom, to patients or human research subjects for medical use. A specific license of either limited or broad scope is issued to authorize possession and use of licensed material. These licenses are issued pursuant to 10 CFR Parts 30, 33, and 35. NRC issues three types of licenses for the use of byproduct material in medical practices and facilities. These include; general in vitro license, specific license of limited scope, and specific license of broad scope.

NRC usually issues a single byproduct material license to cover an entire radionuclide program — except for teletherapy, nuclear-powered pacemakers, and GSR. The teletherapy license will also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units. Although individual licensees may be issued separate licenses for different medical uses, separate licenses are not usually issued to different departments in a medical facility or to individuals employed by or contracted by the medical facility. Only the facility's management may apply for the license.

An applicant should carefully study this report, related guidance, and all applicable regulations before completing NRC Form 313. In order to provide NRC information on specific aspects of the proposed radiation protection program as requested on NRC Form 313, NRC expects licensees to submit attachments to Form 313, containing such information. When necessary, NRC may ask the applicant for additional information in order to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- statements, representations, and procedures contained in the application and in correspondence with NRC
- terms and conditions of the license
- NRC's regulations.

In 10 CFR 30.9, NRC requires that the information in the application be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect an agency decision on issuing the license.

1.1.1 GENERAL IN VITRO LICENSE

In 10 CFR 31.11, "General license for use of byproduct material" for certain in vitro clinical or laboratory testing, NRC establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). Section 31.11 explains the requirements for using materials listed. If the general license alone meets the applicant's needs, only NRC Form 483, "Registration Certificate — In Vitro Testing With Byproduct Material Under General License," need be filed. Medical use licensees authorized pursuant to 10 CFR Part 35 do not need to file the form.

In 10 CFR 31.11, NRC limits possession to a total of 200 microcuries, at any time, of photon-emitting materials listed in 10 CFR 31.11. The use of materials listed in 10 CFR 31.11 within the inventory limits of that section are subject only to the requirements of that section and not to the requirements of 10 CFR Parts 19, 20, 21, and 35, except as discussed in 10 CFR 31.11.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on the NRC Form 313 application. Such applicants generally request an increased limit of 3 millicuries. If requesting an increased inventory limit, the applicant will be subject to the requirements of 10 CFR Parts 19, 20, 21, and 35, including the requirements for waste disposal.

1.1.2 SPECIFIC LICENSE OF LIMITED SCOPE

Specific licenses of limited scope are generally issued to physicians in private practice or in a group practice with a limited number of medical disciplines, and not to physicians located within a licensed medical institution. These licensees are not authorized to perform procedures requiring hospitalization of the patient.

Specific licenses of limited scope are also issued to medical institutions. A medical institution is an organization in which several medical disciplines are practiced. These licenses authorize the medical use of byproduct material by physicians named on the institution's license or authorized by the licensee in accordance with 10 CFR Part 35.

A specific license of limited scope may also be issued to a mobile service (10 CFR 35.80, 10 CFR 35.647): Physicians in private practice and medical institutions may apply for authorization to use byproduct material in a mobile service.

1.1.3 SPECIFIC LICENSE OF BROAD SCOPE

Some medical institutions provide patient care and conduct research programs that use radionuclides for in vitro, animal, and medical procedures. In these cases, the NRC may issue a

specific license of broad scope as discussed in 10 CFR Part 33. Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of byproduct material for unspecified uses, are issued to institutions that (1) have had previous experience successfully operating under a specific institutional license of limited scope and (2) are engaged in medical research, as well as in routine diagnostic and therapeutic uses of byproduct material. DG-0005 was issued for comment in October 1994 to offer additional guidance to applicants for specific medical use license of broad scope. Both DG-0005 and the final version of this draft NUREG report should be consulted for guidance on applying for a medical use license of broad scope.

1.2 THE "AS LOW AS REASONABLY ACHIEVABLE (ALARA)" CONCEPT

10 CFR 20.1101 states that "each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities...." and "the licensee shall use, to the extent practicable, procedures and controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA." Additionally, this section requires that licensees periodically review the content of the radiation protection program and its implementation.

The success of an ALARA program depends on the cooperation of each person working at the licensed facility. Each individual who is authorized to use byproduct material should appropriately instruct all other individuals who work with or in the vicinity of byproduct material and should ensure that the facility and equipment are adequate for safe use. Each worker should comply with procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or RSO.

Management should make a commitment to the ALARA philosophy and implement that commitment with adequate resources. The RSO and management must audit the byproduct material program to ensure the continued safe use of byproduct material. The RSO is responsible for the day-to-day operation of the radiation protection program.

RGs 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA," and 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be ALARA," provide the NRC staff position on this subject. Several other NRC publications contain background information on the ALARA philosophy and its application in the medical environment. For example, NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA"; NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities"; and NUREG-1516, "Effective Management of Radioactive Material Safety Programs at Medical Facilities," all contain information, methods, and references useful in establishing radiation protection programs to maintain exposures ALARA in medical institutions. Applicants should consider the ALARA philosophy as detailed in these reports when developing plans for work with licensed radioactive materials.

1.3 WRITTEN DIRECTIVE (WD) PROCEDURES

10 CFR 35.41 requires medical use licensees to develop, maintain, and implement procedures to provide high confidence that for each administration requiring a WD, the patient's identity is verified prior to the administration and the administration is in accordance with the WD. Information on developing these procedures is found in Appendix S to this document.

1.4 RESEARCH INVOLVING HUMAN SUBJECTS

Effective January 1, 1995, the definition of "medical use" contained in 10 CFR 35.2 was revised to include the administration of byproduct material to human research subjects. Also, 10 CFR 35.6, "Provisions for research involving human subjects," was added to allow limited specific and broad scope medical use licensees to conduct "research involving human subjects," which meets specific criteria. Under 10 CFR 35.6, medical use licensees may conduct such research provided that the research is conducted, funded, supported, or regulated by another Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, the licensee must apply for and receive approval of a specific amendment before conducting such research. Also, whether or not a license amendment is required, licensees must obtain informed consent from human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of those terms under the Federal Policy.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application. These applications are filed with State officials, not with the NRC.

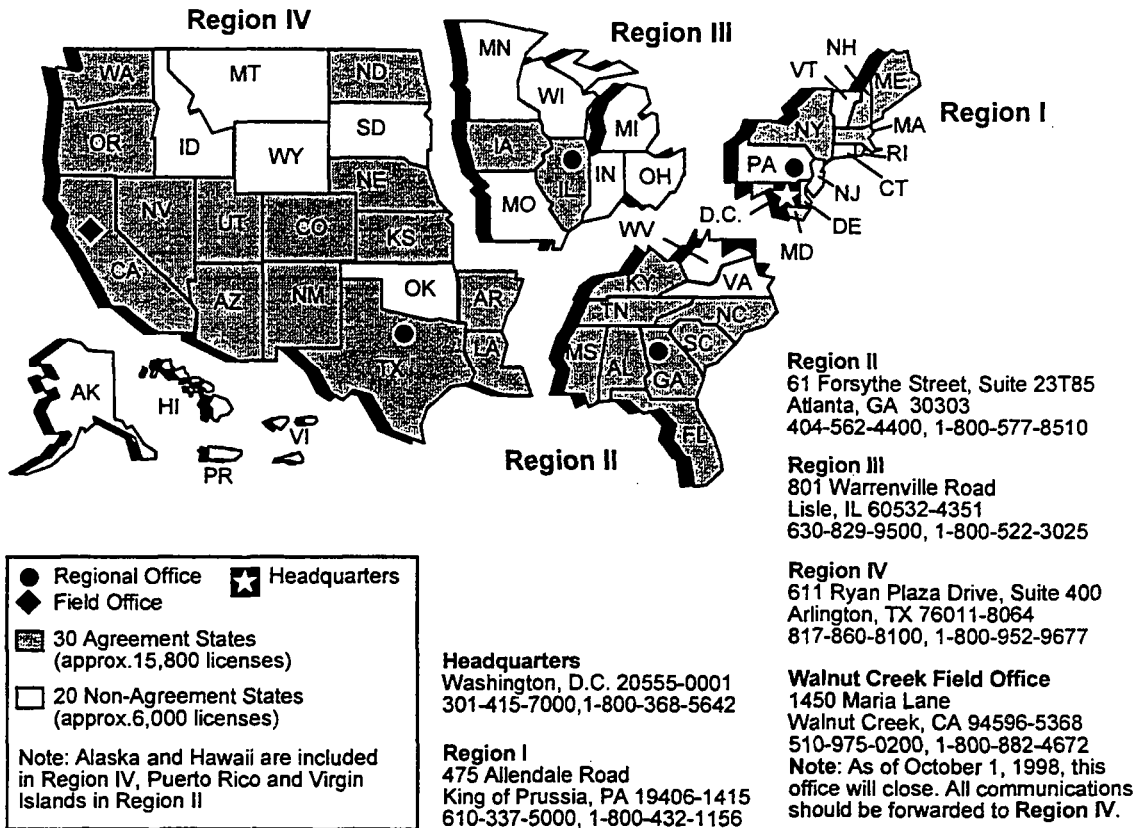
In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees ask their local contact for the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available from NRC upon request.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Locations of NRC Offices and Agreement States



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Figure 2.1 U.S. Map. Location of NRC Offices and Agreement States. Note: As of October 1, 1998, the Walnut Creek Field Office will close. All communications should be forwarded to Region IV.

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional or Field Offices. Or visit NRC's Home Page (<http://www.nrc.gov>), choose "Nuclear Materials," then "Review of State Radiation Control Program Query Form," and then "Directories."

The All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by contacting NRC's Office of State Programs; call NRC's toll free number (800) 368-5642, and then ask for extension 415-3340. Or visit NRC's Home Page (<http://www.nrc.gov>), choose "Nuclear Materials," then choose "Review of State Radiation Control Program Query Form" and follow the directions for submitting a query for "SP-96-022."

3 MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective radiation protection program management is vital to achieving safe and compliant operations (see 10 CFR 35.24). NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely.

"Management" refers to the chief executive officer or that person's delegate or delegates who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation protection, security and control of radioactive materials, and compliance with regulations
- Completeness and accuracy of the radiation protection records and all information provided to NRC (10 CFR 30.9)
- Knowledge about the contents of the license and application
- Compliance with current NRC and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards
- Appointment of a qualified individual to work as the RSO
- Approval of qualified individual(s) to serve as an Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and authorized users (AUs) for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, dated June 1995, "Compilation of NRC Enforcement Policy as of September 10, 1997", and Manual Chapter 87100, Appendix B, "Nuclear Medicine Inspection Field Notes"; see Notice of Availability (on inside front cover of this draft report). NUREG-1600 is also available on the Internet. Visit NRC's Home Page (<http://www.nrc.gov>), choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to medical uses licensees:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20, "Standards for Protection Against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. For ordering information on the regulations, see the Notice of Availability (on inside front cover of this draft report).

- 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC"

In addition to the information provided in the Notice of Availability (on inside front cover of this draft report), to request copies of the above documents, applicants may call the Government Printing Office's (GPO's) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania

15250-7954. You may also contact the GPO electronically at www.gpo.gov. Request single copies of the above documents from NRC's Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers). Note that NRC publishes amendments to its regulations in the Federal Register.

5 HOW TO FILE

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C
- Provide sufficient detail for the NRC to determine that equipment, facilities, training and experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers
- Submit all documents, typed, on 8-1/2 x 11 inch paper
- Avoid submitting proprietary information unless it is absolutely necessary
- Submit an original, signed application and one copy
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c) and 10 CFR 35.12(a), applications must be signed by the management of the facility; see section on "Certification."

Using the suggested wording of responses in this draft report will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document Rooms. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, and radiation dose information, should not be submitted unless specifically requested by NRC.

NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner
- Choose typeface designs that are sans serif, such as **Arial, Helvetica, Futura, Univers**; the text of this document is in a serif font called **Times New Roman**
- Choose 12-point or larger font size
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM, and through the Internet. Additional filing instructions will be provided as these new mechanisms become available. The existing paper process will be used until the electronic process is available.

6 WHERE TO FILE

Applicants wishing to possess or use licensed material in any State or U. S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States. The Walnut Creek, California, Field Office, can respond to routine telephone inquiries until September 30, 1998. Effective October 1, 1998, the Walnut Creek, California, Field Office will close and any communications previously involving that Field Office should be addressed to the Region IV Office.

In general, applicants wishing to possess or use licensed material in an Agreement State must file an application with the Agreement State, not NRC. However, if work will be conducted at Federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. See Section 2, "Agreement States," for additional information.

7 LICENSE FEES

Each application for which a fee is specified, including applications for new licenses and license amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC headquarters in Rockville, Maryland, (301) 415-7544. You may also call NRC's toll free number (800) 368-5642 and then ask for extension 415-7544.

Enter the fee category and the amount of the fee enclosed with the application on NRC Form 313.

8 CONTENTS OF AN APPLICATION

This section explains, item by item, the information requested on NRC Form 313. Items 5 through 11 on the form request specific information about the proposed radiation safety program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item.

Applicants must provide detailed information about the following:

- Proposed facilities and equipment
- Training and experience of byproduct material users and the RSO
- Delegation of authority to RSO
- Financial assurance (if applicable)
- Mobile use of byproduct material (if applicable).

Additionally, in response to Items 9, 10, and 11, the applicant must provide a commitment to develop and implement various procedures to meet the requirements of the applicable regulation. Table 1 in Appendix C is provided to assist applicants determine which procedures must be developed and implemented for the type of medical use requested. Several appendices in this report present sample procedures that the applicant may use in developing their procedures. If a particular item requires the applicant to develop and implement a procedure, the applicant may use the following wording in each response section on the application:

"We have developed and will implement procedures for _____ that meet the requirements of 10 CFR _____."

If an applicant or licensee commits to a section of this report, that commitment will be incorporated as a part of the terms and conditions of the license. The licensee will be inspected against the commitments contained in the referenced section, appendix, or document, just as the applicant/licensee will be inspected against more detailed responses.

If a particular part of a section does not apply simply note "NA" for "not applicable." If a particular section applies, but a procedure does not have to be developed, simply note "N" for "no response required." Short sentence responses, "NA" or "N" responses to Items 5 through 10 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

As indicated on NRC Form 313 (Appendix B), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C to assist with completion of the application. Applicants should note that using the suggested wording of responses will expedite NRC's review.
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8.01 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
<input type="checkbox"/> A. New License	Not applicable
<input type="checkbox"/> B. Amendment to License No.	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal of License No.	XX-XXXXXX-XX

Check box A for a new license request.

Check box B for an amendment * to an existing license, and provide license number.

Check box C for a renewal * of an existing license, and provide license number.

* See "Amendments and Renewals to a License" later in this document. Licensees may request an amendment to an existing license to add authorization for other uses of byproduct material. As described in 10 CFR 35.12(c), a separate application and license is required for the addition of 10 CFR 35.600 uses, with the exception of remote afterloaders.

8.02 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Note: NRC must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NRC IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Timely Notification of Transferring Control

Regulations: 10 CFR 30.34(b), 10 CFR 35.14(b).

Criteria: Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license, or, as some licensees call it, "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses
- Materials are properly handled and secured
- Persons using these materials are competent and committed to implementing appropriate radiological controls
- A clear chain of custody is established to identify who is responsible for final disposal of the material
- Public health and safety are not compromised by the use of such materials

As provided in 10 CFR 35.14(b), if the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b), a licensee must file a written 30 day notification with the NRC instead of obtaining prior NRC written consent.

Response from Applicant: No response is required from an applicant for a new license; Appendix D, excerpted from IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

Reference: See the Notice of Availability on the inside front cover of this draft report to obtain copies of IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, and IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997.

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

Criteria: Immediately following filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date the of filing.

Response from Applicant: None at time of application for a new license. Licensees must notify NRC immediately (i.e., within 24 hours) of filing a bankruptcy petition.

8.03 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable (see Figure 8.1). If byproduct material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. If applying for a license for a mobile service as authorized pursuant to 10 CFR 35.18(b), the applicant should refer to Section 8.42 and Appendix V of this report for specific licensing guidance.

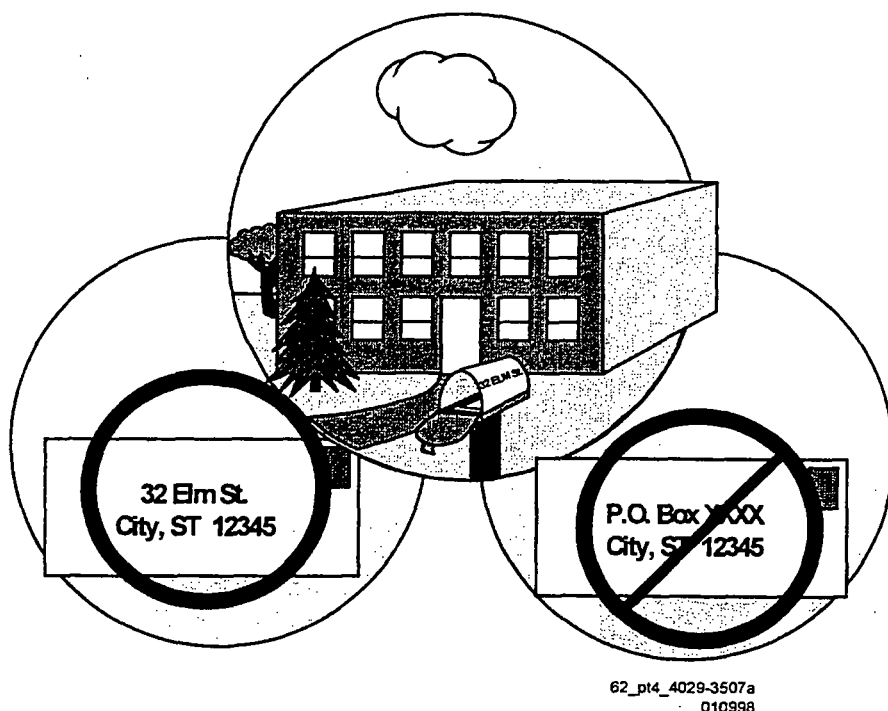


Figure 8.1 Location of Use.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed later under "Financial Assurance and Record Keeping for Decommissioning," licensees do need to maintain permanent records on where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is

terminated). For medical use licensees, acceptable records are sketches or written descriptions of the specific locations where material is used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

8.04 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. The NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

The individual named in Item 4 may or may not be the same individual who signs the application as the "certifying official" on behalf of the licensee and has the authority to make commitments to NRC (see Item 13 on Form 313). Any commitments made by the applicant should be signed by the individual named in Item 13 since only that individual is considered by NRC to have the authority to make commitments on behalf of the applicant. Therefore, NRC will not accept license amendments or renewals signed by the individual identified in Item 4, if this person differs from the one named in Item 13.

NRC recognizes that licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. Licensees are reminded that regardless of the role of the consultant in radiation protection program management, the licensee remains ultimately responsible for all aspects of the licensed program, including the services performed by the consultant.

As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for guidance and should note that using the suggested wording of responses will expedite NRC's review.

8.05 ITEM 5: RADIOACTIVE MATERIAL

Regulations: 10 CFR 30.32, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 30.35, 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use (10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000).

Discussion: Using the table formats below (see Table 8.1), the applicant should indicate the byproduct material requested. For 35.100, 35.200, and 35.300 material, the chemical/physical form may be "Any." For 35.100 and 35.200 material, the total amount requested may be "As Needed." For 35.300 material, the total amount requested must be specified. For 35.400, 35.500, 35.600, and 35.1000 material, express the radionuclide, the chemical/physical form (e.g., sealed source and manufacturer's name and model number), the total amount in Becquerels (Bq), microcuries (uCi), millicuries (mCi), or curies (Ci), and maximum number of sources possessed at any one time.

For sealed sources used in devices, an applicant may wish to request two sources, one to be used in the device and one to be stored in its shipping container, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, it is permissible to request a maximum activity, for the source in the shipping container, that exceeds the maximum activity allowed in the device. To request such authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to, or below, the device source activity limit prior to installation in the device.

If applicable, the applicant should request authorization for possession of depleted uranium [i.e., uranium depleted in uranium-235 (U-235)] in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange. The applicant should review the manufacturer's specifications for each device specified in the license request to determine (1) whether depleted uranium is used for shielding the source(s) within the device and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer's specifications or the source supplier to determine whether depleted uranium is contained within shielding source containers used during source exchange and determine the total quantity of depleted uranium in such containers (in kilograms).

A separate entry should be made for other items that need to be listed (e.g., more byproduct material for in vitro testing than is allowed under 10 CFR 31.11, depleted uranium for linear

accelerator shielding, survey meter calibration source, dosimetry system constancy check source, or material for in vitro, animal, or human research studies). Sources that are authorized by 10 CFR 35.65, "Authorization for calibration and references sources" should *not* be listed. Applicants should number each line entry consecutively following the 10 CFR Part 35 material.

Table 8.1 Sample Format for Byproduct Material

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material included in 10 CFR 35.100	Any	As needed
Any byproduct material included in 10 CFR 35.200	Any	As needed
Any byproduct material included in 10 CFR 35.300	Any	300 millicuries
Cesium 137 (i.e., specific brachytherapy radionuclide)	sealed source (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	sealed source (Manufacturer Name, Model # XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	sealed source (Manufacturer Name, Model # XYZ)	Not to exceed 36 curies per source and 6,600 curies total
Depleted Uranium	Metal	99 kilograms
Any byproduct material identified in 10 CFR 31.11	Prepackaged Kits	50 millicuries

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included, i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange); materials in use or possessed; material used for shielding; and those materials classified as waste awaiting disposal or being held for "decay-in-storage (DIS)."

Response from Applicant: The licensee should submit the information as described above.

8.06 ITEM 5: FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.34(b), 10 CFR 30.35.

Criteria: Licensees authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35 must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, pursuant to 10 CFR 30.35(g), in an identified location, decommissioning records related to structures and equipment where licensed material is used or stored, spills or spread of contamination, and leaking sealed sources (see Figure 8.2). Licensees must transfer these records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) or to the appropriate NRC Regional Office before the license is terminated.

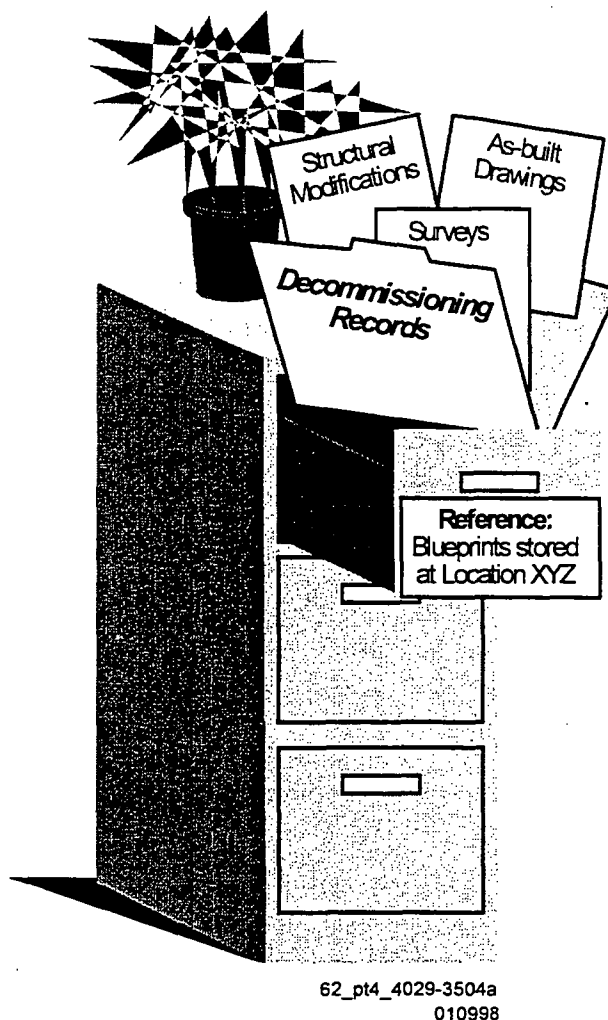


Figure 8.2 Decommissioning Records.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most medical use applicants and licensees do not need to take any action to comply with the financial assurance requirements because either their total inventory of licensed material does not exceed the limits in 10 CFR 30.35 or the half-life of the unsealed byproduct material used does not exceed 120 days. The limits for some sealed sources are shown in Table 8.2. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See Appendix E for additional information.

Table 8.2 Minimum Sealed Source Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity in GigaBq	Activity in Ci
cesium-137 (Cs-137)	3.7×10^6	100,000
cobalt-60 (Co-60)	3.7×10^5	10,000
strontium-90 (Sr-90)	3.7×10^4	1,000

Applicants and licensees wanting to possess licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan (10 CFR 30.35 (b)). Figure 8.3 depicts acceptable methods of providing financial assurance. Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds, except for the Statement of Intent for government licensees. See Appendix E for the recommended wording for a Statement of Intent.

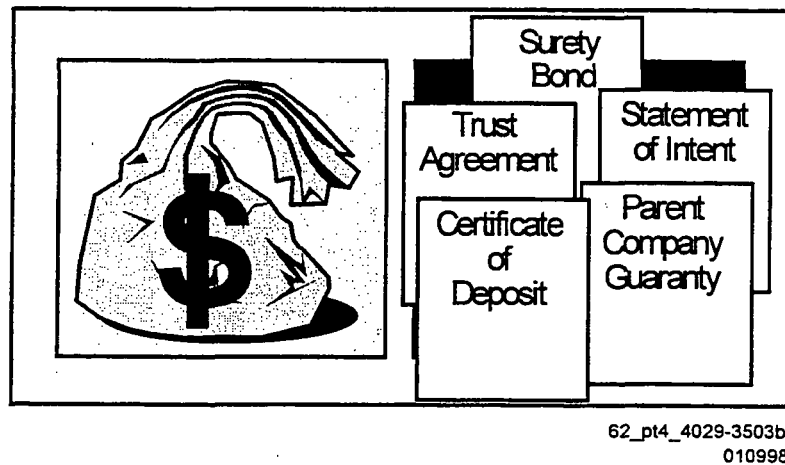


Figure 8.3 Financial Assurance Mechanisms

NRC will authorize possession exceeding the limits shown in Table 8.2 without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange for no more than 30 days.

Licensees using sealed sources as authorized by 10 CFR Part 35, in general, use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, or would not contaminate work areas. Moreover, the licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while in the licensee's possession. However, any significant leakage of the sealed source would warrant further review of decommissioning procedures on a case-by-case basis.

Response from Applicants: No response is needed from most applicants. If financial assurance is required, applicants must submit evidence as described in RG 3.66.

Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) or to the appropriate NRC Regional Office before the license is terminated.

Reference: See the Notice of Availability on the inside front cover of this draft report to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy and Guidance Directive FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.07 ITEM 5: SEALED SOURCES AND DEVICES

Regulation: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210

Criteria: Applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration and reference sources authorized by 10 CFR 35.65). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in a SSDR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license. If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration," dated September 1997, from the NRC Regional Office and submit the information requested therein to NRC for review.

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible and conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective SSDR Certificates, without obtaining NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used according to the registration certificates, applicants may want to obtain a copy of the certificate and review it or discuss it with the manufacturer.

Response from Applicant: No response is necessary.

Reference: See the Notice of Availability on the inside front cover of this draft report to obtain a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration," dated September 1997.

Note: Information on SSD registration certificates is also available on the Internet at <http://www.hsr.d.oeml.gov/nrc/ssdrform.htm> or contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

8.08 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 30.33(a)(1), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use as follows:

10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is not Required
10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is not Required
10 CFR 35.300	Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required
10 CFR 35.400	Medical Use of Sources for Manual Brachytherapy
10 CFR 35.500	Medical Use of Sealed Sources for Diagnosis
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
10 CFR 35.1000	Other Medical Uses of Byproduct Material or Radiation from Byproduct Material (Emerging Technology)

Discussion: For 35.100, 35.200 and 35.300 material, the applicant must define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100, 10 CFR 35.200) and the description of the applicable modality (e.g., any uptake dilution and excretion procedure approved in 10 CFR 35.100).

The use of unsealed byproduct material in therapy involves the administration of a radiopharmaceutical, either orally or by injection, to diagnose, treat or palliate a particular disease. The most common form of radiopharmaceutical therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Less common therapeutic procedures

include ablation of thyroid cancer metastases, treatment of malignant effusions, treatment of polycythemia vera and leukemias, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. Table 8.3 contains a summary of several therapeutic radiopharmaceuticals and their use.

Table 8.3 Radiopharmaceuticals Used in Therapy

Agent	Form	Route of Administration	Therapeutic Use
I-131 sodium iodide	solution/capsules	oral	hyperthyroidism thyroid carcinoma total body scan for thyroid metastases (diagnostic)
phosphorus-32 (P-32) chromic phosphate	colloidal suspension	intraperitoneal or intrapleural cavity injection	peritoneal or pleural effusions
P-32 sodium phosphate	solution	oral or IV	polycythemia vera leukemias
strontium-89 chloride	solution	IV	skeletal metastases
samarium-153 EDTMP	solution	IV	skeletal metastases
rhenium-186 HEDP	solution	IV	skeletal metastases
tin-117m DTPA	solution	IV	skeletal metastases
dysprosium-165 FHMA	aggregate in solution	IV	rheumatoid arthritis
yttrium-90 FHMA	aggregate in solution	IV	rheumatoid arthritis

For 35.400 material, the applicant must define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.400). For 35.400 material, applicants may need to define the purpose of use by describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item.

In manual brachytherapy several types of treatments are available. These may include:

- Interstitial Treatment of Cancer. The following sources are routinely used:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells
 - iridium-192 (Ir-192) as seeds encased in nylon ribbon
 - gold-198, iodine-125 (I-125), and palladium-103 (Pd-103) as a sealed source in seeds

- Eye Plaque Implants

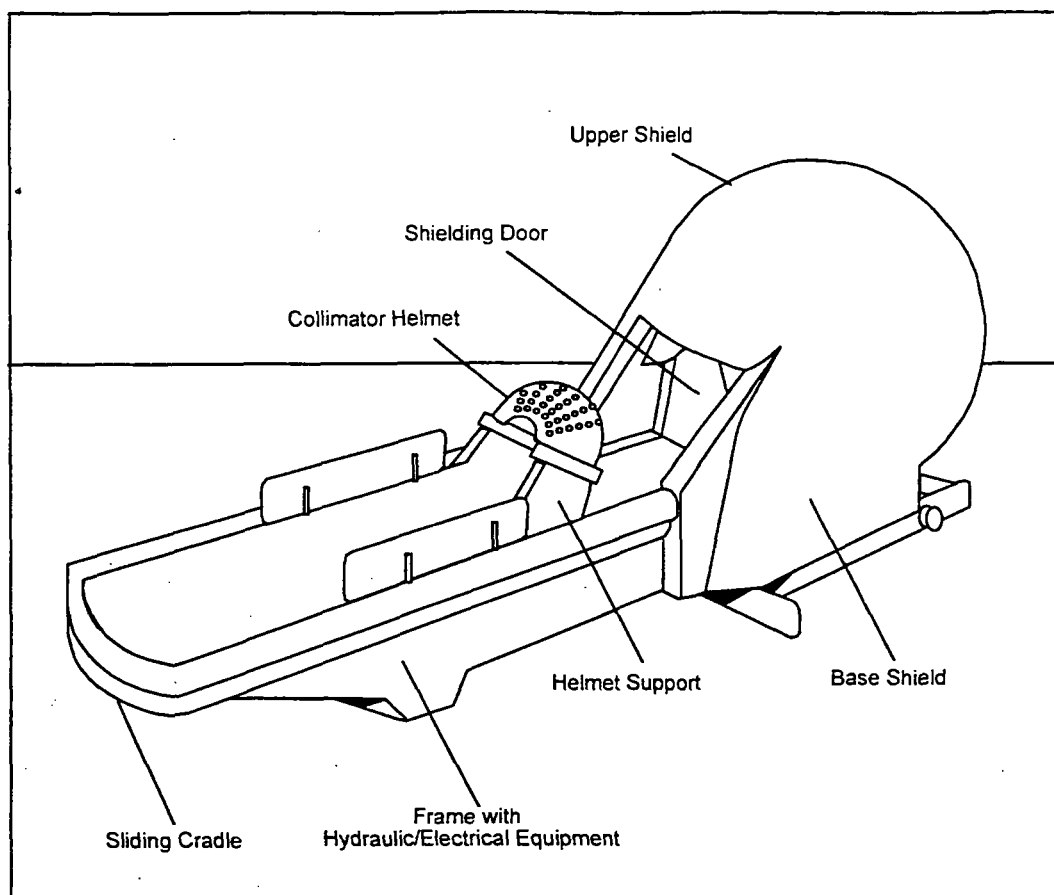
The eye plaque consists of a curved soft plastic insert that has a series of grooves molded into the rear convex surface, which are designed to hold the radioactive seeds. After the plastic insert is loaded with the seeds, a solid gold cover, matched in size to the insert, is placed over the convex surface of the insert and cemented in place to seal the seeds into a fixed array within the plaque. The insert is completely surrounded by the gold cover except for the concave surface that is placed against the eye. When used with I-125 and Pd-103 seeds, the gold cover provides considerable shielding of the normal tissues surrounding the eye and limits the external dose rates surrounding the patient. Although not implanted into the tumor, because the plaque is placed in the orbit of the eye over the tumor site and sutured to the sclera of the eye to stabilize its position on the tumor while in the orbit, this is considered interstitial, not topical, treatment.

- Intracavitary Treatment of Cancer. In addition, for purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use. The following sources are routinely used for the intracavitary treatment of cancer:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells
 - Ir-192 and Pd-103 seeds.
- Topical (Surface) Applications. The following sources are routinely used for topical applications:
 - Cs-137 and Co-60 as sealed sources in needles and applicator cells
 - Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions.

For **35.500 material**, the applicant must define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.500) and describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the following sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR:

- I-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and
- I-125 as a sealed source in a portable imaging device.

For **35.600 material**, the applicant must define the purpose of use by stating the applicable section of 10 CFR Part 35.600 (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Leksell Gamma System Model 23016 {a.k.a. Gamma Knife or Cerebral Stereotactic Radiosurgical Unit} radiation therapy unit for the treatment of humans). A schematic of a GSR unit is provided as Figure 8.4. The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.



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Figure 8.4 Gamma Stereotactic Radiosurgery Unit

For **35.1000 material**, the applicant must define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.1000) and describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item.

One area of an emerging technology is the use of byproduct material to prevent restenosis. Post-operative radiation exposure has recently been shown to reduce the probability of restenosis following balloon angioplasty in patients. Balloon angioplasty can damage the smooth muscle lining the artery, stimulating cell growth that may result in restenosis. Vessel reclosure occurs in approximately 30 percent to 40 percent of angioplasty cases within 6 months because the artery wall collapses or scars and fills with tissue. There are two components to restenosis: the first, *recoil*, is the mechanical collapse of the dilated arteries; and the second, *intimal hyperplasia*, is the proliferation of smooth muscle cells in response to the vascular injury.

Emerging technologies have been developed using radioactive catheters, pellets, and stents to treat coronary and peripheral vascular problems. These therapy devices contain ionizing radiation in the form of a gas, liquid, or solid that retards recoil and proliferation of smooth muscle cells in

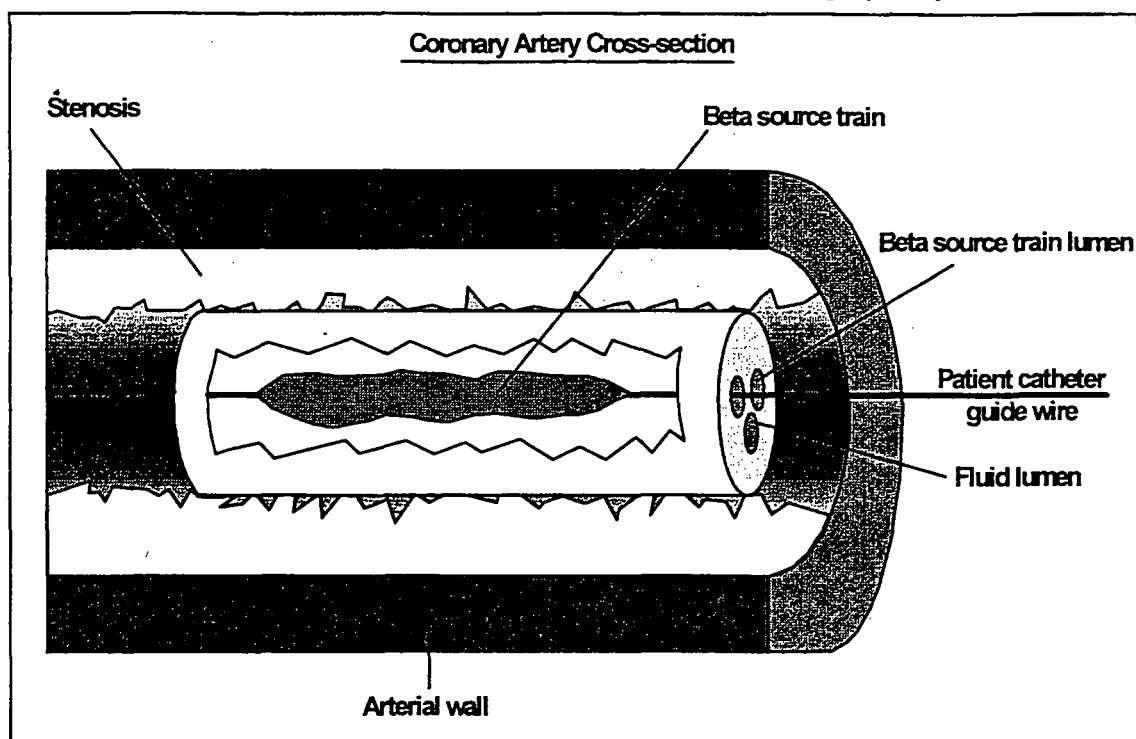
the affected vessel wall. The radiation can be ion implanted, plated, or encapsulated in a sealed source device attached to a guide wire used in the angioplasty procedure. The radioactive device can be either permanently implanted or removed via the guide wire following treatment of the affected vessel wall.

Intracoronary radiation therapy is emerging as the primary discipline of the new technology. Because of the trauma and expense of performing repeat coronary procedures, physicians and medical companies have developed devices that appear to inhibit restenosis rates in clinical trials. Three major innovative types of intravascular radiation therapy devices are being clinically investigated following balloon angioplasty:

1. *Intracoronary Beta Radiation Catheter* (Figure 8.5)—The catheter is not an implant and the radiation is delivered post balloon angioplasty. The beta radiation catheter is unsheathed in the affected coronary artery where the balloon angioplasty had occurred. The catheter delivers a high dose directly to the arterial wall while having a minimal effect on the whole body. Treatment times average around 5 minutes. The clinician controls the delivery and return of the source train. The catheter is retracted from the artery using the guide wire from the angioplasty procedure.
2. *Intracoronary Beta Radiation Stent* (Figure 8.6)—The stent is a permanent implant and the radiation is delivered post balloon angioplasty. The stent is attached to the outside of the balloon catheter. The catheter is inflated and the stent is pressed against the arterial wall which becomes permanently implanted. The balloon is then deflated and retracted from the coronary artery. The stent delivers a high dose directly to the arterial wall while having a minimal effect on the whole body.
3. *Intracoronary Beta Radiation Pellets*—Radiation is delivered post balloon angioplasty. The pellets are temporarily implanted at the angioplasty site in the coronary artery for a short treatment time (approximately 30 minutes). The clinician controls the delivery and return of the source train from the coronary artery. The pellets deliver a high dose directly to the arterial wall while having a minimal effect on the whole body.

Emerging Technology

Beta Radiation Catheter/Post Balloon Angioplasty

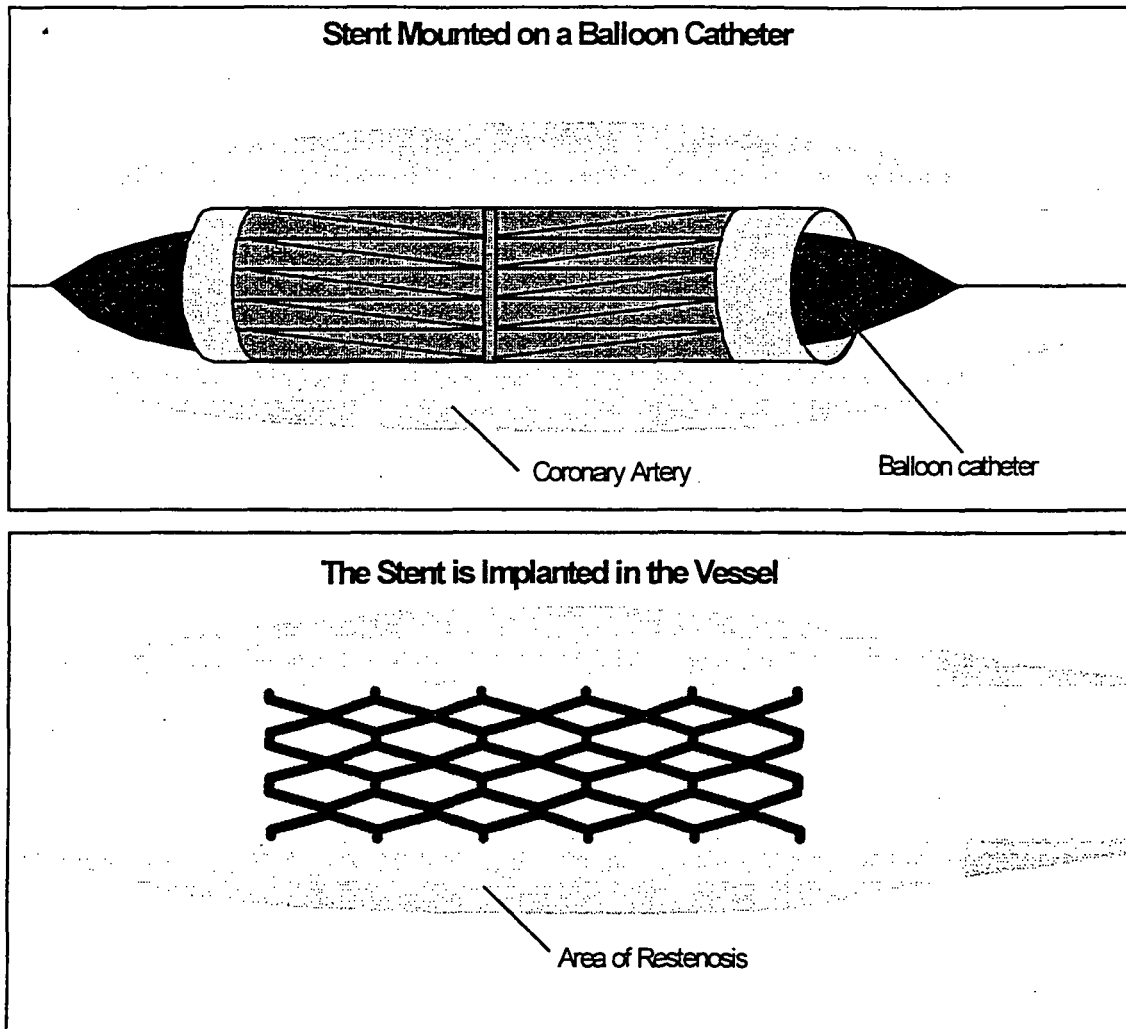


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Figure 8.5 Beta Radiation Catheter

Stent Implantation

Stents Using Beta Radiation



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Figure 8.6 Stent Implantation

A new clinical procedure uses beta radiation sutures to reduce restenosis in renal dialysis patients. Radiation is thought to produce an antiscarring effect by breaking the strands of DNA in the endothelial cells of the affected vessels.

The United States Food and Drug Administration (FDA) considers the use of radiation in the coronary and/or peripheral vasculature for the prevention of restenosis investigational with the potential for risk to patients. Legal and ethical considerations require U.S. patients to be studied under an investigational device exemption application at the time of this writing.

Benchtesting of the radiation device in an emerging technology includes the following criteria:

- Characterization of the radiation source
- Biocompatibility of blood-containing materials used in the delivery system (if applicable)
- Mechanical integrity of components used in the delivery system (if applicable)
- Sterility of the source and delivery system. Bench testing is conducted by the manufacturer and the clinical investigator(s).

Radionuclides that are being used in the emerging technology include P-32, Sr-90, Ir-192, rhenium-186, rhenium-188, xenon-133, and hydrogen-3. The use of beta radiation and/or low energy photons localized to the affected site has the potential to subsequently reduce or eliminate restenosis.

Applicants must also describe non-medical uses and reference the applicable radioactive material provided in response to Item 5.

Appendix C contains sample licenses that provide guidance on how to respond to Item 6.

Response from Applicant: The applicant shall submit the information as described above.

8.09 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

Regulations: 10 CFR 30.33(a)(3), 10 CFR Part 35.

Criteria: The RSO, AUs, AMPs, and ANPs must have adequate training and experience.

Discussion: Individuals responsible for the radiation protection program are licensee senior management, the AUs, RSO, RSC (if applicable), AMPs, and ANPs. In 10 CFR 30.33(a)(3), NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, H, and J of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs. Applicants should note that a résumé or a curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

NRC holds the licensee responsible for the radiation protection program. Therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO and, if applicable, the RSC, in writing, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities. In addition, licensees with multiple modalities or multiple users must develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the radiation protection program (10 CFR 35.24). The licensee may use several mechanisms to ensure that all departments are kept informed of all activities regarding the radiation protection program, such as electronic mail or committee meetings, including an RSC.

Licensees may contract for patient services for which they have no in-house expertise. In those instances in which the contracted service is regulated by the NRC, the licensee should be aware that the licensee remains responsible for regulatory compliance and implementation of the radiation protection program. The licensee should not assume that by hiring a consultant to perform certain tasks it has fully satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to a consultant. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program is effectively implemented by the appropriate individuals.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above.

8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.900, 10 CFR 35.2024

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in 10 CFR 35.50 and 10 CFR 35.900 and allow for the following three training pathways:

- (1) Certification by one of the professional boards approved by the NRC
- (2) Didactic and work experience as described in item b of each section and passing an examination*
- (3) Identification as an AU, AMP, or ANP on the license and have experience in the types of use for which the individual has RSO responsibilities*.

*The requirement for an examination and the limitation that an AU can only be named the RSO for the types of use for which the individual has training and experience will become effective two years after the publication of the final rule (10 CFR Part 35).

In addition, 10 CFR 35.24 requires that the licensee provide the RSO sufficient authority, organizational freedom, and management prerogative to do the following:

- Identify radiation safety problems
- Initiate, recommend, or provide corrective actions
- Stop unsafe operations involving byproduct material
- Verify implementation of corrective actions.

The licensee must also establish in writing the authority, duties, and responsibilities of the RSO.

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must be given sufficient time and resources and have sufficient commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. NRC requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO. Usually, the RSO is a full-time employee of the licensed facility; however, NRC has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or provide support to the facility RSO. Typical RSO duties are illustrated in Figure 8.7 and described in Appendix F. Appendix F also contains a model RSO Delegation of Authority. Appendix G contains forms which can be used to document the RSO's training and experience.

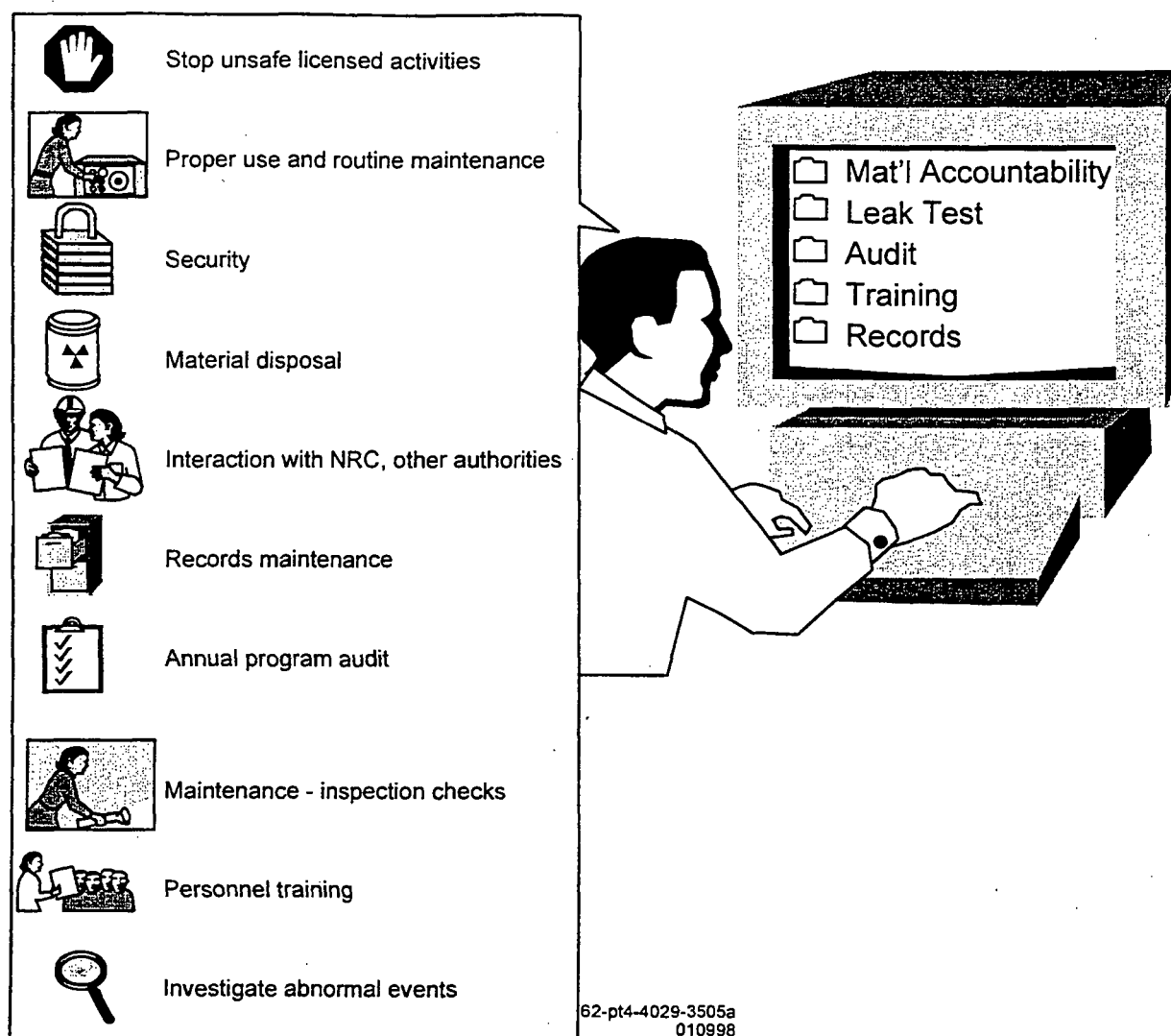


Figure 8.7 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

Response from Applicant: Provide the following:

- Name of the proposed RSO

AND

- Delegation of Authority

AND

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

- Copy of the certification(s) for the board(s) approved by the NRC and as applicable to the types of use for which he or she has RSO responsibilities.

OR

- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Documentation of successful completion of the radiation safety exam (e.g., certificate) [see Note above].

AND

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed.

Note:

- It is a requirement to notify NRC within 30 days if an RSO permanently discontinues his/her duties under the license or has a name change pursuant to 10 CFR 35.14 and to request an amendment to change an RSO pursuant to 10 CFR 35.13.
- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has training and experience with the radiation safety aspects of similar types of use of byproduct material for which he or she has RSO responsibilities and has sufficient time to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Subparts B or J are met. If the training and experience do not appear to meet the Subparts B or J criteria, the NRC may request the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI).

8.11 ITEM 7: AUTHORIZED USERS

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.290, 10 CFR 35.292, 10 CFR 35.390, 10 CFR 35.490, 10 CFR 35.590, 10 CFR 35.690, 10 CFR 35.910, 10 CFR 35.920, 10 CFR 35.930, 10 CFR 35.932, 10 CFR 35.934, 10 CFR 35.940, 10 CFR 35.941, 10 CFR 35.950, 10 CFR 35.960, 10 CFR 35.961.

Criteria: AUs must have adequate training and experience. Successful completion of training as described in 10 CFR 35.57, 10 CFR 35.290, 10 CFR 35.292, 10 CFR 35.390, 10 CFR 35.490, 10 CFR 35.590, 10 CFR 35.690, or in Subpart J, as applicable, is evidence of adequate training and experience.

Discussion: AUs involved in medical use have the following special responsibilities:

- Radiation safety commensurate with use of byproduct material
- Administration of a radiation dose or dosage and how it is prescribed
- Direction of individuals under the AU's supervision in the use of byproduct material
- Preparation of WDs, if required.

Technologists, therapists, or other personnel may use byproduct material under an AU's supervision when permitted by Federal, State or local laws. Supervision is addressed in 10 CFR 35.27, "Supervision."

For in vitro and animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include those individuals who will actually be responsible for the safe use of the byproduct material for the requested use. An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and provide their training and experience. Those AUs may direct the use of byproduct material by users under their supervision for the requested use.

Applicants are reminded of the recentness of training requirements described in 10 CFR 35.59. Specifically, physician-AU applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application, or additional training may be necessary. This time restriction applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed AU and uses requested.

AND

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

- Copy of the certification(s) for the board(s) approved by the NRC and as applicable to the use requested.

OR

- Description of the training and experience demonstrating that the proposed AU is qualified by training and experience for the use requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Documentation of successful completion of the radiation safety exam (e.g., certificate).

AND

- Written certification, signed by a preceptor AU physician, that the above training and experience has been satisfactorily completed.

Note:

- It is a requirement to notify NRC within 30 days if an AU permanently discontinues his/her duties under the license or has a name change pursuant to 10 CFR 35.14.
- Subpart J will be deleted two years after the publication of the final 10 CFR Part 35. Until then, licensees do not have to comply with the training and experience requirements provided in other sections of 10 CFR Part 35 (e.g., radiation safety exam), with the exception of the section titled "Recentness of training".
- Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, the NRC may request the assistance of its ACMUI.
- Authorized use for nonmedical use or for uses that do not involve the intentional exposure of humans (e.g., in vitro and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.980.

Criteria: ANPs must have adequate training and experience. Successful completion of training as described in 10 CFR 35.55, 10 CFR 35.57, or 10 CFR 35.980, and 10 CFR 35.59 is evidence of adequate training and experience.

Discussion: An ANP is defined in 10 CFR 35.2, "Definitions." Training and experience criteria for an ANP is described in 10 CFR 35.55 and 10 CFR 35.980, both titled "Training for an authorized nuclear pharmacist," and 10 CFR 35.57, "Training for experienced nuclear pharmacists." At many licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals.

Applicants are reminded of the recentness of training requirements described in 10 CFR 35.59. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application, or additional training may be necessary. This time restriction applies to board certification as well as to other recognized training pathways.

Response from Applicant:

Provide the following:

- Name of the proposed ANP.

AND

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an ANP.

OR

- Copy of the certification(s) for the radiopharmacy board(s) approved by the NRC.

OR

- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Documentation of successful completion of the radiation safety exam (e.g., certificate).

AND

- Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Note:

- It is a requirement to notify NRC within 30 days if an ANP permanently discontinues his/her duties under the license or has a name change, pursuant to 10 CFR 35.14.
- Subpart J will be deleted two years after the publication of the final 10 CFR Part 35. Until then, licensees do not have to comply with the training and experience requirements provided in Subpart B of 10 CFR Part 35 (e.g., radiation safety exam), with the exception of the section titled "Recentness of training".
- Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Subparts B or J are met. If the training and experience do not appear to meet the Subparts B or J criteria, the NRC may request the assistance of its ACMUI.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.51, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.961.

Criteria: AMPs must have adequate training and experience. Successful completion of training as described in 10 CFR 35.51, 10 CFR 35.57 or 10 CFR 35.961, and 10 CFR 35.59 is evidence of adequate training and experience.

Discussion: An AMP is defined in 10 CFR 35.2, "Definitions." Training and experience criteria for an AMP are described in 10 CFR 35.51, "Training for authorized medical physicist", or 10 CFR 35.961, "Training for teletherapy physicist", and 10 CFR 35.57, "Training for experienced medical physicist." At many licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. Additionally, the American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of the recentness of training requirements described in 10 CFR 35.59. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application, or additional training may be necessary. This time restriction applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP.

OR

- Copy of the certification(s) for the board(s) approved by the NRC.

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

- Documentation of successful completion of the radiation safety exam (e.g., certificate).

AND

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed.

Note:

- It is a requirement to notify NRC within 30 days if an AMP permanently discontinues his/her duties under the license or has a name change, pursuant to 10 CFR 35.14.
- Subpart J will be deleted two years after the publication of the final 10 CFR Part 35. Until then, licensees do not have to comply with the training and experience requirements provided in Subpart B of 10 CFR Part 35 (e.g., radiation safety exam), with the exception of the section titled "Recentness of training".
- Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Subparts B or J are met. If the training and experience do not appear to meet the Subparts B or J criteria, the NRC may request the assistance of its ACMUI.

8.14 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Regulations: 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610, 10 CFR 35.2310.

Criteria: Individuals working with, as well as in the vicinity of, licensed material must have adequate training and experience as required by 10 CFR Parts 19 and 35. For those individuals who work in the vicinity of licensed material and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide training as required by 10 CFR 19.12. Also, 10 CFR 35.310, 10 CFR 35.410 and 10 CFR 35.610 describe additional training requirements for individuals involved with therapeutic treatment of patients. 10 CFR 35.27 requires the licensee's AUs and ANPs to provide training to all personnel using byproduct material under their supervision on the licensee's written procedures.

Discussion: AUs, ANPs, AMPs, and RSOs would be most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, potential radiation doses received by any individual working in or frequenting restricted areas must also be evaluated. All individuals working with or around licensed materials should receive training commensurate with their assigned duties, and if it is likely they could receive doses over 1 mSv (100 mrem) in a year, they must receive instruction as specified by 10 CFR 19.12. For example, a licensee could determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), need to be informed of the nature of the licensed material and the meaning of the radiation symbol, and need to be instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open.

Additionally, since nursing staff often have direct involvement with patients undergoing therapy treatments with byproduct material, the licensee should ensure that nursing staff receive adequate training on the level of risks involved with the particular therapy treatment and emergency response procedures.

In accordance with 10 CFR 35.27(a), individuals working with licensed material under the supervision of an AU must be trained regarding the instructions of the supervising AU for medical uses of licensed material, the written radiation protection procedures established by the licensee, and compliance with NRC regulations and license conditions. In accordance with 10 CFR 35.27(b), an ANP or an AU, as allowed by 10 CFR 35.11(c), shall instruct supervised individuals in the preparation of byproduct material for medical use and require the individuals to follow their instructions and the written radiation protection program, the license conditions, and the NRC regulations.

A model training program is provided in Appendix H.

Response from Applicant: No response is required.

8.15 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 20.1302, 10 CFR 30.33(a)(2), 10 CFR 35.75.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: In 10 CFR 30.33(a)(2), NRC states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Particular attention should be focused on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Response from Applicant: Refer to the subsequent sections for guidance.

8.16 ITEM 9: FACILITY DIAGRAM

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.2102, 10 CFR 30.33(a)(2), 10 CFR 35.14, 10 CFR 35.75.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Applicants must submit an annotated drawing of the room or rooms and adjacent areas in which byproduct material will be received, used, administered, and stored. Identify it as ATT. 9.1. This includes rooms used to confine patients awaiting nuclear medicine treatments and patients undergoing in-patient therapy procedures, rooms used for administering radiopharmaceuticals or radiation doses, radioactive waste storage areas, and all byproduct material use areas including those used for receipt and storage of the byproduct material. Pursuant to 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public," licensees must demonstrate compliance with 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," for unrestricted or controlled areas that are adjacent to rooms in which byproduct material will be received, used, administered, and stored. Figure 8:8 depicts a standard nuclear medicine suite.

Facility Diagram for Nuclear Medicine Suite

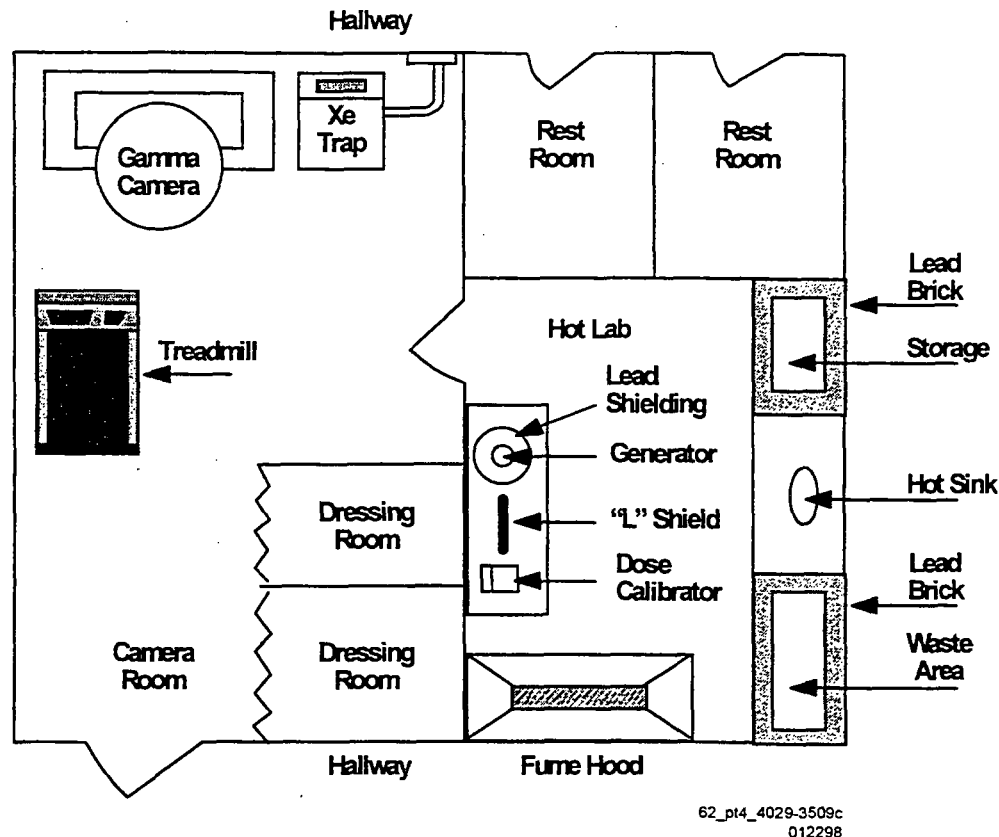
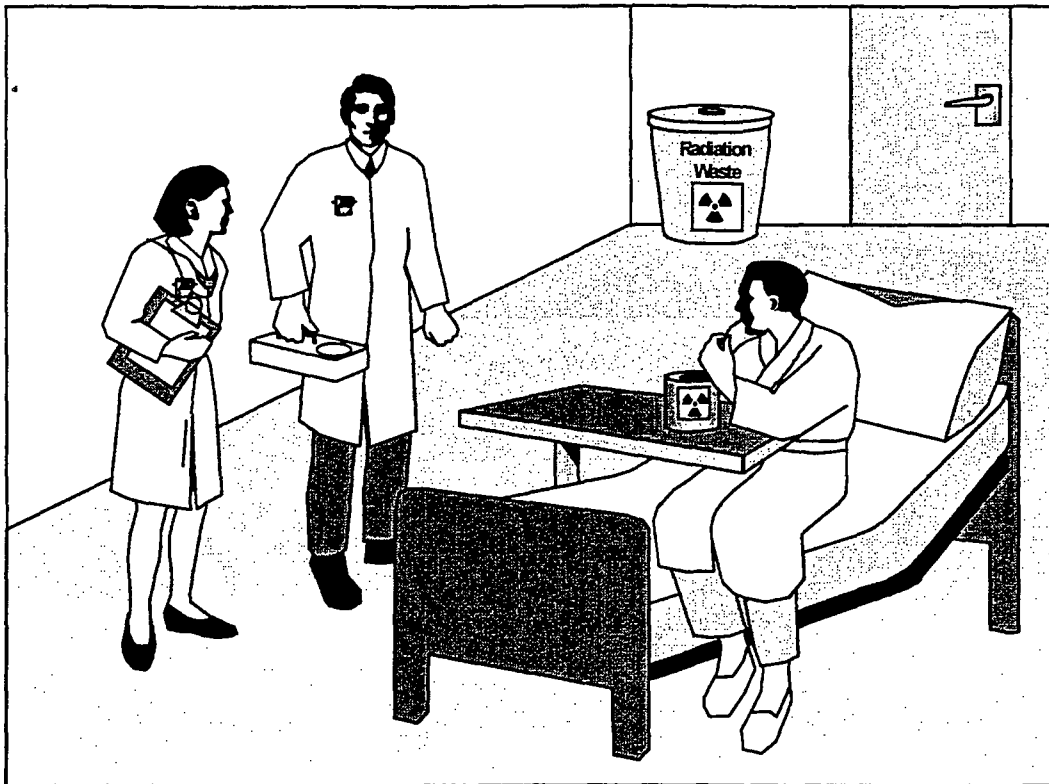


Figure 8.8 Facility Diagram for Nuclear Medicine Suite

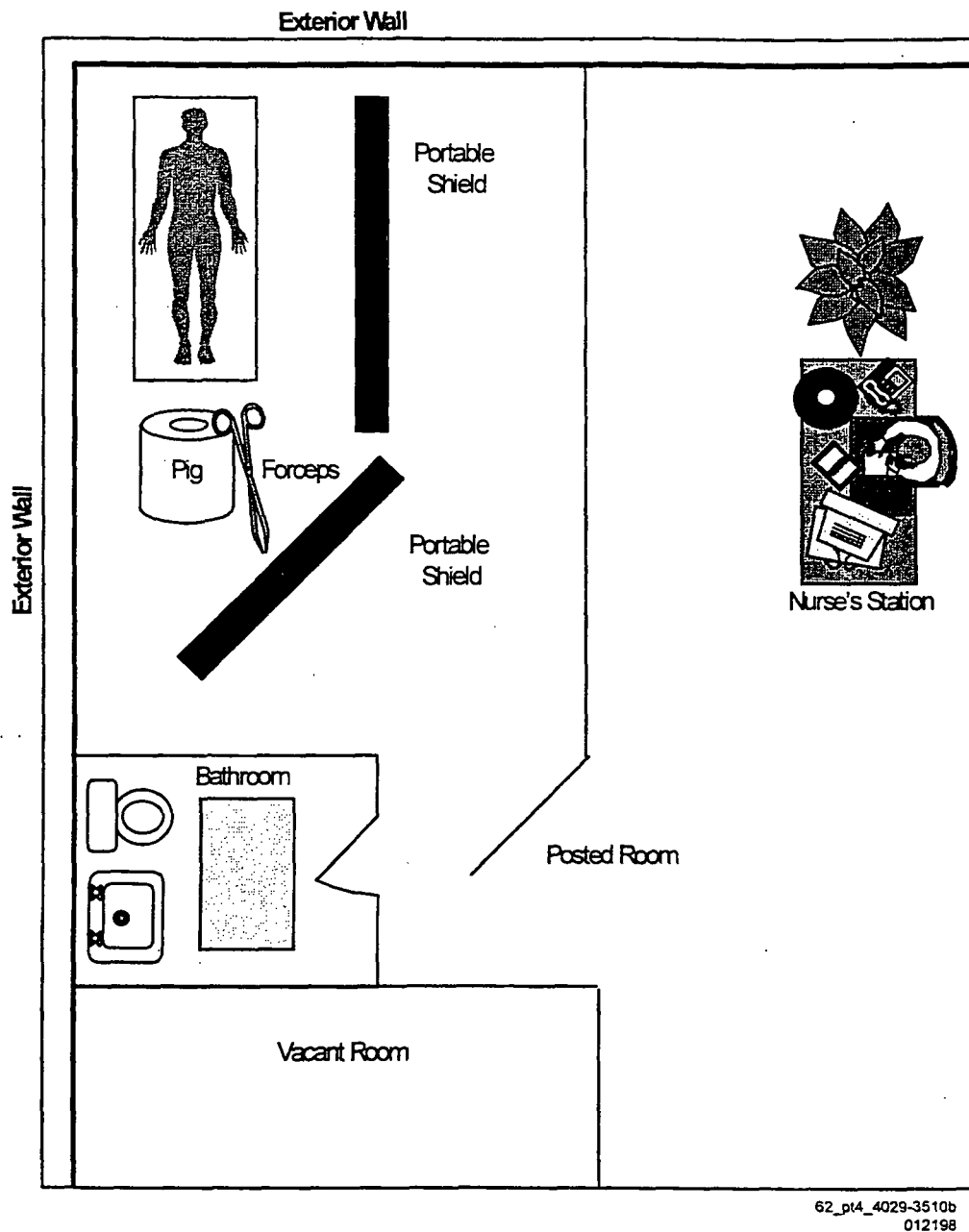
Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of a therapy patient's room or a therapy treatment room. Use of byproduct material in a room that is not described in the license application requires prior NRC approval through a license amendment, except for areas of use where byproduct material is used in accordance with 10 CFR 35.100 and 10 CFR 35.200. Licensees must notify the NRC, pursuant to 10 CFR 35.14, within 30 days following changes in areas of use for 10 CFR 35.100 and 10 CFR 35.200 byproduct material. Figure 8.9 represents an overhead view of a radioiodine patient isolation room that contains some of the required elements discussed in the response from applicant section. Figure 8.10 represents an overhead view of a manual brachytherapy patient isolation room. Based on an evaluation of shielding and planned use of each area, the applicant must have determined whether each area adjacent to the treatment room will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations. For portable shields, the licensee should assure proper placement of the shield prior to each treatment. Applicants must also submit cross-sectional diagrams to illustrate areas above and below the facilities used for patient therapy treatments (e.g., other patient rooms, stairwells, nursing stations and waiting areas). The radiation dose levels associated with these areas must be in compliance with 10 CFR 20.1302, "Compliance with dose limits for individual members of the public."

Radioiodine Treatment - Thyroid Carcinoma



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Figure 8.9 Iodine-131 NaI Administration for the Thyroid Carcinoma Patient. *The patient is required to be isolated in a private room with a private bath. Note: Applicants must also submit cross-sectional diagrams to illustrate areas above and below the patient's room.*



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Figure 8.10 Overhead View of Manual Brachytherapy Patient Treatment Room. *Note: Applicants must also submit cross-sectional diagrams to illustrate areas above and below the patient's room.*

Figure 8.11 represents a combined HDR and teletherapy suite. Based on an evaluation of shielding and the planned use of each area, the applicant must have determined whether each area adjacent to the treatment room used for all therapies involving sealed sources will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations.

Diagram of the HDR and Teletherapy Suite

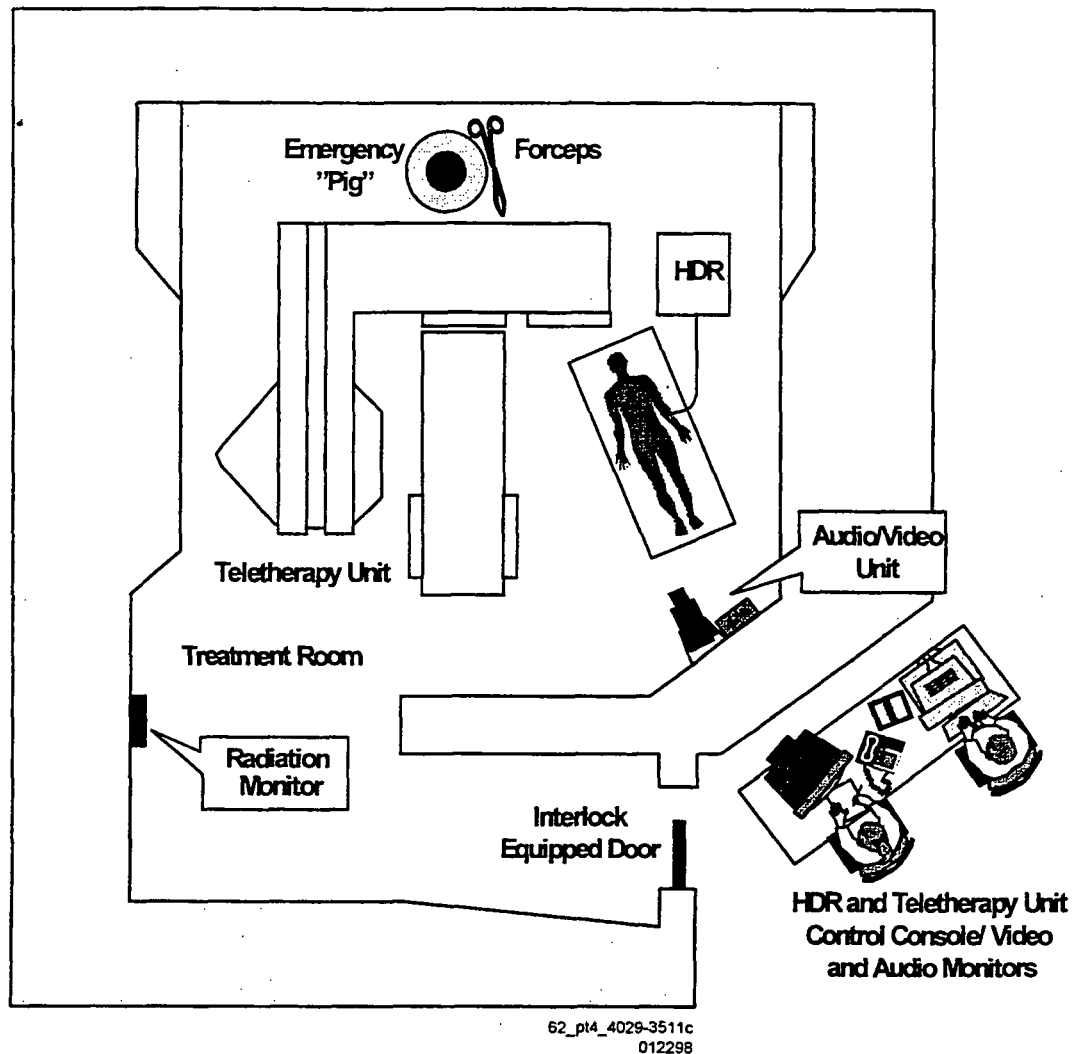


Figure 8.11 Teletherapy and HDR Treatment Room. *Note: Applicants must also submit cross-sectional diagrams to illustrate areas above and below the patient's room.*

It may be necessary to restrict use of the teletherapy unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit.

The teletherapy unit should be equipped with electrical or mechanical stops that limit use of the primary beam of radiation so as to ensure compliance with Subpart D of 10 CFR Part 20. Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber; the angle orientation convention described above applies.

- *For the primary beam directed toward the integral beam absorber*, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall.
- *For the primary beam directed away from the integral beam absorber*, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95 degrees arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall.

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

Response from Applicant: Provide the following on the facility diagrams:

- Scale; use the same scale (preferably 1/4 inch = 1 foot) for all drawings
- Direction of north
- Location, room numbers and principal use of each room or area where byproduct material is used or stored (e.g., patient therapy rooms, radioactive waste storage, nuclear medicine hot lab, manual brachytherapy source storage room)
- Location, room numbers and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway) including areas above and below therapy treatment rooms. Note that areas should be described as restricted or unrestricted as defined in 10 CFR 20.1003
- Type, thickness, and density of any necessary shielding applicable to the quantities, form, and emissions of the radionuclide that will be used (note: beta emitters should be shielded using a material with a low atomic number to minimize the production of bremsstrahlung). Include a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).
- Nature of and distances to all areas adjacent to therapy patient treatment rooms (including above and below). Note that plans are particularly helpful in showing the relationship of the patient treatment room with the rest of the building
- Location of additional radiation safety equipment (e.g., fume hood, L-block, dose calibrator, fixed area monitors, remote handling tools, t-bars, Allen key) within the facility.

In addition to the above, for **remote afterloader facilities**, provide:

- Type, thickness, and density of the shielding materials used on all sides of the treatment room, including the walls, floor, and ceiling
- Location of doors, windows, conduits, and other penetrations and voids in the shielding materials

- Nature of and distances to all areas adjacent to the treatment room (including above and below), with an indication of whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. Note that plans and elevation drawings are particularly helpful in showing the relationship among the treatment room, the roof, and the rest of the building

In addition to the above, for **teletherapy and GSR facilities**, provide:

- Location of the treatment unit and source within the treatment room
- Directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation
- Height of earth against outside walls, as applicable.

In addition to the facility description for **remote afterloader units**, provide detailed calculations of maximum radiation levels (and dose rates) that will exist in each area, restricted and unrestricted, adjacent to the room(s) where treatment is performed using a remote afterloader device, to demonstrate compliance with 10 CFR 20.1201 and 10 CFR 20.1301, respectively. (This includes areas above and below the treatment room.) The calculations should include the following:

- Expected radiation levels for each area adjacent to the room housing the device considering the most adverse source orientations and maximum source activity to be used in the device. These calculations must be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s), meet the requirements of 10 CFR 20.1201 and 10 CFR 20.1301.
- Parameters (equations, constants, assumptions, etc.) used to perform the calculations described above. These parameters must include such factors as distance to each area of concern, the type and thickness of material(s) used in barriers and shields, the transmission factor of the barriers or shields, and the maximum source strength. For HDR and pulsed dose-rate (PDR) remote afterloader devices, the use of portable shielding to meet the dose rate requirements of 10 CFR 20.1201 and 10 CFR 20.1301 is not permitted.
- The maximum anticipated workload data, such as device maximum "on time" per hour and per week and occupancy factors used for all adjacent areas.
- Calculations to determine the dose received by individuals present in unrestricted areas should reflect continuous occupancy (i.e., occupancy factor of 1), unless the applicant can justify using a lower value.
- Demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded. If the calculations demonstrate that these limits cannot be met, provide further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:
 - adding shielding to the barrier in question, with corresponding modification of the facility description if necessary
 - requesting prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of 10 CFR 20.1301(c) will be met. The applicant must demonstrate the

need for and the expected duration of operations which will result in an individual dose in excess of the limits specified in 10 CFR 20.1301(a). A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA (10 CFR 20.1101) must be developed.

- decreasing exposure times and/or limiting the number of patient treatments or increasing the size of the restricted area surrounding the treatment room

In addition to the facility description for **teletherapy and GSR units**, provide:

- A copy of the manufacturer's calculation of source(s) intensity
- Calculations of the maximum radiation levels expected in each adjacent area. The calculations should include the following:
 - maximum anticipated workload data (e.g., maximum number of patients treated per hour and per week; maximum dose and treatment time per patient; maximum on-time per hour and per week)
 - the value of each parameter used in your calculations. These parameters include such factors as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier
 - contributions from primary, leakage (with the source in the on position), and scattered radiation (including low-angle scatter that just misses the integral beam absorber for teletherapy)
 - calculations for each area adjacent to the treatment room, including above and below the room, and a statement as to whether the area will be maintained as a restricted or unrestricted area. Calculations need not be provided for areas that have not been excavated.
 - worst case situations (e.g., use of maximum beam size; all patients treated in 1 hour using the critical orientation that produces high radiation levels in an adjacent area; if the teletherapy integral beam absorber is not used for all patient treatments, calculations based on use of the unattenuated primary beam where appropriate; situations within the capabilities of the teletherapy unit that are not prohibited by electrical or mechanical stops, regardless of the clinical usefulness of these orientations)
 - the dose received by individuals present in unrestricted areas. Consider continuous occupancy (i.e., occupancy factor of 1), unless the licensee can make a compelling argument for using a lower value.
- For each unrestricted area, a statement of how the requirements of 10 CFR 20.1301 (a)(1) and (2) will be met
- Description of the teletherapy unit's mechanical or electrical beam stops that are operational and restrict beam orientation, specify the direction in which the teletherapy head can be moved, and describe the maximum angle (from vertical) of the beam orientation in each direction. Identify the angle orientation convention (e.g., 0 degrees is vertical toward the floor, 90 degrees is horizontal toward the east wall, 180 degrees is vertical toward the ceiling, and 270 degrees is horizontal toward the west wall). If the teletherapy unit has an integral

beam absorber (also called a beam catcher), provide similar information for those orientations in which (1) the primary beam is directed *toward* the integral beam absorber and (2) the primary beam is directed *away* from the integral beam absorber. Sketches may be used to describe how beam stops limit the use of the primary beam.

National Council on Radiation Protection and Measurements (NCRP) Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV" and Report 102, "Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)", may be helpful in responding to the items above.

8.17 ITEM 9: RADIATION MONITORING INSTRUMENTS

Regulations: 10 CFR.20.1101, 10 CFR 20.1501, 10 CFR 20.2102, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 35.61, 10 CFR 35.2061.

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Discussion: Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments must be available for use at all times when byproduct material is in use. The licensee must possess survey instruments sufficiently sensitive to measure the type and energy of radiation used including, survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures since it is not expected that a survey be performed each time a procedure is performed. In these cases it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Survey meter calibrations must be performed by persons, including licensee personnel, who are specifically authorized by the NRC or an Agreement State to perform calibrations. If a calibration service will be used, the applicant should ensure that the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license. Applicants seeking authorization to perform survey meter calibrations must submit calibration facility diagrams in accordance with Section 8.16. Appendix I provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures.

Response from Applicant: Provide the following:

Identify the instrument type, sensitivity, and range for each type of radiation detected. Additionally, if applicants possess only one survey instrument to meet the criteria established in 10 CFR Part 35, they should describe what is done when the survey instrument is being calibrated or repaired and either routine or emergency radiation surveys need to be performed.

AND

Provide one of the following:

- "Radiation monitoring instruments will be calibrated by a person authorized by the NRC or an Agreement State to perform survey meter calibrations."

AND/OR

- "We have developed and implemented written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1101 and that meet the requirements of 10 CFR 35.61."

8.18 ITEM 9: DOSE CALIBRATOR AND OTHER DOSAGE MEASURING EQUIPMENT

Regulations: 10 CFR 30.33, 10 CFR 35.60, 10 CFR 35.62, 10 CFR 35.63, 10 CFR 35.2060, 10 CFR 35.2063.

Criteria: In 10 CFR 35.60, 10 CFR 35.62, and 10 CFR 35.63, NRC describes requirements for the use, possession, calibration, and check of dose calibrators and other equipment used to measure patient dosages.

Discussion: As described in 10 CFR 35.63, dosage measurement is required for licensees who prepare patient dosages. If the licensee uses only unit dosages made by a manufacturer or preparer licensed pursuant to 10 CFR 32.72, the licensee is not required to possess an instrument to measure the dosage. However, pursuant to 10 CFR 35.60, if the licensee prepares their own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages, the licensee is required to possess and calibrate all instruments used for measuring patient dosages. Appendix J provides model dose calibrator calibration procedures. Currently no alpha emitting nuclides are used in unsealed form in medicine. Therefore guidance is not provided in this document on the measurement of these radionuclides. Also, licensees receiving unit dosages of byproduct material and not splitting the dosages may rely on the provider's dose label for the measurement of the dosage.

Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. For other than unit dosages, the activity must be determined by direct measurement or by a combination of measurement and calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides these difficulties include, dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides used. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

Calibrations of dosage measuring equipment may be performed by persons authorized by the NRC or an Agreement State to perform such services. If a calibration service will be used, the applicant must ensure that the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license.

Response from Applicant: If applicable, provide the following:

- "Dosage measuring equipment will be calibrated by a person authorized by the NRC or an Agreement State to perform dosage measuring equipment calibrations."

AND/OR

- "We have developed and will implement written dosage measuring equipment calibration procedures that meet the requirements in 10 CFR 35.60 and 10 CFR 35.62 as applicable."

AND

- Identify the instrument type, manufacturer, and model number. Additionally, if only one dose calibrator is possessed, applicants shall describe what is done at their facility when the dose calibrator is being calibrated or repaired and patient dosages need to be measured.

8.19 ITEM 9: DOSIMETRY EQUIPMENT - CALIBRATION AND USE

Regulations: 10 CFR 35.432, 10 CFR 35.630, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.644, 10 CFR 35.645, 10 CFR 35.2432, 10 CFR 35.2630, 10 CFR 35.2632, 10 CFR 35.2633, 10 CFR 35.2635, 10 CFR 35.2642, 10 CFR 35.2643, 10 CFR 35.2645.

Criteria: In the above regulations, NRC describes requirements for verification of source activity or output. To perform this measurement, the applicant must possess appropriately calibrated dosimetry equipment.

Discussion: The applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) which will be used to perform calibration measurements of sealed sources. Dosimetry systems and/or sealed sources used to calibrate dosimetry systems must be calibrated by a laboratory accredited by NIST or AAPM. The licensee must maintain records of such calibrations for the duration of the license.

The licensee must develop and implement procedures governing calibration of sealed sources used for therapy. The procedures must be approved by the licensee's AMP. The calibration procedures described in AAPM Task Group Nos. 21, 40 or 56, and Report 54, or any published protocol approved by a nationally recognized body, as applicable, may be used. At a minimum, the calibration procedures must address the following:

- Full calibration measurements of the sealed source(s) shall be conducted by the AMP(s).
- The method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).
- A commitment to maintain a record of calibration measurements and associated calculations.
- The frequency for calibration measurements must be specified. Full calibrations must be performed: before first medical use; whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration; following installation of new sources or reinstallation of the unit in a new location not previously described in the license and before patient treatment is resumed; following device repairs involving sealed sources; and at intervals not to exceed 1 year. Manual brachytherapy sources must only be calibrated initially, prior to use.

Response from Applicant:

Provide the following:

- "We will calibrate dosimetry equipment in accordance with the requirements in 10 CFR 35.630."

AND

- "We have developed and will implement a written therapy sealed source calibration procedure that meets the requirements in 10 CFR 35.432, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.644, and 10 CFR 35.645 (as applicable to the type of medical use requested)."

AND

- Identify the instrument type, manufacturer, and model number.

References: Copies of AAPM Task Group No. 40, "Comprehensive QA for Radiation Oncology", AAPM Report No. 54, "Stereotactic Radiosurgery", AAPM Task Group No. 56, "Code of Practice for Brachytherapy Physics", may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or ordered electronically at the following address: www.aapm.org.

8.20 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Regulations: 10 CFR 30.33(a)(2), 10 CFR Part 35.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: The applicant must describe other equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application (e.g. fume hoods, xenon traps, emergency response equipment, area monitors, remote handling tools, source transport containers, patient viewing and intercom systems, interlock systems, etc.). Identify it as ATT. 9.4.

Describe additional facilities and equipment for the **radiopharmaceutical therapy program** to safely receive, use, store, and dispose of radioactive material. Particular attention should be focused on facilities you will use for radioactive drug therapy administration and patient accommodations (i.e., private room/private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood) because of the volatility of the radiopharmaceutical. If the patient has exceeded the release limits of 10 CFR 35.75 the patient must be accommodated in a private room with a private bath as described in Item 8.16 of this report. Sources of patient contamination include airborne I-131 and radioactivity in the patient's urine, perspiration, and saliva.

To facilitate decontamination of the patient room, floors, toilet areas, sink areas, countertops, and other permeable surfaces the licensee should consider covering areas with disposable materials having plastic on one side and absorbent material on the other. In addition, items handled by the patient may be covered with plastic. These articles would include the telephone, faucet and toilet handles, television remote, door handles, and nurse call buttons. P-32 is effectively shielded by a plastic syringe and once the radionuclide has been administered to the patient, there is no external radiation hazard and P-32 does not require that the patient be placed in isolation. However, P-32 administered in colloidal form can result in contaminated bandages and dressings and designated waste containers should be maintained in the patient room.

For **teletherapy, GSR and HDR facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. A beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit meets the requirements of 10 CFR 35.615(c). In addition, the beam-on monitors traditionally installed in therapy treatment rooms are capable of providing a visible indication (e.g., flashing light) of an exposed or partially exposed source.

The applicant shall describe the system, required by 10 CFR 35.615(d), used to view and communicate with the patient continuously while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used shall be specified. If a closed-circuit television system (or some other electronic system) will be used for viewing the patient, the backup system or procedure used in case the electronic system malfunctions shall be specified or a commitment must be made to suspend all treatments until the electronic system is repaired and functioning again. The communication system must allow the patient to communicate with the unit operator in the event of any medical difficulties. An open microphone system is recommended to allow communication without requiring the patient to move to activate buttons.

The applicant must also provide adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. 10 CFR 35.615(b), in part, requires that each door leading into the treatment room be provided with an interlock to control the on-off mechanism of the therapy unit. The interlock must cause the source to move to the off condition or shield the source(s) if the door to the treatment room is opened when the source is exposed. The interlock system must prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Additionally, the interlock must be wired so that the source(s) cannot be returned to the on condition after interlock interruption until the treatment room door is closed and the system is reset at the control panel.

Due to the unique characteristics of **PDR remote afterloaders**, related to the relatively HDR sources and lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure protection of the patient during treatment. In addition to the above, it is necessary to ensure the following:

- The PDR device's control console is *not* accessible to unauthorized personnel during treatment
- A primary care provider check the patient to ensure that the patient's device has not been moved, kinked, dislodged, disconnected, etc.
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device must indicate that the source is in the "safe" or retracted position connected with the signal indicating the presence of radiation from the room radiation monitor in such a manner that an audible alarm is generated whenever the room monitor indicates the presence of radiation and the device indicates a safe condition.
 - The alarm circuit must also be wired in such a manner that the audible alarm is also generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist.

- The "source safe and radiation present" signal must also be self-testing. This requires that if a "source not safe" input is received without a corresponding "radiation present" signal, the circuit will generate an interlock/warning circuit failure signal that will cause the source to retract. This circuit will require manual resetting before attempting to continue treatment.
- The audible alarm must be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times.
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm may be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry may not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute are prohibited.

If the alarm circuit is inoperative for any reason, a commitment must be made to prohibit initiating any patient treatments with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

For patient rooms where **low dose-rate (LDR) remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant must describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Response from Applicant: Provide a description of additional facilities and equipment required by 10 CFR Parts 30 and 35. For **teletherapy, GSR, and remote afterloader facilities**, include a description of the:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
- Methods for controlling occupancy for each restricted area
- Area radiation monitoring equipment
- Viewing and intercom systems (except for LDR units)
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, x-ray machine) are located in the treatment room.
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

8.21 ITEM 10: RADIATION PROTECTION PROGRAM

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 30.34(e), 10 CFR 35.24, 10 CFR 35.26, 10 CFR 35.2024, 10 CFR 35.2026.

Criteria: 10 CFR 20.1101 states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must assure compliance with established standards, procedures, and provisions of NRC regulations. Additionally, any calculations or measurements used to demonstrate compliance with NRC regulations must be representative of typical quantities in use or maximum patient doses (dosages). The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. 10 CFR 30.34(e) permits NRC to incorporate into licenses additional requirements and conditions that it deems appropriate or necessary to protect health and safety or to minimize danger to life and property. 10 CFR 35.24 describes the licensee's management's authorities and responsibilities for the radiation protection program. 10 CFR 35.26 describes when the licensee may revise the radiation protection program without NRC approval. One of the allowances to change the program without approval is when the revision does not reduce radiation safety. Examples of when this might apply include replacement of survey instruments with comparable survey instruments or reassignment of task among employees.

Discussion: Applicants/licensees must provide information on the proposed radiation protection program to minimally include the following items (as applicable):

- Audit Program
- Leak Tests
- Operating and Emergency Procedures
- Material Receipt and Accountability
- Area Surveys
- Occupational Dose
- Public Dose
- Transportation
- Minimization of Contamination
- Mobile Nuclear Medicine
- Procedures for Administrations Requiring WDs

Response From Applicant: Respond to subsequent sections of this document regarding Item 10 of the application.

8.22 ITEM 10: AUDIT PROGRAM

Regulations: 10 CFR 20.1101, 10 CFR 20.2102.

Criteria: Licensees must annually review the content and implementation of the radiation protection program to ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license
- Occupational doses and doses to members of the public ALARA (10 CFR 20.1101)
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: The licensee must develop and implement procedures for the audit program. Appendix K contains model procedures. All areas indicated in Appendix K may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit. Generally, audits are conducted at least once every 12 months.

Currently the NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, problems are corrected comprehensively and in a timely manner. IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject, and specifically describes the corrective action process to include three steps:

- (1) Conduct a complete and thorough review of the circumstances that led to the violation
- (2) Identify the root cause of the violation
- (3) Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

The NRC will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. Depending on the significance of a violation, if a violation is identified by the licensee and these steps are taken, the NRC may exercise discretion and may elect not to cite a violation. The NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

For additional information on NRC's use of discretion on issuing a notice of violation, refer to "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG 1600, dated June 1995).

Pursuant to 10 CFR 20.2102, licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Audit records should contain the following information: audit findings, noted deficiencies, and corrective actions.

Response from Applicant: The applicant is not required to, and should not, submit its audit program to the NRC for review.

References: See the Notice of Availability on the inside front cover of this draft report to obtain copies of: NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," dated June 1995, and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996. NUREG-1600 is also available on the Internet. Visit NRC's Home Page (<http://www.nrc.gov>), choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

8.23 ITEM 10: OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.2102, 10 CFR 20.2106.

Criteria: Applicants must do either of the following:

- Maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the allowable limits as shown in Figure 8.12.

OR

- Monitor external and/or internal occupational radiation exposure, if required by 10 CFR Part 20.

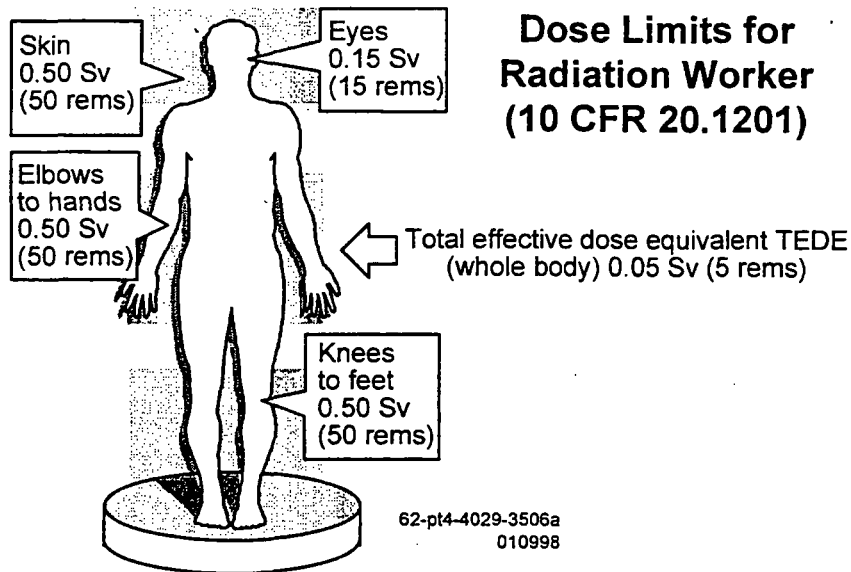


Figure 8.12 Annual Dose Limits for Radiation Workers.

Discussion: The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists, etc.) to determine whether monitoring is required to demonstrate compliance with Subpart F of 10 CFR Part 20. Licensees must consider the internal and external dose and the occupational workers assigned duties when evaluating the need to monitor occupational radiation exposure.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent

may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

When evaluating dose from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

A model procedure for monitoring occupational exposure is provided in Appendix L.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, i.e., film badges or thermoluminescent dosimeters (TLDs), that will be used by personnel. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors [i.e., required if likely to receive a dose in excess of 0.05 Sv (5 rem) shallow-dose equivalent (SDE)] in addition to whole body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices should be worn so that the part of the body likely to receive the greatest proportion of its permissible dose equivalent will be monitored.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See American National Standards Institute (ANSI) N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters" for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters; and procedures and frequency for calibration and maintenance of pocket dosimeters as required by 10 CFR 20.1501(b).

When personnel monitoring is needed, most licensees use either film badges or TLDs that are supplied by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor. Film badges are usually exchanged monthly due to technical concerns about film fading. TLDs are usually exchanged quarterly. Applicants must verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 10 CFR 20.1204 and 20.1502. If internal dose monitoring is necessary, the applicant must measure the following:

- Concentrations of radioactive material in air in work areas
- Quantities of radionuclides in the body
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

For example, for individuals preparing or administering therapeutic dosages of I-131, licensees may need to assess thyroid burden measurements. For those individuals who are occupationally exposed to lesser quantities of I-131, RG 8.20, "Applications of Bioassay for I-125 and I-131, Revision 1", has suggested frequencies of bioassays for individuals, based on quantities handled, type of compounds (volatile/non-volatile), and facilities used.

The applicant should describe in their procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both in vivo and in vitro) will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. The applicant must describe the equipment and facilities dedicated to the bioassay program. If a commercial bioassay service will be used, ensure that the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license.

RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements," outline acceptable criteria that may be used by applicants in developing their bioassay programs.

10 CFR 20.1202 describes the requirements for summing external and internal doses. Applicants must ensure that their occupational monitoring procedures include criteria for summing external and internal doses.

Response from Applicant: Provide the following:

- A description of facilities and equipment used for monitoring occupational exposure.

AND

- A statement that: "We have developed and will implement written procedures for monitoring occupational dose in accordance with 10 CFR 20.1101 and that meets the requirements in Subparts C and F of 10 CFR Part 20."

Reference: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available for purchase from GPO and on the Internet at the following address:

<http://ts.nist.gov/ts/htdocs/210/214/dosim.htm>. Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically at the following address: www.ansi.org. See the Notice of Availability on the inside front cover of this draft report to obtain copies of RG 8.20, "Applications of Bioassay for I-125 and I-131, Revision 1," RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements."

8.24 ITEM 10: PUBLIC DOSE

Regulations: 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107.

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored (see Figure 8.13). Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using byproduct material under their supervision should have access to these keys.

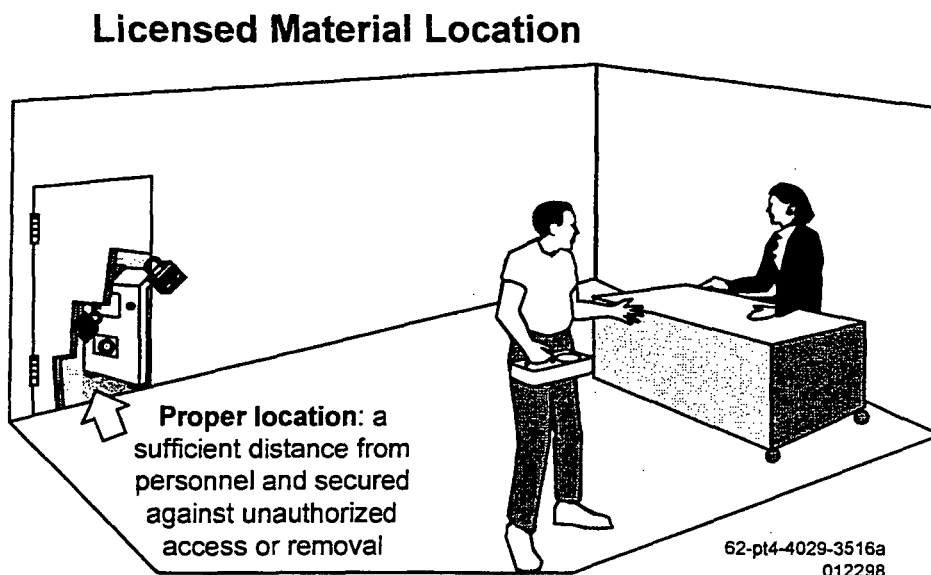


Figure 8.13 Proper Security of Licensed Material. *Licensed Material should be located away from occupied areas and secured to prevent unauthorized use or removal.*

Public dose is also affected by the choice of storage and use locations and conditions. Licensed material may present a radiation field, and must be located so that the public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time, increasing the distance, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to licensed material either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the "inverse square" law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of licensed material. See Appendix M for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public dose limits.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of licensed material within a designated room, changes the type or frequency of licensed material use, or changes the occupancy of adjacent areas) then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Response from Applicant: No response is required from the applicant in a license application, but this matter will be examined during inspection. During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix M for examples of methods to demonstrate compliance with public dose limits.

8.25 ITEM 10: MINIMIZATION OF CONTAMINATION

Regulations: 10 CFR 20.1406

Criteria: Applicants for new licenses must ensure that facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed byproduct material. As described in Item 8.37, "Spill Procedures", cleanup procedures should be implemented for any contamination event.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: No response is necessary. This item will be reviewed during NRC inspections.

8.26 ITEM 10: OPERATING AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.34(e), 10 CFR 30.50, 10 CFR 35.75, 10 CFR 35.310, 10 CFR 35.315, 10 CFR 35.404, 10 CFR 35.406, 10 CFR 35.410, 10 CFR 35.415, 10 CFR 35.610, 10 CFR 35.615.

Criteria: Before using licensed material, licensees must do the following:

- Develop, implement, and maintain specific operating and emergency procedures containing the following elements:
 - Instructions for opening packages containing licensed material, using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements
 - Instructions for conducting area radiation level and contamination surveys
 - Instructions for administering licensed material in accordance with the WD
 - Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material
 - Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s)
 - Steps to ensure that patient release is in accordance with 10 CFR 35.75
 - Steps to take in case a therapy patient undergoes emergency surgery or dies
 - Instructions for calibration of survey and dosage measuring instruments
 - Periodic spot checks of therapy device units, sources, and treatment facilities
 - Instructions for radioactive waste management.

AND

- Make operating and emergency procedures available to all users
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

The licensee should also consider the following when developing their radiation protection program:

- Steps to take to keep radiation exposures ALARA
- Steps to maintain licensed material accountability.

Discussion: Applicants shall develop operating and emergency procedures that minimize radiation safety risks, while keeping radiation exposures ALARA. These procedures must be specific to the type and form of the licensed material used.

Sealed sources and radiopharmaceuticals used for therapy can deliver significant doses in a short period of time. Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Therefore, operating procedures will also need to address access control. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g. keys, lock combinations, security badges, etc.). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

In the event that a therapy patient should undergo emergency surgery or die, it is necessary to ensure the safety of others attending the patient. As long as the body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in section 5.3 of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." Appendix N also provides model procedures for responding to emergency surgery or death of the therapy patient.

Applicants must develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.).

The NRC must be notified when licensed material in excess of 10 times the quantity specified in appendix C to part 20 is lost or stolen. The RSO must be proactive in evaluating whether NRC notification is required for any incident involving licensed material. Refer to the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, and 10 CFR 21.21) for a description of when notifications are required.

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

Reference: Copies of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at the following address: www.ncrp.com.

8.27 ITEM 10: MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2201, 10 CFR 30.34(e), 10 CFR 30.35(g)(2), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 35.67.

Criteria: Accountability of licensed material must be ensured at all times to prevent loss, theft, or misuse.

Discussion: As illustrated in Figure 8.14, licensed materials must be tracked from "cradle to grave" in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation safety program:

- Physical inventories of sealed sources at intervals not to exceed 6 months
- Ordering and receiving licensed material
- Package opening
- Use records.

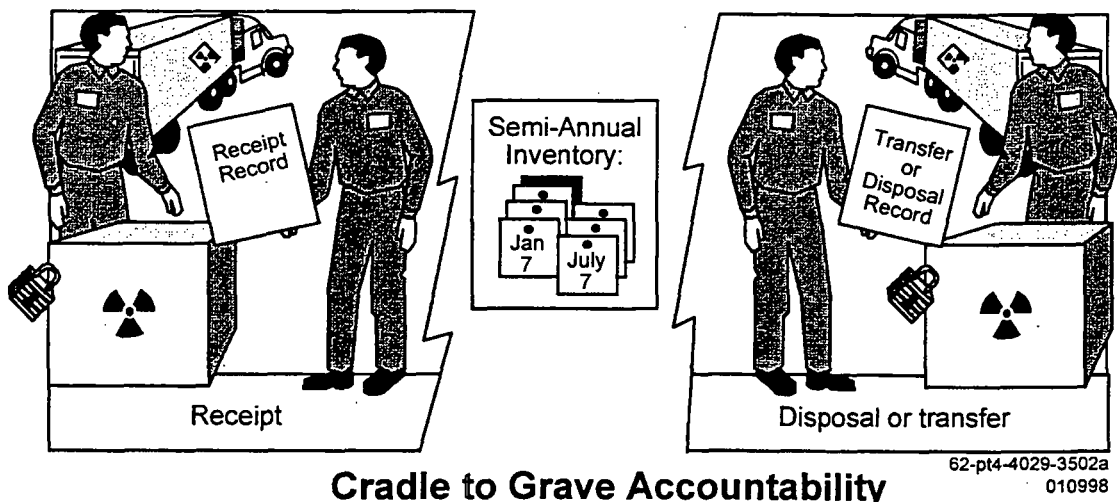


Figure 8.14 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories of sealed sources.

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

8.28 ITEM 10: ORDERING AND RECEIVING

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 30.34(e), 10 CFR 30.51.

Criteria: 10 CFR 20.1906 describes the requirements for receiving packages containing licensed material. Applicants are reminded that security of licensed material, required by 10 CFR 20.1801 and 10 CFR 20.1802, must be considered for all receiving areas. 10 CFR 30.51 requires licensees to maintain records showing the receipt of byproduct material.

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposures from packages are minimized.

Appendix O contains model procedures for ordering and receiving licensed material.

Response from Applicant: No response is required.

8.29 ITEM 10: OPENING PACKAGES

Regulations: 10 CFR 20.1906, 10 CFR 20.2103.

Criteria: Licensees must ensure that packages are opened safely and that the requirements of 10 CFR 20.1906 are met. Licensees must retain records of package surveys in accordance with 10 CFR 20.2103.

Discussion: Licensees must develop and implement procedures for opening packages to ensure that the survey requirements of 10 CFR 20.1906 are met and that radiation exposures are minimized. Appendix P contains model procedures. Applicants are reminded that 10 CFR 20.1906(b) requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it arrives during normal working hours, or not later than 3 hours from the beginning of the next working day, if it arrived after working hours.

Response from Applicant: Provide the following:

A statement that "We have developed and will implement written package opening procedures that meets the requirements of 10 CFR 20.1906."

8.30 ITEM 10: SEALED SOURCE INVENTORY

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.51, 10 CFR 35.67, 10 CFR 35.406, 10 CFR 35.2067.

Criteria: NRC requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession. Inventory records must be maintained for 3 years.

Discussion: The licensee must conduct a semiannual physical inventory of all sealed sources and brachytherapy sources in your possession, pursuant to 10 CFR 35.67. Individual GSR sources are exempt from the semiannual physical inventory as stated in 10 CFR 35.67(g). However, the licensee must maintain records of GSR sources receipt and disposal, pursuant to 10 CFR 30.51, to indicate the current inventory of sources at the licensee's facility. The licensee shall retain each inventory in accordance with 10 CFR 35.2067. In addition, 10 CFR 35.406 requires the licensee to make a record of brachytherapy source accountability when removing and returning brachytherapy sources from the storage location.

Response from Applicant: No response is necessary.

8.31 ITEM 10: USE RECORDS

Regulations: 10 CFR 30.51, 10 CFR 35.2063, 10 CFR 35.2204, 10 CFR 35.2406.

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

Discussion: Licensees are required to make and maintain records of dosage activity prior to medical use. Records of each dosage must be made and include:

- Radionuclide
- Generic name or its abbreviation or trade name
- Lot number
- Patient's or human research subject's name and identification number if one has been assigned
- Prescribed dosage and activity at the time of dosage determination, or a notation that the total activity is less than 1.1 mega-Bq (30 uCi)
- Date and time of dosage determination
- Name of the individual who determined the dosage.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements.

If molybdenum concentration is measured pursuant to 10 CFR 35.204, records of molybdenum concentration must be made and include:

- Ratio of the measurements expressed as uCi of molybdenum per mCi of technetium-99m
- Date and time of the measurement
- Name of the individual who made the measurement.

If the licensee uses manual brachytherapy sources, the following records of use must be made:

- Each time temporary implant brachytherapy sources are removed from storage, a record will be made and include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage.
- Each time temporary implant brachytherapy sources are returned to storage, a record will be made and include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage.

- For permanent implants, a record will be made and include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources returned to storage, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

Response from Applicant: No response is required.

8.32 ITEM 10: LEAK TESTS

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 35.67, 10 CFR 35.2067, 10 CFR 35.3067.

Criteria: NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Records of test results must be maintained for 3 years.

Discussion: Licensees must perform leak testing of any sealed source or brachytherapy source in accordance with 10 CFR 35.67. Appendix Q provides model leak testing procedures. Pursuant to 10 CFR 35.67, licensees are required to perform leak tests at six month intervals or at other intervals approved by the NRC or an Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 uCi) of radioactivity. Leak tests samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking (see Figure 8.15)

Leak Testing

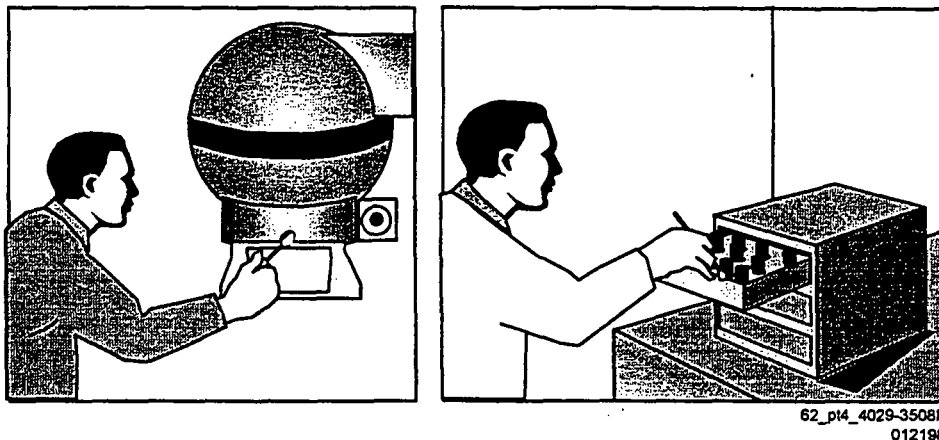


Figure 8.15 Leak Test Sample

The leak test may be performed in house or by a contractor who is authorized to perform leak tests as a service to other licensees.

The licensee or contractor does not need to leak test sources if:

- Sources contain only byproduct material with a half-life less than 30 days
- Sources contain only byproduct material as a gas
- Sources contain 3.7 mega-Bq (100 uCi) or less of beta-emitting or gamma-emitting material or 0.37 mega-Bq (10 uCi) or less of alpha-emitting material

- Sources contain Ir-192 seeds in nylon ribbon
- Sources are stored for less than a 10-year period and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

Response from Applicant: No response is necessary.

References: See the Notice of Availability on inside front cover of this draft report to obtain a copy of Draft RG FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

8.33 ITEM 10: AREA SURVEYS

Regulations: 10 CFR 20.1101, 10 CFR 20.1003, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1501, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2107, 10 CFR 35.70, 10 CFR 35.2070.

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations.
- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 10 CFR 20.1201.
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access, removal, or use.

Discussion: Licensees must develop and implement area survey procedures. Appendix R contains model procedures with suggested survey frequencies. At a minimum, licensees must perform daily surveys in all areas where radiopharmaceuticals requiring a WD were prepared for use or administered (i.e., diagnostic activities exceeding 30 uCi of I-131 and all therapy treatments); however, for administrations, requiring a WD, in patients' rooms, the licensee should perform adequate surveys of patients' rooms after patient release and prior to release of the room for unrestricted use.

In addition, therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed. When developing area survey procedures, the licensee should consider: (1) a survey of the therapy patient's bed linens before removing them from the patient's room, and (2) a survey of the operating room and the patient's room after source implantation.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 and that meets the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

8.34 ITEM 10: PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

Regulations: 10 CFR 35.40, 10 CFR 35.41, 10 CFR 35.2040.

Criteria: 10 CFR 35.40 describes the requirements for WDs. 10 CFR 35.41 requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

Discussion: The procedures do not need to be submitted to the NRC. This allows licensees the flexibility to revise the procedures to enhance their effectiveness without obtaining NRC approval. Appendix S provides guidance for developing the procedures.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41."

8.35 ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 30.34(e), 10 CFR 35.69, 10 CFR 35.70, 10 CFR 35.310.

Criteria: Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material.

Discussion: Licensees must have adequate equipment and operating controls to ensure that radioactivity, surface contamination, and effluent releases are maintained within regulatory limits.

Users of licensed material must perform surveys required by 10 CFR 20.1302(a) (i.e., surveys of radiation levels and release of effluents to unrestricted and controlled areas). In addition, applicants should establish a program to constrain doses from air emissions in accordance with 10 CFR 20.1101(d). Records of the results of the measurements are required by 10 CFR 20.2103(b)(4).

Applicants must show how releases to the environment will be ALARA. The general guideline is 10 percent of the limit specified in 10 CFR 20.1301(a)(1). Licensees that possess sufficient quantities of radioactive material to exceed 10 CFR Part 20 air emissions limits should demonstrate a basis for compliance with the applicable requirements. Such basis could include one or more of the following:

- Measured concentrations of radionuclides in air effluents are below 10 CFR Part 20, Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr).
- Bounding calculations show that air effluents could not exceed 10 CFR Part 20, Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr).
- Dose modeling shows that dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr.

In addition, licensees must develop procedures for implementing protective measures occupational workers should take to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields
- Wearing laboratory coats and gloves when handling unsealed byproduct material
- Monitoring hands after handling unsealed byproduct material.

Appendix T contains model procedures for safe use of unsealed licensed material.

Response from Applicant: Submit the following:

A statement that: "We have developed and will implement procedures for safe use of unsealed licensed material that meets the requirements of 10 CFR 20.1101, 10 CFR 20.1301 and 10 CFR 35.69."

8.36 ITEM 10: MAINTENANCE OF THERAPY DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 20.1101, 10 CFR 30.34(e), 10 CFR 35.605, 10 CFR 35.655, 10 CFR 35.2605, 10 CFR 35.2655.

Criteria: Licensees must ensure that therapy devices containing sealed sources are maintained according to manufacturer's written recommendations and instructions and according to the SSDR and the regulations. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure proper functioning of the source exposure mechanism. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

Discussion: Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also means any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), or affect the source drive controls.

The NRC requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 10 CFR 35.605 prior to response to this item. 10 CFR 35.605 allows for limited service activities with regard to LDR remote afterloader units.

Response from Applicant: No response is necessary if the licensee contracts with personnel who are licensed by the Commission or an Agreement State to perform maintenance and repair services on the specific therapy device possessed by the licensee. However, if the applicant requests that an employee, who is trained by the manufacturer, be authorized to perform maintenance and repair, the applicant must submit the following:

- Name of the proposed employee and types of maintenance and repair requested.

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.

AND

- Copy of the manufacturer's training certification and an outline of the training.

Note: The applicant should specify only those maintenance and repair functions described in a certificate or letter from the manufacturer of the device which documents the employee's training in the requested function(s).

8.37 ITEM 10: SPILL PROCEDURES

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1406, 10 CFR 20.2102, 10 CFR 20.2202, 10 CFR 20.2203, 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.50, 10 CFR 30.51.

Criteria: Before using licensed material, the licensee must develop and implement a radiation protection program that includes proper response to spills of licensed material.

Discussion: The applicant must develop and implement procedures to be used in the event of spills or other contamination events in order to prevent the spread of radioactive material. Appendix N contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified, e.g., RSO, staff, state and local authorities, and the NRC, when applicable. Additionally, the instructions should contain procedures on evacuation of the area, containment of spills and other releases, appropriate methods for reentering, and decontaminating facilities that may have been accidentally contaminated.

Response from Applicant: Submit the following:

A statement that: "We have developed and will implement written procedures for safe response to spills of licensed material that meets the requirements in 10 CFR 20.1101."

8.38 ITEM 10: EMERGENCY RESPONSE FOR SEALED SOURCES OR DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 21.51, 10 CFR 30.34(e), 10 CFR 30.50, 10 CFR 30.51, 10 CFR 35.410, 10 CFR 35.610.

Criteria: Before handling sealed sources or using devices containing sealed sources, the applicant must develop and implement procedures for emergency response. 10 CFR 35.610 requires, in part, that instructions and telephone numbers of AUs, AMPs and RSO be posted at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to turn off the primary beam of radiation with the controls outside of the treatment room, remove the patient from the radiation field, or if any other abnormal operation occurs.

Discussion: The applicant must develop and implement procedures to be used in response to emergencies involving sealed sources or devices containing sealed sources in order to prevent inadvertent release of, or exposure to, licensed material. Appendix N contains model emergency response procedures for teletherapy units. Emergency procedures must address all types of licensed material and devices used and should be posted in restricted areas where sealed sources are used or stored. The instructions must specifically state the names and telephone numbers of persons to be notified, e.g., RSO, staff, state and local authorities, and the NRC, when applicable. Additionally, the instructions must contain procedures on evacuation and security of the involved area(s), source recovery, area reentry, and decontamination of facilities (if applicable). All equipment necessary for complying with emergency procedures shall be immediately accessible in the treatment room or console area; for example, these may include remote handling tools, t-bars, Allen keys, and shielded containers.

The applicant must establish and agree to follow written procedures for emergencies that may occur, e.g., a manual brachytherapy source becomes dislodged, a therapy source fails to retract or return to the shielded position, a GSR couch fails to retract. A copy of the manufacturer's instructions should be given to each individual involved with therapy treatments. Practice drills, using nonradioactive (dummy) sources (when possible), including dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for patient removal must be practiced annually. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, must at a minimum address the following as applicable to the type of medical use:

- When the procedures are to be implemented, such as, any circumstance under which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation

- The actions specified for emergency source recovery or shielding which primarily consider minimizing exposure to the patient and healthcare personnel while maximizing safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures must clearly specify which steps are to be taken under different scenarios. The procedure must specify situations in which surgical intervention may be necessary and the steps that should be taken in the event that surgical intervention is required.
- Identification of the location of emergency source recovery equipment and specification of what equipment may be necessary for the various scenarios described in the procedure. At a minimum, emergency equipment must include shielded storage containers, remote handling tools, and, if appropriate, supplies necessary to surgically remove applicators or sources from the patient.
- Giving first consideration to minimizing the exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). Note: If a first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement written procedures for safe response to emergencies involving sealed sources that meets the requirements in 10 CFR 20.1101 and 10 CFR 35.610 (if applicable)."

8.39 ITEM 10: PATIENT OR HUMAN RESEARCH SUBJECT RELEASE

Regulations: 10 CFR 35.75, 10 CFR 35.2075.

Criteria: Licensees may release from confinement patients or human research subjects (patients) who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). Licensees must provide radiation safety instructions to patients released in accordance with 10 CFR 35.75 (b).

Discussion: 10 CFR 35.75 requires that the licensee provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed one mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed one mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions shall also include: (1) guidance on the interruption or discontinuation of breast-feeding; and (2) information on the potential consequences of failure to follow the guidance. This implies that the licensee will confirm whether a patient is breast-feeding prior to release of the patient.

In addition, 10 CFR 35.75 (c) requires that the licensee maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the TEDE is calculated by: (1) using the retained activity rather than the activity administered; (2) using an occupancy factor less than 0.25 at 1 meter; (3) using the biological or effective half-life; or (4) considering the shielding by tissue.

In 10 CFR 35.75 (d), the licensee is required to maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

Appendix U provides guidance to the applicant for determining when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or treated with implants containing radioactive material (Section 1)
- Instructions to the patient are required by 10 CFR 35.75(b) (Section 2)
- Records are required by 10 CFR 35.75(c) and (d) to be generated and maintained (Section 3).

The appendix lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

Response from Applicant: Provide the following:

A statement that: "We have developed and will provide written instructions to patients or human research subjects, released pursuant to 10 CFR 35.75, that meet the requirements in 10 CFR 35.75."

8.40 ITEM 10: SAFETY PROCEDURES FOR TREATMENTS WHERE PATIENTS ARE HOSPITALIZED

Regulations: 10 CFR 20.1501, 10 CFR 20.1801, 10 CFR 20.2103, 10 CFR 35.315, 10 CFR 35.404, 10 CFR 35.415, 10 CFR 35.615, 10 CFR 35.2404.

Criteria: Applicants must develop and implement procedures to ensure that access to therapy treatment rooms and exposure rates from therapy treatments are limited to maintain doses to occupational workers and members of the public ALARA.

Discussion: 10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615 (LDR and PDR) requires the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients hospitalized in accordance with 10 CFR 35.75. The precautions are to ensure compliance with the exposure limits in 10 CFR Part 20.

10 CFR 35.404(b) requires licensees to perform a radiation survey of the patient immediately after removing the last source from the patient. This is done to confirm that all sources have been removed and accounted for. A record of the patient survey must be maintained for 3 years. 10 CFR 35.615(e) requires that licensed activities where sources are placed within the patient's body be limited to treatments which allow for expeditious removal of a decoupled or jammed source.

Applicants must consider the following elements:

- Provide a private room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage
- Post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room
- Either monitor material and items removed from the patient's or the human research subject's room (e.g., patient linens, surgical dressings, etc.) to determine that their radioactivity cannot be distinguished from the natural background radiation level or to confirm that they do not contain brachytherapy sources with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste
- Notify the RSO and AU as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

10 CFR 20.1501 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized in accordance with 10 CFR 35.75 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

10 CFR 20.1801 requires licensees to secure licensed material in storage from unauthorized access or removal. Therefore, licensees must ensure that access to rooms where patients are hospitalized, in accordance with 10 CFR 35.75, is limited to authorized personnel. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material and unnecessary personnel exposures.

In order to control exposures to individuals in accordance with 10 CFR Part 20, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant: No response is required.

8.41 ITEM 10: SAFETY AND DEVICE CALIBRATION PROCEDURES

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2107, 10 CFR 30.34(e), 10 CFR 35.604, 10 CFR 35.610, 10 CFR 35.615, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.644, 10 CFR 35.645, 10 CFR 35.652, 10 CFR 35.655, 10 CFR 35.657, 10 CFR 35.2310, 10 CFR 35.2404, 10 CFR 35.2605, 10 CFR 35.2632, 10 CFR 35.2633, 10 CFR 35.2635, 10 CFR 35.2642, 10 CFR 35.2643, 10 CFR 35.2645, 10 CFR 35.2652, 10 CFR 35.2655.

Criteria: Applicants must develop and implement procedures for providing radiation safety for the use of sealed sources in devices. Applicants must also develop and implement procedures to ensure that therapy sources and devices are calibrated and operating correctly.

Procedures should be complete and self-contained. Pertinent information contained in equipment manuals and other publications may be extracted and included in your operating procedures. Applicable AAPM documents may be referenced.

Discussion: Provided below is a separate discussion for each functional area where sealed sources in devices are used. The applicant should review the functional area(s) that apply to the type of medical use requested.

Diagnostic Sealed Sources and Devices

Good health physics practice dictates that the applicant will provide personnel with clear and specific instructions on usage of sealed sources or devices containing sealed sources. These procedures may include but are not limited to:

- Service and repair of the device
- Routine proper use for sealed sources or devices containing sealed sources in accordance with the NRC license and 10 CFR Parts 19 and 20
- Reviews and discussions of the sealed sources "device specific" manufacturer literature and instructions
- Description of checks performed on the device to verify its proper operation after it has been moved and before it is used on patients. This should include manufacturer instruction for start-up, warm-up time and phantom analysis for bone mineral analyzers
- Safety and security measures

Teletherapy and GSR Sealed Sources and Devices

Good health physics practice dictates that the applicant will provide personnel with operating procedures to give them clear and specific directions in their duties and responsibilities. These duties may include, safety device checks, instrument calibration, periodic spot checks, quality control checks, and leak tests. Operating procedures should not contain information that does not apply specifically to persons to whom they are directed. For example, housekeeping personnel would not follow the same procedures as therapy technologists. Applicants shall develop and implement procedures to ensure that access to therapy treatment rooms and exposure rates from therapy treatments are limited to maintain doses to occupational workers and members of the public ALARA. The applicant must establish and agree to adhere to written procedures governing the operation of the therapy unit. The applicant shall have written operating procedures specifically developed for and given to particular groups of staff members (e.g., therapists) outlining the responsibilities of each group to ensure your facility's compliance with NRC regulations, the terms and conditions of the license, and the commitments made in license applications and correspondence with NRC. The procedures must include:

- Use of the therapy unit, including security of the device, the console and the console keys
- Safety device checks
- Periodic spot check measurements
- Inspection and servicing
- Full calibration measurements
- Relocation of unit
- Recordkeeping

The functional areas listed above are described in more detail below.

Use of the Therapy Unit

The operating procedures should specify who may operate the unit, how the unit may be used (i.e., in what orientations, for what purposes), typical treatment times and setups, how the unit is to be operated (i.e., the sequence of steps to be followed to begin treatment), and who must be present during the treatment. For example, the AU and AMP must be present for GSR treatments. The operating procedures shall contain instructions to ensure that the patient is alone in the room when the primary beam is on and may specify certain daily checks of the unit to ensure its proper operation.

Safety Device Checks

Safety devices shall be checked periodically to ensure that they are operating properly. Such devices include timers, mechanical and electrical interlocks, warning lights and alarms, helmet position indicator microswitches, safety switches, door interlocks, beam collimators, and other devices that actively warn of, limit, or prevent radiation exposure to either patients or personnel. The frequencies required by the regulations for each safety device varies from daily to annually.

The results shall be recorded. The operating procedures should contain instructions for making the checks, the frequency of such checks, prompt correction of any malfunctions or defects noted, and retention of appropriate records. A simple checklist may be used to complete the task and recordkeeping quickly and efficiently.

When checks of safety devices indicate defects or malfunctions, there may be some delay before the defects or malfunctions can be corrected. The operating procedures should describe the steps that personnel will follow should a delay occur. For example, use of the therapy unit might be prohibited until the problem is corrected.

Documents such as ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment", NCRP Report 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," NUREG/CR-6323, "Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices", NUREG/CR-6324, "Quality Assurance for Gamma Knives" AAPM Report No. 54, "Stereotactic Radiosurgery" provide standards and recommendations for the frequency and procedures for making certain tests. If the standards or recommendations in these documents conflict with NRC regulations or license conditions, the minimum acceptable frequency is that specified in the regulation or license condition.

Relocation of Therapy Unit

10 CFR 35.13 requires that the NRC approve your plans and proposed location *before* a therapy unit is relocated. The operating procedures should ensure that the necessary amendment to the NRC license is obtained before the therapy unit is relocated.

Inspection and Servicing of the Therapy Unit

10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first. This work, to ensure proper functioning of the source exposure mechanism, must be done by a person or firm specifically licensed to do so by the NRC or an Agreement State. Preventive maintenance should also be addressed to ensure that as systems deteriorate from use they are identified and repaired. These items related to the GSR should be included in these sections, such as hydraulic system maintenance; collimator helmet supports, holes, plugs, bushings, and other helmet positioning equipment; and the systems related to the patient couch and the shielding door. Persons holding an Agreement State license are granted a general license to perform the same activities in non-Agreement States, pursuant to the requirements of 10 CFR 150.20. Operating procedures shall be sufficient to ensure compliance with NRC regulations.

Periodic Spot-Check Measurements of Teletherapy Units

10 CFR 35.642 specifies that output spot-check tests must be performed once in each calendar month and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system

needed to make the output measurements. 10 CFR 35.642 also describes spot-checks that must be performed at each source installation. The operating procedures should specify when, how, and by whom the spot-check measurements will be made. The measurements required shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot-check measurements; however, the AMP must review the spot-check measurements within 15 days, as required by 10 CFR 35.642(c).

Teletherapy Full Calibration Measurements

10 CFR 35.632 requires that a licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy source before the first medical use of the unit and under the conditions listed in 10 CFR 35.632(a)(2). Operating procedures shall be sufficient to ensure compliance with 10 CFR 35.632.

Periodic Spot-Check Measurements of GSR Units

10 CFR 35.645 specifies that output spot-check tests must be performed once in each calendar month, and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system needed to make the output measurements. 10 CFR 35.645 also describes additional spot-checks that must be performed monthly, daily, and after each source exchange. The operating procedures should specify when, how, and by whom the spot-check measurements will be made. The measurements required shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot-check measurements; however the AMP must review and initial the spot-check results within 15 days, as required by 10 CFR 35.645(b).

GSR Full Calibration Measurements

10 CFR 35.635 requires that a licensee authorized to use a GSR unit for medical use shall perform full calibration measurements on each GSR source before the first medical use of the unit and under the conditions listed in 10 CFR 35.635(a)(2). Operating procedures shall be sufficient to ensure compliance with 10 CFR 35.635.

Remote Afterloader

Good health physics practice dictates that the applicant will provide personnel with operating procedures to give them clear and specific directions in their duties and responsibilities. These duties may include, safety device checks, instrument calibration, periodic spot checks, quality control checks, and leak tests. Operating procedures should not contain information that does not apply specifically to persons to whom they are directed. For example, housekeeping personnel would not follow the same procedures as therapy technologists. Applicants shall develop and implement procedures to ensure that access to therapy treatment rooms and exposure rates from therapy treatments are limited to maintain doses to occupational workers and members of the public ALARA. The applicant must establish and agree to adhere to written procedures

governing the operation of the therapy unit. The applicant shall develop written operating procedures specifically for and given to particular groups of staff members (e.g., therapists) outlining the responsibilities of each group to ensure your facility's compliance with NRC regulations, the terms and conditions of the license, and the commitments made in license applications and correspondence with NRC. The procedures must include:

- Conduct of surveys following source replacement in remote afterloader devices and when the HDR/PDR device location changes significantly from that existing during previous surveys. At a minimum, the survey program must include surveys defined in the SSDR to ensure that the maximum and average radiation levels from the surface of the remote afterloader device safe do not exceed the levels stated in the SSDR with the source(s) in the shielded position.
- Conduct of surveys incident to use including patient and device surveys performed immediately after each use of the device, or upon responding to a device alarm, to ensure that the source has been returned to the fully shielded position. The patient must be surveyed, pursuant to 10 CFR 35.604, with a portable radiation detection survey instrument to confirm that the source(s) has been removed and returned to the safe shielded position. The survey instrument should be capable of measuring dose rates of 1 – 1000 mrem per hour at 1 meter.
- Steps to ensure that:
 - The device, console, and treatment or storage room will be secured when unattended.
 - The patient will be alone in the treatment room, unless contraindicated, during HDR/PDR therapy.
 - Nursing personnel follow the AU's and RSO's specific instructions regarding care to be provided to a patient during the treatment process. If the treatment is to be conducted over a period of several hours and direct patient care will be required, such instructions should be provided to the nursing staff in writing.
 - Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system should have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and should be relabeled) in accordance with the manufacturer's instructions.
 - A treatment procedure will not be conducted if a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container.
 - During patient treatments, require the AU and the AMP to be present as defined in 10 CFR 35.615.
 - If the interlock system malfunctions, the device will be locked in the off position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
 - If a radiation monitor used to indicate the source position is found to be either inoperable or intermittently inoperable, the device will be locked in the off position and not used, except as may be necessary for repair or replacement, until the radiation monitor is shown to be functioning properly.

- 10 CFR 35.643 and 10 CFR 35.644 require that a licensee authorized to use a remote afterloader unit for medical use shall perform periodic spot-checks on each unit and facility. Operating procedures shall be sufficient to ensure compliance with the regulations.
- 10 CFR 35.633 requires that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before the first medical use of the unit and under the conditions listed in 10 CFR 35.633(a)(2). Operating procedures shall be sufficient to ensure compliance with 10 CFR 35.633.

Recordkeeping

The licensee must maintain certain records to comply with NRC regulations, the conditions of your license, and commitments made in your license application and correspondence with NRC. Operating procedures should identify which individuals within your organization are responsible for maintaining which records. Examples of documents that must be maintained include:

- Copies of NRC licenses, your license applications, and correspondence with the NRC in support of a license request
- Personnel dosimetry records
- Records of survey instrument calibrations
- Records of calibration of the dosimetry system used for full calibration measurements
- Records of calibration or intercomparison of the dosimetry system used for spot-check measurements
- Results of full calibration measurements
- Results of spot-check measurements
- Results of leak tests
- Records of training of new personnel and annual refresher training of personnel
- Records of training in emergency procedures
- Records of full inspection and servicing of the therapy unit
- Records of receipt and disposal of radioactive material

Response from Applicant: Submit the following:

A statement that: "We have developed and will implement written procedures for safe use of sealed sources and calibration of sources that meets the requirements of 10 CFR 20.1101 and the applicable sections of Subpart H.

References: Copies of ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically at the following address: www.ansi.org. Copies of NCRP Report 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at the following

address: www.ncrp.com. See the Notice of Availability on the inside front cover of this draft report to obtain copies of NUREG/CR-6323, "Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices," and NUREG/CR-6324, "Quality Assurance for Gamma Knives." Copies of AAPM Report No. 54, "Stereotactic Radiosurgery," may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or ordered electronically at the following address: www.aapm.org.

8.42 ITEM 10: MOBILE MEDICAL SERVICE

Regulations: 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 35.80, 10 CFR 35.647, 10 CFR 35.2080, 10 CFR 35.2647, 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.37, 10 CFR 71.38, Subpart H of 10 CFR Part 71, 10 CFR 150.20, 49 CFR Parts 171-178, .

Criteria: In addition to the requirements in 10 CFR 35.80, mobile medical service licensees must comply with all other applicable regulations.

Discussion: Appendix V describes specific licensing items pertaining to mobile services. The temporary job site at medical care facilities (client's address) is where mobile medical service licensees use byproduct material. Mobile medical service licensees may transport licensed material and equipment from the van into a client's building, or may bring patients into the van. In either case, the van should be located on the client's property that is under the client's control. In-van imaging services may not be considered an NRC licensed activity if services are limited to patient imaging (i.e., byproduct material is not administered), and byproduct material is not possessed or used.

Self-contained mobile service involves a mobile treatment or administration facility that provides ready to deliver mobile services on arrival at a client's site. The facility is entirely self-contained with a shielded treatment or administration area, remote afterloader device (if applicable), and safety equipment (e.g., dose calibrators, patient viewing systems, intercom, etc.).

Transportable mobile service involves transport of the byproduct material for use in a pre-existing shielded treatment or administration facility at the client site. The mobile service licensee may provide the byproduct material, associated equipment, and trained personnel, or the client may choose to provide the trained personnel to use the byproduct material. Patient treatments with remote afterloaders for this type of service require prior installation of the device in an appropriately shielded and permanently located treatment room. Other support equipment, such as viewing systems, area monitors, and intercoms, must have been separately installed and available for use in the treatment room prior to commencing treatment of patients.

Class 1 (byproduct material, trained personnel, and facility) mobile service providers are authorized to provide the device/facility (e.g., in-van use) and the treatment of (or administration to) patients at the client site. Class 1 mobile service providers are responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).

Class 2 (byproduct material and trained personnel) mobile service providers are authorized to provide the transportation to and use of the byproduct material within the client's facility. Class 2 mobile service providers are also responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).

Class 3 (byproduct material only) mobile service providers are authorized to provide the byproduct material to a client site so that the client can perform treatments (or administrations). Under this class of service, the mobile service provider authorization is limited to the possession, limited servicing, and transport of the byproduct material and associated equipment. The client will need a separate authorization (license) to perform patient treatments (or administrations) with the byproduct material and the client will be responsible for all aspects of byproduct material use and patient treatment(s) (or administrations), as applicable, including, but not limited to, dose calibrator measurements, sealed source calibration, remote afterloader device function checks and all safety system checks.

A mobile service provider may apply for one or multiple classes of service. However, a single client site may be authorized for only a single class of service. This restriction on client sites is intended to eliminate possible confusion that may arise over responsibilities for use and control of byproduct materials that could arise at client sites authorized for multiple classes of service.

For Class 1 and Class 2, mobile medical service licensees must ensure that patients treated meet the release criteria in 10 CFR 35.75.

Note: NRC licensees requesting reciprocity for activities conducted in Agreement States are subject to the general license provisions of equivalent Agreement State regulations as described in 10 CFR 150.20. This general license authorizes persons holding a specific license from the NRC to conduct the same activity in Agreement States if the specific license issued by the NRC does not limit the authorized activity to specific locations or installations. NRC licensees who wish to conduct operations at temporary job sites in an Agreement State should contact that State's radiation control program office for information about State regulations. To ensure compliance with Agreement State reciprocity requirements, a licensee shall request authorization well in advance of scheduled work. In addition to the requirements specified in 10 CFR 150.20, applicants performing procedures through a mobile service should contact the applicable State regulatory agency to determine if mobile services are allowed within the State through reciprocity and to clarify requirements associated with the authorization to practice medicine within the State jurisdiction.

Response from Applicant: Refer to Appendix V for the type of additional information to provide.

8.43 ITEM 10: TRANSPORTATION

Regulations: 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.37, 10 CFR 71.38, Subpart H of 10 CFR Part 71, 49 CFR Parts 171-178.

Criteria: Applicants should develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: The general license in 10 CFR 71.12 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. Before offering a Type B package for shipment, the licensee needs to be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.12 general license. For information about QA plans, see Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7544.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites (e.g., at the licensee's facilities)
- Actually takes possession of the licensed material under its license
- Uses an approved Type B package
- Is registered with NRC as a user of the Type B package
- Has an NRC-approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to medical use licensees. Appendix W lists major DOT regulations that apply to medical licensees.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, a licensee needs to have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1983 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. See the Notice of Availability on inside front cover of this draft report to obtain a copy of the Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979, and Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986.

8.44 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1101, 10 CFR 20.2001-2007, 10 CFR 20.2102, 10 CFR 20.2108, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 35.92, 10 CFR 35.2092, 10 CFR 71.5.

Criteria: Licensed materials must be disposed of in accordance with NRC requirements by: transfer to an authorized recipient; DIS; release to the environment; or treatment or disposal of the licensed material as described in 10 CFR 20.2004. Appropriate records must be maintained.

Discussion: Licensees must develop and implement procedures for waste disposal of licensed material in accordance with 10 CFR 20.1101. Appendix X contains model procedures for DIS and generator or other licensed material return. In 10 CFR 20.2001, NRC requires that licensees dispose of licensed material by specific means. In 10 CFR 20.2006, NRC requires that for licensed material transferred to a land disposal facility, the licensee must comply with the specific requirements in Appendix F to 10 CFR Part 20, i.e., manifest, certification, and control and tracking. In 10 CFR 35.92, NRC specifies the requirements for handling of waste by DIS. In 10 CFR 71.5, NRC requires that licensees who transport licensed material or offer it for transport, comply with the regulations of DOT in 49 CFR Parts 170–189. Applicants shall address the following items (as applicable):

- Except for material suitable for DIS and some animal carcasses, solids must be transferred to an authorized recipient licensed to receive such waste in accordance with 10 CFR 20.2006 or in applicable regulations in 10 CFR Parts 30, 40, 60, 61, 70, or 72. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.
- When setting up a program for DIS, applicants/licensees should consider short-term and long-term storage. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.
- Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Applicants should describe the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water pursuant to 10 CFR 20.1302 and 20.2003, respectively.

- Regulations for disposal in the sanitary sewer appear in paragraph 20.2003. Material must be readily soluble or dispersible in the water. There are monthly and annual limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.2003 (b)) Make a record of the date, radionuclide, estimated activity that was released, and of the sink or toilet at which the material was released.
- Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released and estimated concentration, and of the vent site at which the material was released.
- Liquid scintillation - counting media containing 1.85 kilo-Bq (0.05 mCi) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.2005 (a) (1)). Make a record of the date, radionuclide, estimated activity, calculated concentration, and how the material was disposed.
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must receive specific approval from the NRC. Contact your regional NRC office for guidance on treatment or disposal of material by incineration in accordance with 10 CFR 20.2004.
- Applicants wishing to use waste volume reduction operations, e.g., compactors, must provide the below detailed description along with their response to Item 8.16 (Facility Diagram):
 - A description of the compactor to demonstrate that it is designed to safely compact waste generated in your operations. (e.g., manufacturer's specifications, annotated sketches, photographs)
 - The types, quantities, and concentrations of waste to be compacted
 - An analysis of the potential for airborne release of radioactive material during compaction activities
 - The location of the compactors within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors and procedures for monitoring filter blockage and exchange
 - Methods used to monitor worker breathing zones and/or exhaust systems
 - The types and frequencies of surveys that will be performed for contamination control in the compactor area
 - The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

General Guidance for Waste Disposal

- All radioactivity labels must be removed or obliterated from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed. If waste is to be incinerated, labels may not need to be

defaced. Contact your regional NRC office for guidance on this subject.

- Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

DIS

For radionuclides of byproduct material with a half-life of less than 120 days, licensees may dispose of waste in ordinary trash as long as they follow the below criteria:

- Hold byproduct material for decay until the waste cannot be distinguished from background level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding
- Remove or obliterate all radiation labels
- Maintain proper records.

Returning Sources

Because of the nature of the material contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in 10 CFR 20.2001(a)(1). Authorized recipients are the original manufacturer of the sealed source, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., their license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive the material using one of the methods described in 10 CFR 30.41. Additionally, 10 CFR 71.5 requires that licensees who transport licensed material or offer it for transport, comply with the regulations of DOT in 49 CFR Parts 170–189. Records of the transfer must be maintained as required by 10 CFR 30.51.

Licensees should promptly dispose of unused sealed sources to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Response from Applicant: Provide the following:

A statement that: "We have developed and will implement written waste disposal procedures for licensed material that meet the requirements of 10 CFR 20.1101, the applicable section of Subpart K to 10 CFR Part 20, and 10 CFR 35.92."

The next two items on NRC Form 313 are to be completed on the form itself.

8.45 ITEM 12: FEES

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.46 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. These representatives must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An application for licensing a private practice should be signed by a senior partner or the president. An application for licensing a medical institution (e.g., hospital, or medical center) must be signed by its chief executive officer (or delegate). The individual who signs the application should be identified by title of the office held. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature.

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.
- It is a violation of 10 CFR 30.9 and 10 CFR 30.10 to make a false statement on an application. Civil sanctions including revocation of the license and/or orders removing individuals from licensed activity may be taken.

9 AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

10 CFR 35.13 describes activities that require a license amendment. These include the following:

- Receipt or use of byproduct material for a clinical procedure permitted by Part 35, but not permitted by the license
- Permitting anyone to work as an AU, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b)
- Changing RSO
- Ordering byproduct material in excess of the amount, or radionuclide or form different than currently authorized on the NRC license
- Changing an area or address of use identified in the application or on the license.

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request
- Submit in duplicate, either an NRC Form 313 or a letter requesting amendment or renewal
- Provide the license number
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

Using the suggested wording of responses in this draft report will expedite NRC's review.

10 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d) and (j), 10 CFR 30.51(f).

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days, when its license has expired or a decision has been made plans to permanently cease licensed activities at the entire site regardless of contamination levels.
- Notify NRC, in writing, within 60 days, when principal activities have not been conducted for 24 months or a decision has been made to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to NRC requirements.
- Certify the disposition of licensed materials by submission of NRC Form 314, "Certificate of Disposition of Materials" or equivalent information.
- Before a license is terminated, send the records important to decommissioning (as required by 10 CFR 30.35(g)) to the appropriate NRC regional office. If licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

For guidance on the disposition of licensed material, see the section on "Waste Management." For guidance on decommissioning records, see the section on "Financial Assurance and Record Keeping for Decommissioning."

Licensees should promptly dispose of unused licensed material to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then the applicant must perform decommissioning activities and submit NRC Form 314 or equivalent information.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional or Field Offices; see Appendix Y.

Appendix A

List of Documents Considered in Development of This Draft NUREG

List of Documents Considered in Development of This Draft NUREG

This draft report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), and Information Notices (IN) listed in Table A.1. When this draft report is issued in final form, the documents in Table A.1 will be considered superseded and should not be used. Other references were also used in this draft report and are listed below.

Table A.1

Document Identification	Title	Date
RG 10.8, Revision 2	Guide for the Preparation of Applications for Medical Use Programs	8/87
Appendix X to RG 10.8, Revision 2	Guidance on Complying With New Part 20 Requirements	6/92
Draft RG DG-0009	Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs	3/97
Draft RG FC 414-4	Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs	12/85
P&GD FC 87-2	Standard Review Plan (SRP) for License Applications for the Medical Use of Byproduct Material	12/87
Supplement 1 TO P&GD FC 86-4; Revision 1	Mobile Remote Afterloading Brachytherapy Licensing Module	5/97
P&GD FC 86-4, Revision 1	Information Required for Licensing Remote Afterloading Devices	9/93
Addendum to Revision 1 to P&GD FC 86-4	Information Required for Licensing Remote Afterloading Devices--Increased Source Possession Limits	7/95
P&GD 3-15	Standard Review Plan for Review of Quality Management Programs	6/95
RG 8.39	Release of Patients Administered Radioactive Materials	4/97

RG 8.33	Quality Management Program	10/91
P&GD 3-17 (previously 16)	Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants	
RG 8.23*	Radiation Safety Surveys at Medical Institutions, Revision 1	1/81

Additionally, the below references were used.

References

Title 10, Code of Federal Regulations

1. Part 2 - Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders
2. Part 19 - Notices, Instructions, and Reports to Workers; Inspections
3. Part 20 - Standards for Protection Against Radiation
4. Part 21 - Reporting of Defects and Noncompliance
5. Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material
6. Part 31 - General Domestic Licenses for Byproduct Material
7. Part 32 - Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material
8. Part 33 - Specific Domestic Licenses of Broad Scope for Byproduct Material
9. Part 35 - Medical Use of Byproduct Material
10. Part 40 - Domestic Licensing of Source Material
11. Part 70 - Domestic Licensing of Special Nuclear Material
12. Part 71 - Packaging and Transportation of Radioactive Material
13. Part 150 - Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274
14. Part 170 - Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended
15. Part 171 - Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC

Title 49, Code of Federal Regulations

1. Part 172 - Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements
2. Part 173 - Shippers--General Requirements for Shipments and Packages
3. Part 177 - Carriage by Public Highway
4. Part 178 - Specifications for Packagings

NRC Regulatory Guides (RG)

1. RG 1.86 - Termination of Operating Licenses for Nuclear Reactors, June 1974
2. RG 3.66 - Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72, June 1990
3. RG 7.10, Revision 1 - Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, June 1986
4. RG 8.4 - Direct-Reading and Indirect-Reading Pocket Dosimeters, February 1973
5. RG 8.7 - Instructions for Recording and Reporting Occupational Radiation Exposure Data, Revision 1, June 1992
6. RG 8.9 - Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program, Revision 1, June 1993
7. RG 8.10 - Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable, Revision 1-B, September 1975
8. RG 8.13 (Draft) - Instruction Concerning Prenatal Radiation Exposure, October 1994
9. RG 8.18 - Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable, Revision 1, October 1982
10. RG 8.20 - Applications of Bioassay for I-125 and I-131, Revision 1, September 1979
11. RG 8.25 - Air Sampling in the Workplace, Revision 1, June 1992.
12. RG 8.29 - Instruction Concerning Risks from Occupational Radiation Exposure, Revision 1, February 1996
13. RG 8.34 - Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, July 1992.
14. RG 8.36 - Radiation Dose to the Embryo/Fetus, July 1992
15. RG 10.2 - Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope, Revision 1, December 1976
16. RG 10.5 (Draft) - Applications for Type A Licenses of Broad Scope, October 1994
17. RG 10.8, 1997 - Revision (Draft NUREG 1569 - never published), Program-Specific Guidance for Medical Use Licensees
18. RG FC 412-4 (Draft) - Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985
19. RG FC 413-4 (Draft) - Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985

NRC Information Notices (IN)

1. IN 89-25, Revision 1 - Unauthorized Transfer of Ownership or Control of Licensed Activities
2. IN 94-70 - Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals
3. IN 96-28 - Suggested Guidance Relating to Development and Implementation of Corrective Action
4. IN 97-30 - Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises

NRC Policy and Guidance Directives (P&GD)

1. P&GD FC 90-2, Revision 1 - Standard Review Plan for Evaluating Compliance with Decommissioning Requirements, April 1991

NRC NUREGs

1. NUREG-0267, Revision 1 - Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, October 1982
2. NUREG-1134 - Radiation Protection Training for Personnel Employed in Medical Facilities, May 1985
3. NUREG-1492 - Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, February 1997
4. NUREG-1516 - Effective Management of Radioactive Materials Safety Programs at Medical Facilities, May 1997
5. NUREG-1539 - Methodology and Findings of the NRC's Materials Licensing Process Redesign, April 1996
6. NUREG-1541 (Draft) - Process and Design for Consolidating and Updating Materials Licensing Guidance, April 1996
7. NUREG-1556, Volume 3 (Draft) - Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration, September 1997
8. NUREG-1600 - General Statement of Policy and Procedures for NRC Enforcement Actions, June 1995 and Compilation of NRC Enforcement Policy as of September 10, 1997
9. NUREG/CR-4444 - Radiation Safety Issues Related to Radiolabeled Antibodies, 1991
10. NUREG/CR-4884 - Interpretation of Bioassay Measurement, July 1987
11. NUREG/CR-6323 - Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices: A Preliminary Application, September 1995
12. NUREG/CR-6324 - Quality Assurance for Gamma Knives, September 1995

National Council on Radiation Protection and Measurements (NCRP) Publications

1. NCRP Report No. 30 - Safe Handling of Radioactive Materials, 1989
2. NCRP Report No. 37 - Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970
3. NCRP Report No. 40 - Protection Against Radiation from Brachytherapy Sources, 1972
4. NCRP Report No. 49 - Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies up to 10 MeV, 1976
5. NCRP Report No. 57 - Instrumentation and Monitoring Methods for Radiation Protection, 1978
6. NCRP Report No. 58 - A Handbook of Radioactivity Measurement Procedures, Second Edition, 1985
7. NCRP Report No. 69 - Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, 1981
8. NCRP Report No. 71 - Operational Radiation Safety - Training, 1983

9. NCRP Report No. 87 - Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, February 1987
10. NCRP Report No. 102 - Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use), 1989
11. NCRP Report No. 105 - Radiation Protection for Medical and Allied Health Personnel, 1989
12. NCRP Report No. 107 - Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, 1990
13. NCRP Commentary No. 11 - Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, February 1995

International Commission on Radiological Protection (ICRP) Publications

1. ICRP Report No. 26 - Recommendations of the International Commission on Radiological Protection, 1977
2. ICRP Report No. 30 - Limits for Intakes of Radionuclides by Workers, 1978
3. ICRP Report No. 35 - General Principles of Monitoring for Radiation Protection of Workers, 1982
4. ICRP Publication No. 53 - Radiation Dose to Patients from Radiopharmaceuticals, 1987
5. ICRP Publication 54 - Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation, 1987

ANSI Standards

1. ANSI N13.4-1971 (R1983) - Specification of Portable X- or Gamma Radiation Survey Instruments
2. ANSI N13.5-1972 (R1989) - Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation
3. ANSI N13.6-1966 (R1989) - Practice for Occupational Radiation Exposure Records Systems
4. ANSI N14.5-1987 - Leakage Tests on Packages for Shipment of Radioactive Materials
5. ANSI N42.12-1994 - Calibration and Usage of Sodium Iodide Detector Systems
6. ANSI N42.13-1986 (R1993) - Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides
7. ANSI N42.15-1990 - Performance Verification of Liquid Scintillation Counting Systems
8. ANSI N42.17A-1989 - Performance Specifications for Health Physics Instrumentation-Portable Instrumentation for Use in Normal Environmental Conditions
9. ANSI N322 - Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters
10. ANSI N323A-1997 - Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments
11. ANSI N449.1-1978 (R1984) - Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment

American Association of Physicists in Medicine (AAPM) Reports

1. AAPM Radiation Therapy Committee Task Group No. 40 - Comprehensive QA for Radiation Oncology, 1994
2. AAPM Radiation Therapy Committee Task Group No. 56 - Code of Practice for Brachytherapy Physics, 1997
3. AAPM Radiation Therapy Committee Task Group No. 59 - HDR Treatment Delivery Safety, 1997 Draft
4. AAPM Report No. 41 - Remote Afterloading Technology, 1993
5. AAPM Report No. 54 - Stereotactic Radiosurgery, 1995

Other Technical Publications

1. International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, 1968
2. U.S. Department of Health, Education, and Welfare, "Radiological Health Handbook," 1970
3. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients - The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970
4. International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970
5. IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971
6. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978
7. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10⁻⁶ a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980
8. Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981
9. Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984
10. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable over Ten Years Post Intake," *Radiation Protection Dosimetry*, Volume 11, No. 1, 1985
11. "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987
12. J. R. Johnson and D. W. Dunford, "GENMOD--A Program for Internal Dosimetry Calculations," AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987
13. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, 1988

14. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal*, Volume 55, No. 6, 1988
15. A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990
16. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990
17. M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991
18. P. Early, D. B. Sodee, "Principles and Practice of Nuclear Medicine," 2nd ed., 1995
19. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," *Pediatric Nuclear Medicine*, 1995
20. "Intravascular Brachytherapy - Guidance for Data to be Submitted to the Food and Drug Administration In Support of Investigational Device Exemption (IDE) Applications," Draft Version 1.3, 1996
21. R.O. Dunkelberger, II, "Which Probe Should I Use," *Baltimore-Washington Health Physics Society Newsletter*

Appendix B
NRC Form 313

(7-98)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐
☐
☐

- A. NEW LICENSE
B. AMENDMENT TO LICENSE NUMBER _____
C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

Appendix C

License Application Checklist and Sample Licenses

License Application Checklist and Sample Licenses

The instructions on Table C.1, the Applicability Table, may be followed to determine whether the information must be provided or if "NA" may be the response to each item that follows.

To determine those items to which you must respond, "highlight" the columns under the categories of materials you requested in item 5. If any "Y" beside an item is highlighted, you must provide detailed information in response to the item. If the letters "NA" (not applicable) are highlighted, you may respond "NA" on your application. If any "N" beside an item is highlighted, no information in response is required; however the NRC regulations that apply to the given category apply to your type of license. If any "P" beside an item is highlighted, you must provide a commitment to develop and implement a procedure in response to the item. Note that some modules have additional item numbers that may need to be addressed.

In addition, sample licenses are included that may provide guidance on the particular type of medical use you are requesting.

Table C.1 Applicability Table

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.600	35.600	35.100	AP P
N/A	Unsealed Byproduct Material - Low Dose	Y								
N/A	Unsealed Byproduct Material - High Dose		Y							
N/A	Manual Brachytherapy			Y						
N/A	Sealed Sources for Diagnosis				Y					
N/A	Teletherapy Devices					Y				
N/A	Remote Afterloader Devices						Y			
N/A	Gamma Stereotactic Radiosurgery Devices							Y		
N/A	Emerging Technologies								Y	
8.6	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	Y	Y	E
8.7	Sealed Source Registry	N	N	N	N	N	N	N	N	

8.10	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	Y	Y	F, G
8.11	Authorized User Training and Experience	Y	Y	Y	Y	Y	Y	Y	Y	G
8.12	Authorized Nuclear Pharmacists Training and Experience	Y	Y	N/A	N/A	N/A	N/A	N/A	Y	G
8.13	Authorized Medical Physicist Training and Experience	N/A	N/A	Y	N/A	Y	Y	Y	Y	G
8.14	Training Program	N	N	N	N	N	N	N	N	H
8.16	Facility Diagram and Equipment	Y	Y	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instrument Calibration	P	P	P	N	P	P	P	P	I
8.18	Dose Calibrator Calibration	P	P	N/A	N/A	N/A	N/A	N/A	P	J
8.19	Dosimetry Equipment and Therapy Sealed Source Calibration	N/A	N/A	P	N/A	P	P	P	P	
8.20	Other Equipment and Facilities	Y	Y	Y	Y	Y	Y	Y	Y	
8.22	Audit Program	N	N	N	N	N	N	N	N	K
8.23	Occupational Dose	P	P	P	P	P	P	P	P	L
8.24	Public Dose	N	N	N	N	N	N	N	N	M
8.25	Minimization of Contamination	N	N	N	N	N	N	N	N	
8.26	Operating and Emergency Procedures	N	N	N	N	N	N	N	N	N
8.28	Ordering and Receiving	N	N	N	N	N	N	N	N	O
8.29	Opening Packages	P	P	P	P	P	P	P	P	P
8.30	Sealed Source Inventory	N	N	N	N	N	N	N	N	
8.31	Use Records	N	N	N	N	N	N	N	N	
8.32	Leak Tests	N	N	N	N	N	N	N	N	Q
8.33	Area Surveys	P	P	P	P	P	P	P	P	R
8.34	Written Directive Procedures	N/A	P	P	N/A	P	P	P	P	S
8.35	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	N/A	N/A	P	T

8.36	Maintenance of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	Y	Y	
8.37	Spill Procedures	P	P	N/A	N/A	N/A	N/A	N/A	P	N
8.38	Emergency Response for Sealed Sources or Devices	N/A	N/A	P	P	P	P	P	P	N
8.39	Patient or Human Research Subject Release	P	P	P	N/A	N	N	N	P	U
8.40	Safety Precautions for Therapy Treatments where Patients are Hospitalized	N/A	N	N	N/A	N/A	N	N/A	N	
8.41	Safety and Device Calibration Procedures	N/A	N/A	N/A	P	P	P	P	P	
8.42	Mobile Use of Radionuclides	Y	Y	Y	Y	Y	Y	Y	Y	V
8.43	Transportation	N	N	N	N	N	N	N	N	W
8.44	Waste Management	P	P	P	P	P	P	P	P	X

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Gamma Knife		3. License number 99-12345-01
2. 100 Main Street King of Prussia, Pennsylvania 19406		4. Expiration date May 31, 2002
		5. Docket No. 030-54321 Reference No.
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Sealed Sources (Model No. _____ Serial No. _____)	A. _____ curies per source and _____ curies total
9. Authorized use:		
A. One source to be used in _____ Stereotactic Radiosurgery device for therapeutic treatment of humans. One source in its shipping container as necessary for source replacement.		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 100 Main Street, King of Prussia, Pennsylvania.
11. A. Licensed material shall be used by or under the supervision of a team of at least three individuals, to include the following: a Neurosurgeon, a Radiation Therapist, and a Medical Physicist, each of whom is specifically named on the license.
 - B. Radiation Therapists for this license are John Smith, M.D. and Jessica Water, M.D.
 - C. Neurosurgeons for this license are Richard Adams, M.D. and Martin Rossi, M.D.
 - D. The Medical Physicists for this license are Kimberly Therapy, Ph.D. and Ronald Stereo, M.S.
12. The Radiation Safety Officer for this license is Kimberly Therapy, Ph.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-12345-01Docket or Reference Number
030-54321

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated December 15, 1996
 - B. Letter dated March 4, 1997
 - C. Letter dated May 8, 1997

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Medical Institution Limited		3. License number 99-02120-01
2. 1234 Main Street Anytown, Pennsylvania 02120		4. Expiration date March 31, 2009
		5. Docket No. 030-02120 Reference No.
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any, except generators	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. 300 millicuries
D. Any byproduct material identified in 10 CFR 35.400	D. Sealed sources	D. 500 millicuries
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources (Manufacturer No. xxx, Model No. yyy)	E. Not to exceed 0.5 curies per source and 1 curie total
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. 50 millicuries
G. Cesium 137	G. Sealed source (Manufacturer No. aaa, Model No. bbb)	G. 200 millicuries
H. Americium 241	H. Sealed sources (Manufacturer No. zzz, Model No. ccc)	H. Not to exceed ___ millicuries per source and ___ millicuries total
I. Depleted Uranium	I. Metal	I. 99 kilograms

[NOTE: INSERT TOTAL POSSESSION LIMIT IN ITEMS 8.C, D, F AND G. INSERT MANUFACTURER AND MODEL NUMBER OF SEALED SOURCES IN PARENTHESIS IN ITEM 7.E, G AND H. INSERT ACTIVITY PER SOURCE AND TOTAL ACTIVITY FOR SEALED SOURCES IN ITEM 8.E and H. DEPLETED URANIUM SHOULD NOT EXCEED 999 KILOGRAMS IN ITEM 8.I. AT 1,000 KILOGRAMS, A LICENSEE IS REQUIRED TO FILE A STATEMENT ANNUALLY REGARDING FOREIGN ORIGIN SOURCE MATERIAL SEE 40.64(b).]

9. Authorized use:

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 99-02120-01

Docket or Reference Number 030-02120

[NOTE: INSERT MANUFACTURER AND MODEL NUMBER OF DEVICE IN ITEM 9.G. AMERICIUM 241 IN ITEM 6.H IS NOT COVERED BY 10 CFR 35.67 (Calibration and Reference Sources), OTHERWISE IT WOULD NOT NEED TO BE LISTED.]

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
- B. Any imaging and localization procedure approved in 10 CFR 35.200.
- C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
- D. Any brachytherapy procedure approved in 10 CFR 35.400.
- E. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. In vitro studies.
- G. Non-human use. For use in a _____ Model _____ for calibration and checking of licensee's survey instruments.
- H. Use as an anatomical marker.
- I. Shielding in a linear accelerator.

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located at 1234 Main Street, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Jane Diagnostic, M.D.

[NOTE: THERE MUST BE AT LEAST ONE AUTHORIZED USER LISTED IN CONDITION 12 WHO IS AUTHORIZED FOR EACH OF THE MATERIALS AND USES LISTED IN ITEM 6. FOR EXAMPLE: IF JOHN THERAPY, M.D. LEFT THE INSTITUTION AND NO AUTHORIZED USER QUALIFIED FOR HIS MATERIAL AND USE AUTHORIZATIONS WAS ADDED TO THE LICENSE, 35.400 MATERIALS AND DU WOULD NEED TO BE REMOVED FROM THE LICENSE. HOWEVER, IF THOMAS GROUP, D.O. LEFT, NO CHANGES TO THE LICENSEES' MATERIALS USE AUTHORIZATION WOULD BE NEEDED.]



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 99-02120-01

Docket or Reference Number 030-02120

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

Jane Diagnostic, M.D.

35.100; 35.200; 35.300; 35.500;
Cesium 137; Americium 241

Thomas Group, D.O.

35.100; 35.200; Strontium 89 for uses
identified in 35.300

John Therapy, M.D.

35.400; Depleted Uranium

James Pathology, Ph.D.

In-vitro studies

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

[NOTE: THE CESIUM-137 SEALED SOURCE, LISTED IN ITEM 6.G AND THE AMERICIUM SOURCE IN ITEM 6.H, ARE NOT COVERED BY PART 35 (35.67, 35.400, 35.500 and 35.600) AND REQUIRE THAT LICENSE CONDITIONS 14-16 REGARDING USES OF SEALED SOURCES BE LISTED ON THE LICENSE. SEALED SOURCE CONDITIONS NEED NOT BE LISTED ON A MEDICAL LICENSE UNLESS THE LICENSE AUTHORIZES A SEALED SOURCE NOT COVERED BY PART 35.]

14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
16. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

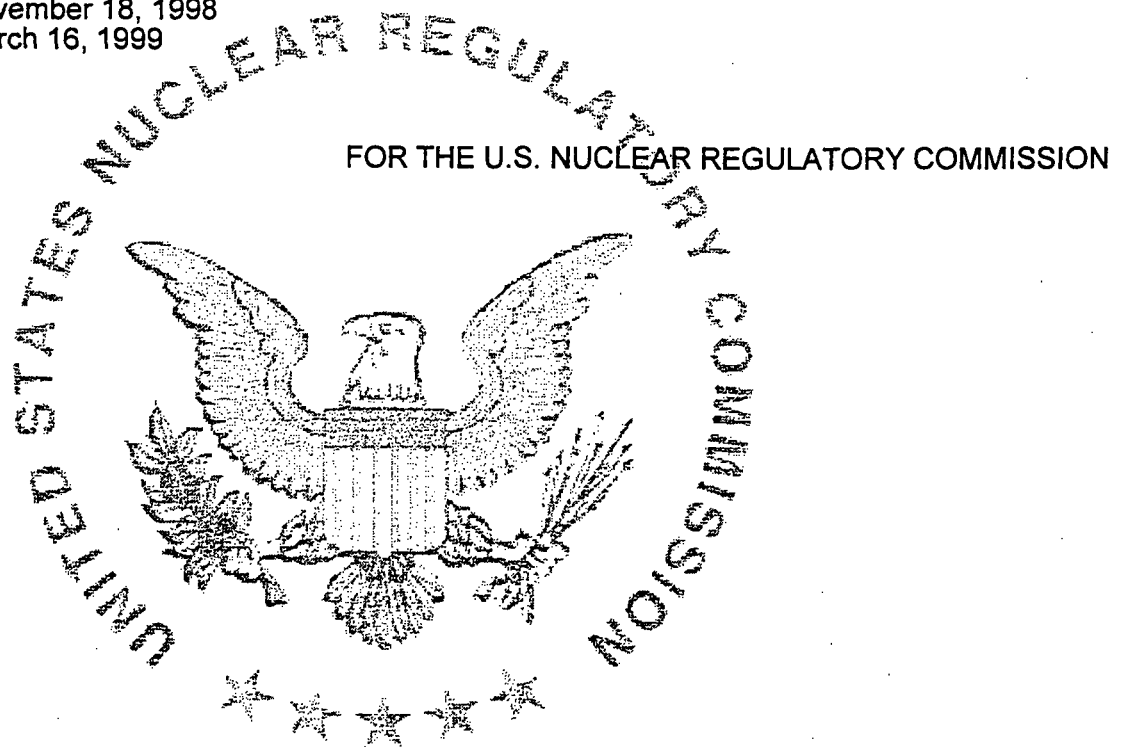
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 99-02120-01

Docket or Reference Number 030-02120

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated June 10, 1998
- B. Letter dated November 18, 1998
- C. Letter dated March 16, 1999

Date March 20, 1999*Original signed by*

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Medical Institution Limited with differing authorizations for two locations of use and 35.75 limitation on 35.300 uses	3. License number 99-02120-04 is amended in its entirety to read as follows:	
2. 3140 Highland Road Hermitage, Pennsylvania 02120	4. Expiration date March 31, 2004	
	5. Docket No. 030-02120 Reference No.	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. ___ millicuries
D. Any byproduct material identified in 10 CFR 35.500	D. Sealed sources	D. Not to exceed ___ curies per source and ___ curies total
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. ___ millicuries
9. Authorized use:		
A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100		
B. Any imaging and localization procedure approved in 10 CFR 35.200.		
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.		
D. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).		
E. <u>In vitro</u> studies.		

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number

99-02120-04

Docket or Reference Number

030-02120

Amendment No. 01

CONDITIONS

10. A. Licensed material may be used at the licensee's facilities located at South Division, 110 Main Street, Greenville, Pennsylvania.
- B. Licensed material in Items 6.A., 6.B., excluding generators and gas, and 6.E. may be used at the licensee's facilities located at North Division, 2200 Memorial Drive, Farrell, Pennsylvania.
11. The Radiation Safety Officer for this license is Frank N. Stein, M.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

Frank N. Stein, M.D.

35.100; 35.200; 35.300; 35.500

In vitro studies

Kevin Leonard, M.D.

35.100; 35.200; 35.300; 35.500

In vitro studies

Tom B. Jones, M.D.

35.100; 35.200; 35.300; 35.500

In vitro studies

Gilbert Lawrence, M.D.

35.300

John Miller, M.D.

35.100; 35.200; 35.500

Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction

In vitro studies

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

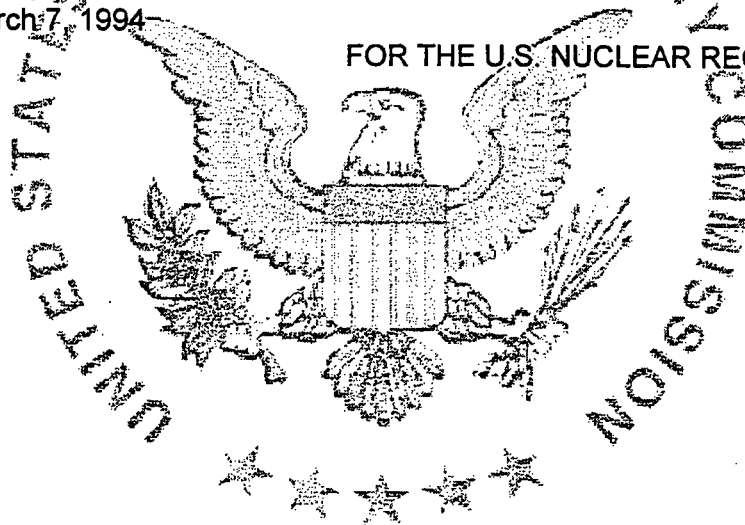
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-02120-04Docket or Reference Number
030-02120

Amendment No. 01

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern, unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated January 10, 1993
- B. Letter received July 13, 1993
- C. Letter dated March 7, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION



Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

In accordance with the application dated
September 30, 1994

1. Sample Pacemaker License

3. License number SNM-22160 is amended in its
entirety to read as follows:

2. 100 Medical Center Drive
King of Prussia, Pennsylvania 19406

4. Expiration date October 31, 1999

5. Docket No. -070-22160
Reference No.

6. Byproduct, source, and/or special
nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may
possess at any one time under this
license

A. Plutonium

A. Sealed source (principal
radionuclide Pu-238)

A. Not to exceed _____ milligrams
per source and _____ grams
total

9. Authorized use:

A. As a component of _____ nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____, this authorization includes: follow-up, explantation, recovery, disposal and implantation.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 100 Medical Center Drive, King of Prussia, Pennsylvania.
11. The Radiation Safety Officer for this license is Chief Radiologist, M.D.
12. The physicians responsible for implantation, follow-up, explantation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are Chief Cardiosurgeon, M.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number SNM-22160

Docket or Reference Number 070-22160

Amendment No. 01

13. The specified possession limit for cardiac pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.
14. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated September 30, 1994
- B. Letter received October 15, 1994



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Sample Medical Private Practice
permitting only out-patient therapy
2. 123 Clinic Road
King of Prussia, Pennsylvania 02200

3. License number 99-02200-01

4. Expiration date March 31, 2004

5. Docket No. 030-02200

Reference No.

6. Byproduct, source, and/or special nuclear material

A. Technetium 99m

B. Iodine 131

C. Strontium 90

D. Palladium 103

E. Iodine 125

7. Chemical and/or physical form

A. Any

B. As identified in 10 CFR 35.300

C. As identified in 10 CFR 35.400

D. As identified in 10 CFR 35.400

E. As identified in 10 CFR 35.400

8. Maximum amount that licensee may possess at any one time under this license

A. 30 millicuries per unit dose not to exceed 150 millicuries total

B. 60 millicuries

C. 55 millicuries

D. 500 millicuries

E. 500 millicuries

[NOTE: ALTHOUGH MANY ELEMENTS OF 35.300 AND 35.400 ARE REPRESENTED IN 6 B-E BELOW, FULL 35.300 AND 35.400 AUTHORIZATIONS ARE NOT PRESENT. SEPARATE LINE ITEM LISTINGS MUST APPEAR.]

9. Authorized use:

[NOTE: IN ADDITION TO "TIE DOWN" COMMITMENTS FROM THE LICENSEE, ITEMS 9. D AND E RESTRICT AUTHORIZED USE TO PERMIT ONLY OUT-PATIENT PROCEDURES.]

- A. Any imaging and localization procedure approved in 10 CFR 35.200.
- B. Diagnosis and treatment of hyperthyroidism, and treatment of cardiac dysfunction.
- C. Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and approved in 10 CFR 35.400.
- D. and E. Any manual brachytherapy procedure approved in 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 123 Clinic Road, King of Prussia,

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-02200-01Docket or Reference Number
030-02200

Pennsylvania.

11. The Radiation Safety Officer for this license is Melba Toast, M.D.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

Melba Toast, M.D.

35.200; Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction

Patty Melt, M.D.

Strontium 90 for treatment of superficial eye conditions; Palladium 103 for uses identified in 10 CFR 35.400; Iodine 125 for uses identified in 10 CFR 35.400

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated April 22, 1993
 - B. Letter dated July 8, 1993
 - C. Letter dated February 10, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee			
1. Sample High Dose Rate Remote Afterloader		3. License number	99-02230-01
2. 111 Afterloader Road		4. Expiration date	August 31, 2001
Brachytherapy, New Jersey 02230		5. Docket No.	030-02230
		Reference No.	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Iridium 192	A. Sealed Sources (Model No. xxx Serial No. yyy)	A. 10 curies per source and 20 curies total	
9. Authorized use:			
[NOTE: INSERT THE SEALED SOURCE MANUFACTURER AND MODEL NUMBER IN 7.A PARENTHESIS ABOVE. INSERT HDR AFTERLOADING UNIT MANUFACTURER AND MODEL NUMBER IN BLANK IN 9.A BELOW.]			
A. One source to be used in a _____ High Dose Rate Remote Afterloading Brachytherapy Device for therapeutic treatment. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 111 Afterloader Street, Brachytherapy, New Jersey.
11. The Radiation Safety Officer for this license is Cecil Source, M.D.
12. The Medical Physicist for this license is Albert Einstein, Ph.D.
13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

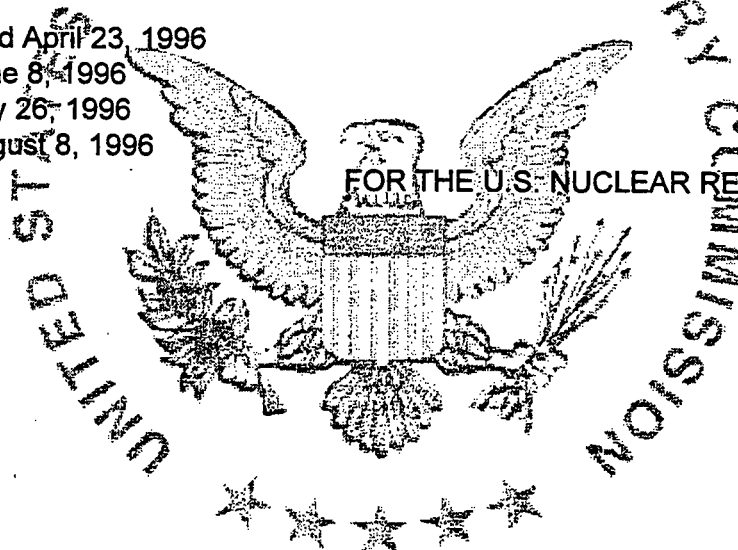
Authorized UserMaterial and Use

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-02230-01Docket or Reference Number
030-02230

Cecil Source, M.D.

Iridium 192 for uses in a High Dose Rate
Remote Afterloading Brachytherapy Device

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations:
- A. Application dated April 23, 1996
 - B. Letter dated June 8, 1996
 - C. Letter dated July 26, 1996
 - D. Letter dated August 8, 1996



Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Teletherapy		3. License number 99-02300-01
2. 200 Cobalt Street King of Prussia, Pennsylvania 02300		4. Expiration date October 31, 2004
		5. Docket No. 030-02300 Reference No.
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Sealed sources (Model No. xxx; Serial No. yyy)	A. Not to exceed 5,500 curies per source and 11,000 curies total
B. Depleted Uranium	B. Metal	B. kilograms
9. Authorized use: [NOTE: INSERT TELETHERAPY SEALED SOURCE MANUFACTURER AND MODEL NUMBER IN 7.A PARENTHESIS ABOVE. DEPLETED URANIUM POSSESSION LIMIT IN 8.B ABOVE MAY NOT EXCEED 999 KILOGRAMS. INSERT TELETHERAPY UNIT/DEVICE MANUFACTURER AND MODEL NUMBER IN BLANK IN 9.A BELOW.]		
A. One source for medical use described in 10 CFR 35.600, in a _____ teletherapy unit. One source in its shipping container or as necessary for replacement of the source in the teletherapy unit.		
B. Shielding in a teletherapy unit.		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 200 Cobalt Street, King of Prussia, Pennsylvania.
11. The Radiation Safety Officer for this license is Sarah Smith, M.S.
12. The Medical Physicist for this license is Sarah Smith, M.S.
13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-02300-01Docket or Reference Number
030-02300

David Jones, M.D.

35.600; Depleted uranium

14. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated March 4, 1994
B. Letter dated May 12, 1994
C. Letter dated October 7, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

Original signed by _____

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Sample In-Vitro Testing Laboratory

2. 1234 Clinical Way
Petri, Delaware 02410

In accordance with the application dated July 17, 1994,

3. License number 99-02410-01 is amended in its entirety to read as follows:

4. Expiration date September 30, 2004

5. Docket No. 030-02410
Reference No.

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Hydrogen 3

A. Any

A. 5 millicuries

B. Carbon 14

B. Any

B. 5 millicuries

C. Phosphorus 32

C. Any

C. 5 millicuries

D. Iron 59

D. Any

D. 2 millicuries

E. Iodine 125

E. Labelled compounds

E. 10 millicuries

9. Authorized use:

A. through E. In vitro laboratory studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1234 Clinical Way, Petri, Delaware.

11. A. Licensed material shall be used by, or under the supervision of, Maria Kitt, Ray D. O'Tracer or Otto Radiograph.

B. The Radiation Safety Officer for this license is Maria Kitt.

12. Licensed material shall not be used in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 99-02410-0

Docket or Reference Number 030-02410

Amendment No. 01

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 17, 1994
B. Letter dated September 8, 1994

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date _____

By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix D

**Information Needed for Transfer of
Control**

Information Needed for Transfer of Control

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license (10 CFR 30.34(b)). If NRC finds that the transfer is in accordance with the Act, NRC may, at the NRC's option, authorize the transfer by license amendment. Otherwise, a new license authorizing the transfer may be issued. The licensee must provide the following information concerning changes of control. If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as RSO, AUs, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will continue to exist without an NRC license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
9. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.

10. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
11. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35. Include both information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.
12. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site and should provide evidence of adequate resources to fund decommissioning, or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, either that it accepts full responsibility for open inspection items and/or any resulting enforcement actions, or that the transferee proposes alternative measures for meeting the requirements, or that the transferor provides a commitment to close out all such actions with NRC before license transfer.

13. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, including the conditions of transfer, with the transferee made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
14. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If the transferee does not make such a commitment, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Appendix E

**Guidance on Financial Assurance
Determination**

Guidance on Financial Assurance Determination

Determining Need for Financial Assurance for Decommissioning

The half lives of unsealed byproduct material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only to consider licensed material in sealed sources to evaluate the need for financial assurance. Use Table E.1 to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed byproduct material with half lives greater than 120 days, refer to 10 CFR 30.35 and Appendix B to Part 30 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in Table E.1 and must be used in determining the need for financial assurance for both sealed and unsealed byproduct material.

Table E.1 Worksheet for Determining Need for Financial Assurance for Sealed Sources

Step Number	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerels.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit financial assurance. RG 3.66,* "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below, since this mechanism is not described in RG 3.66.

* See the Notice of Availability (inside front cover of this draft report) to obtain copies of RG 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," (dated June 1990).

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]

TO: U. S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 [or appropriate regional address]

STATEMENT OF INTENT

As [Title] of [Licensee Name], I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by U. S. Nuclear Regulatory Commission Material License No. _____. This authority is established by [Name of Document(s) Governing Control of Funds]. Within this authority, I intend to have funds made available when necessary, in an amount up to [Dollar Amount] to decommission [Description of Facilities]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [Name of Documents] is attached as evidence that I am authorized to represent [Licensee Name] in this transaction.

[SIGNATURE]

[NAME]

[TITLE]

Attachment: As stated

Appendix F

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.1). Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions
- Individuals installing, relocating, maintaining, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or that personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Licensed material is properly secured
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, or fire
- Medical events and precursor events are investigated and reported to the NRC. Cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Audits of the radiation protection program are performed at least annually and documented
- If violations of regulations or license conditions or program weaknesses are identified, effective corrective actions are developed, implemented, and documented

- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____ have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads

Appendix G

**Documentation of Training and
Experience**

Documentation of Training and Experience

General Guidance

Applicants must provide documentation specific enough to show clearly that all of the required training and experience elements in the applicable sections of 10 CFR Part 35 have been met. Required training and experience should be documented on the provided NRC Forms 313A and 313B or in a letter.

The required training and experience described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document as having had related continuing education, retraining, and experience since the required training and experience were obtained. Complete retraining is neither practical nor necessary in most cases. Examples of acceptable continuing education and experience are:

1. Successful completion of didactic review courses that include radiation safety practices relative to the proposed type of authorized medical use.
2. Practical and laboratory experience with patient procedures using radioactive material, for the same use(s) for which the applicant is requesting authorization.
3. Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization.
4. For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an inservice to review the emergency procedures relative to the therapy unit to be used by the applicant.

The simplest and most straightforward method of demonstrating acceptable training and experience is through certification by one of the professional boards recognized by the NRC. Equally straightforward is evidence that the applicant is listed as an AU on an NRC or Agreement State license or permit issued by a medical broad scope licensee, provided that the applicant is authorized for the same types of use(s) being requested in the application under review, and that the applicant meets the requirements for recentness of training criteria described in 10 CFR 35.59. For AUs who have been previously authorized under a medical broad scope license, the applicant should submit either verification of previous authorization(s) granted by the broad scope licensee or evidence of acceptable training and experience.

The NRC recognizes supervised work and practical experience, such as that described in 10 CFR 35.292(b), conducted under a preceptor in a licensed material use program. A preceptor is an AU who provides frequent direction, instruction and direct oversight of the student as the student completes the required work and practical experience in the use of byproduct material.

Preceptorships may occur at various licensed facilities, from a large teaching university hospital to a small private practice. Upon completion of the supervised work and practical experience, the applicant should either submit the preceptor forms provided as NRC Forms 313A and 313B to NRC Form 313, "Materials License Application" or a letter from the preceptor that indicates that the applicant has obtained all required experience elements.

There is no NRC requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. NRC recognizes that the AU may or may not be the physician who interprets such studies. Additionally, NRC regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals.

TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)
2. For Physicians, State or Territory Where Licensed

3. Certification

Specialty Board	Category	Month and Year Certified

4. Didactic Training

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
Other			

5. Practical Experience with Radiation. (Actual use of radionuclides or equivalent experience)

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Clock Hours and Dates	Related Radiation Safety Exam Score

6. Formal Training			
Degree, Area of Study	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.294).

7. _____ The individual named in item 1. of this form is competent to function independently as an authorized _____
 (Yes/No) *Note: Response to Item 7. is applicable to proposed authorized users, medical physicists, or radiation safety officer for the type of medical use requested.*

8. The training and experience indicated above was obtained under the supervision of:	10. Preceptor's Signature
a. Name of Supervisor _____	
b. Mailing Address _____	11. Preceptor's Name (Printed Clearly)
c. City _____	
9. Materials License Number	12. Date

PRECEPTOR STATEMENT

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

Supplement B must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

1. Name of Individual, Proposed Authorization (e.g., Authorized User), and Applicable Training Requirements (e.g., 10 CFR 35.490):

Name, Proposed Authorization, and Applicable Training Requirements

Street Address

City

State

Zip Code

2. Supervised Experience of Above Named Individual

Radionuclide	Type of Use	Number of Cases Involving Personal Participation	Location and Corresponding Materials License Number, Dates, and Clock Hours of Experience

PRECEPTOR STATEMENT *(Cont'd)*

2. Supervised Experience of Above Named Individual *(Cont'd)*

Radionuclide	Type of Use	Number of Cases Involving Personal Participation	Location and Corresponding Materials License Number, Dates, and Clock Hours of Experience

3. _____ The individual named in item 1. of this form is competent to operate independently a nuclear pharmacy.
 (Yes/No) *Note: Response to Item 3. is only applicable to proposed authorized nuclear pharmacists.*

4. The training and experience indicated above was obtained under the supervision of:

a. Name of Supervisor _____

b. Mailing Address _____

c. City _____

6. Preceptor's Signature _____

7. Preceptor's Name (Printed Clearly) _____

5. Materials License Number _____

8. Date _____

Appendix H

Model Training Program

Model Training Program

Model Training Program for Medical Uses of Radionuclides, Sealed Sources and Medical Devices Containing Sealed Sources

Personnel shall be instructed before assuming duties with, or in the vicinity of radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least three years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Usage of Byproduct Material

We will instruct the professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) providing or involved in the care of patients during diagnostic or therapeutic procedures in the following topics, commensurate with his/her duties:

1. Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues (10 CFR 19.12)
2. Basic radiation protection to include concepts of time, distance, and shielding (10 CFR 19.12)
3. Concept of maintaining exposure ALARA (10 CFR 20.1101)
4. Risk estimates, including comparison with other health risks (10 CFR 19.12)
5. Posting requirements (10 CFR 20.1902)
6. Proper use of personnel dosimetry (when applicable) (10 CFR 20.1201)
7. Access control procedures (10 CFR 20.1601, 10 CFR 20.1802)
8. Proper use of radiation shielding, if used (10 CFR 19.12)
9. Patient release procedures (10 CFR 35.75)
10. Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care. (10 CFR 19.12)
11. Occupational dose limits and their significance (10 CFR 20.1201)
12. Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208)
13. Worker's right to be informed of occupational radiation exposure (10 CFR 19.13)
14. Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12)
15. Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12)
16. Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11)

17. Proper recordkeeping required by NRC regulations (10 CFR 19.12, 10 CFR 35.27)
18. Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas (10 CFR 20.1501)
19. Proper use of required survey instruments (10 CFR 20.1501)
20. Emergency procedures (10 CFR 19.12)
21. Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36)
22. Dose to individual members of the public (10 CFR 20.1301)
23. Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (10 CFR 35.27)

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Therapeutic Quantities of Byproduct Material (Including Greater than 30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, we will instruct staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist) in the following topics, commensurate with his/her duties:

1. Leak testing of sealed sources (10 CFR 35.67)
2. Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
3. Operating instructions (10 CFR 35.27, 10 CFR 35.610)
4. Computerized treatment planning system (10 CFR 35.657)
5. Dosimetry protocol (10 CFR 35.610)
6. Detailed pretreatment quality assurance checks (10 CFR 35.27)
7. Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410)
8. Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
9. Visitor control procedures, such as visitor's stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
10. Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR; correct positioning of the helmet) (10 CFR 35.41)
11. Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
12. Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610)
13. Previous incidents, events and/or accidents (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)

14. For remote afterloaders, teletherapy units, and GSR units; initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:
 - a. Design, use, and function of the device, including safety systems and interpretation of various error codes/conditions, displays, indicators, and alarms;
 - b. Hands-on training in actual operation of the device under the direct supervision of an experienced user including "dry runs" (using dummy sources) of routine patient set-up/treatment and implementation of the licensee's emergency procedures; and
 - c. A method of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists

In addition to the training and experience requirements of 10 CFR 35.51 or 10 CFR 35.961, we will verify that the AMP has specific training and experience in performing the measurements and calculations associated with the specific type of therapy treatments that we are requesting (e.g, manual brachytherapy, remote afterloader therapy, teletherapy, GSR therapy) and that the training involved the use of the treatment planning system that will be used for therapy at our facility.

Additional Training for Therapy Authorized Users

In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.490, 10 CFR 35.690 or Subpart J, we will verify that the therapy physician has specific training and experience in performing the specific therapy treatment that we are requesting, including training in the treatment planning system, quality control system, and clinical procedures that will be used at our facility.

Training for Contractors

We will ensure that individuals who work under a contractual arrangement be instructed in the topics described above, equivalent to instruction given to facility employees and commensurate with their duties.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in housekeeping, dietary services, laboratory services, security, custodial services, etc.

For individuals whose assigned activities during normal and abnormal situations are likely to result in a dose in excess of 1 mSv (100 mrem), we will provide instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, we may choose to prohibit ancillary personnel from entering restricted or controlled areas unless escorted by trained personnel. Topics of instruction will include the following:

1. Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12)
2. Health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12)
3. The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12)
4. Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12)
5. Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12)
6. Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12)

Appendix I

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

- Low energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. Generally the detection efficiency is on the order of 2 percent for low energy beta emitters. Particular attention to surveying method (e.g., speed and height above surface) is needed to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.
- Medium to high energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges 15 to 40 percent, depending on the beta energy.
- Low energy gamma emitters, such as I-125, can be detected with a sodium iodide probe. If the probe possesses a thin window and thin crystal, the detection efficiency is approximately 20 percent.
- Medium to high energy gamma emitters, such as Tc-99m, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. The sensitivity of GM probes is much lower than for sodium iodide probes, therefore, sodium iodide probes are the preferred alternative.

Model Procedure for Calibrating Survey Instruments

(Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: www.ansi.org.)

We will implement the following procedure when calibrating survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use, and after servicing. (Battery changes are not considered "servicing.") Instruments used to monitor higher energies are most easily

calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source should emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.

- A radioactive sealed source(s) used for calibrating survey instruments will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by NIST
 - Emit the type of radiation measured
 - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed
 - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- The inverse square and radioactive decay law must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061).
- Instrument readings should be within $\pm 10\%$ of known radiation values at calibrated points; however, readings within $\pm 20\%$ shall be acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters are calibrated as follows:
 - Linear Readout Instruments must be calibrated at no fewer than two points on each scale. Calibration shall be checked near the ends of each scale (approximately 20 percent and 80 percent of each scale).
 - Logarithmic Readout Instruments must be calibrated at one point (midpoint) on each decade.
 - Digital Readout Instruments with either manual or automatic scale switching for indicating exposure rates must be calibrated at no fewer than two points on each scale. Calibration shall be checked near the ends of each scale (approximately 20 percent and 80 percent of each scale).
 - Digital Readout Instruments without scale switching for indicating exposure rates must be calibrated at one point (midpoint) on each decade.
 - Integrating Instruments must be calibrated at two dose rates (approximately 20 percent and 80 percent of the dose rate range).
- Readings above 1000 mR/hr (250 microcoulombs/kilogram per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.

- Survey meter calibration reports will indicate the procedure used and the data obtained. The description of the calibration should include:
 - A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector
 - A description of the calibration source, including the calibration procedure and the exposure rate at a specified distance on a specified date
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used
 - The name of the person who performed the calibration and the date it was performed
- The following information should be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated)
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

Calculating the Efficiency of the NaI(Tl) Uptake Probe

The sodium iodide (thallium doped) [NaI(Tl)] uptake probe is commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. RG 8.20 gives the details of bioassay requirements for I-131 radionuclides. Appendix B to Part 20 considers the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of radionuclides for occupational exposure. Converting counts per minute (cpm) to disintegrations per minute (dpm) in determination of accurate bioassay values is of importance in determining thyroid burdens with radioiodine. We will calculate the efficiency of nuclear counting systems on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy

of standards will be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

- Calculate efficiency of the instrument.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in microcuries}} = \text{efficiency in cpm/microcurie}$$

where: cpm = counts per minute
 std = standard
 bkg = background

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be attached:

- The date of the next efficiency due
- Results of efficiency calculation(s)

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. We will calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in microcuries}} = \text{efficiency in cpm/microcurie}$$

where: cpm = counts per minute
 std = standard
 bkg = background

The date of the efficiency test will be attached to the instrument as a calibration sticker or tag and the following information should be attached:

- The date of the next efficiency due date
- Results of efficiency calculation(s)

Reference: Draft RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

Appendix J

Model Procedures for Dose Calibrator Calibration

Model Procedures for Dose Calibrator Calibration

Model Procedures for Testing Dose Calibrators Used to Measure Photon-Emitting Radionuclides

- We will test for the following at the indicated frequency. We will consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. We will record, for all tests, the name of the individual who performed the test.

Note: A licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 MBq (30 μ curies)] if the geometry or linearity error exceeds 10 percent.

1. Constancy, at least once each day prior to assay of patient dosages ($\pm 10\%$).
 2. Linearity, at installation and at least annually thereafter ($\pm 10\%$).
 3. Geometry dependence, at installation ($\pm 10\%$).
 4. Accuracy, at installation and at least annually thereafter ($\pm 10\%$).
- After repair, adjustment, or relocation to another building of the dose calibrator, we will repeat the above tests before use.
 - **Constancy** means reproducibility in measuring a constant source over a long period of time. We will assay at least one relatively long-lived source such as Cs-137, Co-60, cobalt-57 (Co-57) *, or radium-226 (Ra-226) * using a reproducible geometry each day before using the calibrator. We will consider the use of two or more sources with different photon energies and activities.

* Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

We will use the following procedure:

1. Assay each reference source using the appropriate dose calibrator setting (e.g., use the Cs-137 setting to assay Cs-137).
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
3. For each source used, record (e.g., plot, log, etc.) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, and the date of the check.

4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings. Record (e.g., plot, log, etc.) the results.
5. Notify the RSO or the AU if the test results fall outside $\pm 10\%$ of the expected results.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 1.1 MBq (30 μ curies). This test will be done using a vial or syringe of technetium-99m (Tc-99m) whose activity is at least as large as the maximum activity normally assayed for administration.

We will use the following procedure:

Time Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.
2. Repeat the assay at approximately 4 hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 1.1 MBq (30 μ curies). For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
3. Convert the time and date information you recorded to hours elapsed since the first assay.
4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, and the date(s) of the test.
5. Notify the RSO if the worst deviation is more than $\pm 10\%$.

Shield Method

If we decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate the sleeves.

We will use the following procedure:

Note: The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves.

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1% of decay of Tc-99m).
2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
4. Continue for all sleeves.
5. Complete the decay method linearity test steps 2 through 5 above.
6. From the data recorded in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.
7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step 3.
8. Continue for all sleeves.
9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity. Record the net activity.
 2. Steps 3 through 5 below must be completed within 6 minutes.
 3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
 4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
 5. Continue for all sleeves.
 6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, and the date(s) of the test.
 7. Notify the RSO if the worst deviation is more than $\pm 10\%$.
- **Geometry independence** means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-centimeter cubed (cc) plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials and your predetermined safety margin is $\pm 10\%$.

Note: If you do not use these volumes, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

We will use the following procedure:

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/milliliter (ml). Set out a second small beaker or vial with water.
2. To test the geometry dependence for a 3-cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water, and assay again. Record the volume and activity indicated.

4. Repeat the process until you have assayed a 2.0-cc volume.
 5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternately, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."
 6. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, and the date of the test.
 7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the $\pm 10\%$ percent error lines.
 8. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
 9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water, and assay again. Record the volume and activity indicated.
 10. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
 11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."
 12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, and the date of the test.
 13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the $\pm 10\%$ percent error lines.
- **Accuracy** means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by NIST or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 keV and 500 keV (e.g., Co-57 or Ba-133) will be used. We will consider using at least one reference source whose activity is within the range of activities normally assayed.

We will use the following procedure:

1. Assay a calibrated reference source at the appropriate settings (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.
2. The measurement should be within ± 10 percent of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for any other calibrated reference sources possessed.
4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test.

5. Notify the RSO if the test results do not agree, within $\pm 10\%$, with the certified value of the reference source(s).
 6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.
- We will, through the RSO, ensure that the operation of the dose calibrator is in accordance with approved procedures and regulatory requirements.

Appendix K

Suggested Medical Licensee Audit

Suggested Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____ Date of Last Audit _____

Next Audit Date _____

Auditor: _____ Date _____
(Signature)

Management Review _____ Date _____
(Signature)

1. AUDIT HISTORY

- A. Were previous audits conducted annually [20.1101]?
- B. Were records of previous audits maintained [20.2102]?
- C. Were any deficiencies identified during previous audit?
- D. Were corrective actions taken? (Look for repeated deficiencies).

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Radiation Safety Officer

- 1. If the RSO was changed, was license amended [35.13]?
- 2. Does new RSO meet NRC training requirements [35.50 or 35.900, 35.57, 35.59]?
- 3. Is RSO fulfilling his/her duties [35.24]?

B. Multiple places of use?

If yes, list locations

- C. Are all locations listed on license? [L/C]
 - D. Were annual audits performed at each location [20.1101]?
- If no, explain.

- E. Describe scope of the program (staff size, number of procedures performed, etc.).
- F. Licensed Material
 - 1. Does the license authorize all of the NRC-regulated radioactive material used and possessed?
 - 2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is financial assurance adequate?
- G. Are the sealed sources possessed as described in the Sealed Source and Device Registration (SSDR) Certificate? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed? [32.210]?
- H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- I. If places of use changed, was the license amended [35.13 (e)]?
- J. If control of license was transferred or bankruptcy filed, was NRC prior consent obtained or notification made, respectively [30.34(b)]?

3. RADIATION SAFETY PROGRAM

- A. Minor changes pursuant to [35.26]?
- B. Records of changes maintained [35.2026]?
- C. Content and implementation reviewed annually by the licensee [20.1101(c)]?
- D. Records of reviews maintained [20.2102]?

4. USE BY AUTHORIZED INDIVIDUALS [L/C]

Compliance is established by meeting at least one criterion under each category.

- A. Authorized Nuclear Pharmacist [35.55 or 35.980, 35.57, 35.59]
DOES NOT APPLY TO FACILITIES THAT ARE REGISTERED/LICENSED BY
FDA/STATE AGENCY AS A DRUG MANUFACTURER WITH DISTRIBUTION
REGULATED UNDER PART 32

___(1) Certified by specialty board

___(2) Identified on NRC or Agreement State license

___(3) Identified on permit issued by broad scope licensee

___(4) Listed on facility license

B. Authorized User [35.57, 35.59, and 35.290, 35.292, 35.390, 35.490, 35.590, 35.690, or Subpart J]

___(1) Certified by specialty board

___(2) Identified on NRC or Agreement State license

___(3) Identified on permit issued by broad scope licensee

___(4) Listed on facility license

C. Authorized Medical Physicist [35.51 or 35.961, 35.57, 35.59]

___(1) Certified by specialty board

___(2) Identified on NRC or Agreement State license

___(3) Identified on permit issued by broad scope licensee

___(4) Listed on facility license

5. MOBILE SERVICE?

A. Operates services per [35.80, 35.647]?

B. Compliance with 20.1301 evaluated and met?

C. Letter signed by management of each client [35.80(a)]?

D. Licensed material was not delivered to client's address (unless client was authorized) [35.80(b)]?

E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [35.80(c)]?

F. Survey instruments checked for proper operation before used at each address of use [35.80(d)]?

G. Survey of all areas of use prior to leaving each client address [35.80(e)]?

H. Additional technical requirements for mobile remote afterloaders per [35.647]?

6. AMENDMENTS SINCE LAST INSPECTION [35.13]?

A. Any Amendments since last inspection [35.13]?

7. NOTIFICATIONS SINCE LAST INSPECTION [35.14]?

- A. Appropriate documentation provided to the NRC for authorized nuclear pharmacists, authorized medical physicist, or authorized user no later than 30 days after the individual starts work [35.14(a)]?
- B. NRC notified within 30 days after authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name, licensee's mailing address or name changes without a transfer of control of the license, or licensee has added to or changed an area of use for 35.100 or 35.200 use [35.14(b)]?
- C. Any Notifications since last inspection [35.14]?

8. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Have workers been provided with required instructions [19.12, 35.27]?
- B. Is the individual's understanding of current procedures and regulations adequate?
- C. Training program implemented?
 - 1. Operating procedures [35.310, 35.410, 35.610]?
 - 2. Emergency procedures [35.310, 35.410, 35.610]?
 - 3. Periodic training required [35.310, 35.410, 35.610]?
 - 4. Records of reviews of radiation safety program maintained [20.2102]?
 - 5. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [10 CFR 19.12]?
 - 6. Was each supervised user instructed in preparation of material, principles and procedures for radiation safety, device usage and administration of written directives, as appropriate, [35.27]?
 - 7. Are training records maintained for each individual [35.2310]?
 - 8. Briefly describe training program:
- D. Additional instructions/training
 - 1. Unit operation, inspection, associated equipment, survey instruments [35.610]?
 - 2. License conditions applicable to the use of the unit?
 - 3. Emergency drills [35.610]?
- E. Revised Part 20
Workers cognizant of requirements for:
 - 1. Radiation Safety Program [35.24, 35.26, 20.1101]?
 - 2. Annual dose limits [20.1301, 20.1302]?
 - 3. New forms 4 and 5?
 - 4. 10% monitoring threshold [20.1502]?
 - 5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
 - 6. Grave Danger Posting [20.1902]?
 - 7. Procedures for opening packages [20.1906]?

9. MANUAL BRACHYTHERAPY AND UNSEALED THERAPY TRAINING

A. Safety instruction to personnel provided include: [10 CFR 35.310, 10 CFR 35.410]:

1. Control of patient and visitors?
2. Routine visitation to patients in accordance with 10 CFR 20.1301(a)(1) and (3)?
3. Contamination control and size/appearance of sources?
4. Safe handling and shielding instructions?
5. Waste control?
6. RSO and AU notification in emergency or death?
7. Records retained [35.2310]?

10. FACILITIES

- ### **A.**
1. Facilities as described in license application?
 2. Therapy device facilities provided with electrical interlock system [35.615(b)]?

B. Storage areas:

1. Materials secured from unauthorized removal or access [20.1801]?
2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802]?

C. Therapy unit operation

1. Console keys controlled adequately [20.1801, 35.610(a)(1)]?
2. Restricted to certain source orientations and/or gantry angles [L/C]?
3. Ceases to operate in restricted orientation(s) [L/C]?

11. DOSE OR DOSAGE MEASURING EQUIPMENT

A. Possession, use, calibration, and check of instruments to measure activities of photon emitting radionuclides [10 CFR 35.60]:

1. Instrumentation possessed and used?
2. Constancy and proper operation checked at the beginning of each day of use?
3. Accuracy, linearity, and geometry dependence test performed before initial use and following repair for each instrument?
4. Accuracy and linearity test annually?
5. Dosage readings mathematically corrected for geometry or linearity errors greater than $\pm 10\%$?
6. Approved procedures followed?
7. Records maintained and include required information [10 CFR 35.2060]?

B. Instrumentation - Alpha- or beta-emitting radionuclides [35.62]?

1. List type of equipment used to assay alpha and beta particles:
2. Licensee has procedures for use of instrumentation [10 CFR 35.62(b)]?
3. Accuracy, linearity and geometric dependence tests are performed prior to initial use and following repair [35.62(b)(1)]?
4. Instruments are checked for constancy and proper operation at the beginning of each day of use? [35.62(b)(4)]
5. Accuracy and linearity tests performed annually [35.62(b)(2) and (3)]?
6. Records maintained [10 CFR 35.2060]?

C. Determination of dosages of unsealed byproduct material [35.63]?

1. Each dosage determined and recorded prior to medical use [35.63(a)]?
2. Measurement made either by direct measurement or by decay correction [35.63(b)]?
3. Measurement for a dosage of photon-emitting radionuclide prepared by the licensee made by direct measurement or by combination of measurement and calculation [35.63(c)]?
4. Measurement of an alpha- or beta-emitting radionuclide prepared by the licensee made by direct measurement or by combination of measurements and calculations [35.63(c)]?

D. Calibration and reference sources [35.65]

1. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74 or equivalent Agreement State regulations and sources do not exceed 30 millicuries each [35.65(a)]?
2. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(b)]?
3. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 200 microcuries each and does not exceed $10E-3$ times the quantities in Appendix B of Part 30 [35.65(c)]?
4. Technetium-99m in individual amounts as needed [35.65(d)]?

E. Licensee uses generators?

1. First eluate after receipt used for radiopharmaceuticals tested for Mo-99 breakthrough [35.204(b)]?
2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 uCi per mCi of Tc-99m [35.204(a)]?
3. Records maintained [35.2204]?

F. Dosimetry Equipment [35.630]

1. Calibrated system available for use [35.630(a)]?
2. Calibrated by NIST or an AAPM-accredited lab within previous two years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per [35.630(a)(2)]?
3. Calibrated within the previous four years [35.630(a)(2)]?
4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?
5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

12. RADIATION PROTECTION AND CONTROL OF RADIOACTIVE MATERIAL**A. Use of radiopharmaceuticals:**

1. Protective clothing worn?
2. Personnel routinely monitor their hands?
3. No eating/drinking in use/storage areas?
4. No food, drink, or personal effects kept in use/storage areas?
5. Proper dosimetry worn?
6. Radioactive waste disposed in proper receptacles?
7. Syringe shields and vial shields used [35.69]?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources and brachytherapy sources [35.67(b)(1)]?
2. Inventory of sealed sources and brachytherapy sources performed at intervals not to exceed six months [35.67(g)]?
4. Records maintained [35.2067]?

13. RADIATION SURVEY INSTRUMENTS**A. Survey instruments used to show compliance with Part 20 and 30.33(a)(2).**

1. Appropriate operable survey instruments possessed or available [10 CFR Part 20]?
2. Calibrations [35.61(a) and (b)]:
 - a. Before first use, annually & after repairs?
 - b. Within 20% in each scale or decade of interest?
3. Records maintained [35.2061]?

B. Radiation surveys performed [20.1501, 35.70]?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [35.70]?
2. Weekly in all areas where radiopharmaceuticals or waste is stored?
3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered or stored?
4. Trigger levels established?
5. Techniques can detect 0.1 mR/hr, 2000dpm?
6. Quarterly in brachytherapy source storage area?
7. Surveys as defined in the Sealed Source and Device Registry made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Registry [35.652(a)] and records maintained [35.2652]?
 - a. After new source installation?
 - b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s)?

14. PUBLIC DOSE

- A. Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year [10 CFR 20.1301(a)(1)]?
- B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour [10 CFR 20.1301(a)(2)]?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [10 CFR 20.1801]?
- F. Records maintained [10 CFR 20.2103, 10 CFR 20.2107]?

15. PATIENT RELEASE

- A. Individuals released when TEDE less than 0.5 rem [35.75(a)]?
- B. Instructions to breast-feeding women include required information [35.75(b)]?
- C. Release records maintained if 35.2075(b) criteria are met [35.2075(a)]?
- E. Records of instructions given to breast-feeding women maintained, if required [35.2075(c)]?

16. RADIOPHARMACEUTICAL THERAPY

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release and contamination controls [35.315(a)]?
- B. RSO and AU promptly notified if patient died or had a medical emergency [35.315(b)]?

17. BRACHYTHERAPY

- A. Safety precautions implemented to include posting, stay times, and emergency response equipment [35.415]?
- B. Patients surveyed immediately after implant [35.404(a)]?
- C. Patients surveyed immediately after removing the last temporary implant source [35.404(b)]?
- E. Records maintained [35.2404]?

18. RADIOACTIVE WASTE

- A. Disposal
 - 1. Decay-in-storage [35.92]
 - 2. Procedures followed [35.92]?
 - 3. Labels removed or defaced [20.1904, 35.92]?
- B. Special procedures performed as required [L/C]?
- C. Improper/unauthorized disposals [20.2001]?
- D. Records maintained [20.2103(a), 20.2108, 35.2092]?
- E. Effluents
 - 1. Release to sanitary sewer [20.2003]?
 - a. Material is readily soluble or readily dispersible [20.2003(a)(1)]?
 - b. Monthly average release concentrations do not exceed App. B, Table 2 values?
 - c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003]?
 - d. Procedures to ensure representative sampling and analysis implemented [20.1501]?
 - 2. Release to septic tanks [20.2003]?
 - a. Within unrestricted limits [App B, Table 2, Part 20]?

3. Waste incinerated?
 - a. License authorizes [20.2004(a)(3)]?
 - b. Directly monitor exhaust ?
 - c. Airborne releases evaluated and controlled [20.1501, 20.1701]?
4. Air effluents and ashes controlled [20.1101, 1201, 1301, 1501, 2001, L/C]?
{See also IP 87102, RG 8.37}
 - a. Air effluent less than 10 mrem constraint limit [20.1101]
 - b. If no, reported appropriate information to NRC
 - i. Corrective actions implemented and on schedule?
 - c. Description of effluent program
 - i. Monitoring system hardware adequate?
 - ii. Equipment calibrated, as appropriate?
 - iii. Air samples/sampling technique (i.e. charcoal, HEPA, etc.) analyzed with appropriate instrumentation?

F. Waste storage

1. Protection from elements and fire?
2. Control of waste maintained [20.1801]?
3. Containers properly labeled and area properly posted [20.1902, 20.1904]?
4. Package integrity adequately maintained?

G. Waste disposal

1. Sources transferred to authorized individuals [20.301, 20.2001, 30.51]?
2. Name of organization: _____

H. Records of surveys and material accountability are maintained [20.2103, 20.2108]?

19. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- A. Describe how packages are received and by whom:
- B. Written package opening procedures established and followed [20.1906(e)]?
- C. All incoming packages with a DOT label wiped, unless exempted (gases and special form) [20.1906(b)(1)]?
- D. Incoming packages surveyed [20.1906(b)(2)]?
- E. Monitoring in (C) and (D) performed within time specified [20.1906(c)]?
- F. Transfer(s) performed per [30.41]?
- G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i)]?

- H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51]?
- I. Package receipt/distribution activities evaluated for compliance with 20.1301?

20. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

A. Shipments are:

- ☐ delivered to common carriers
- ☐ transported in own private vehicle
- ☐ both
- ☐ no shipments since last audit

B. Return radiopharmacy doses or sealed sources?

- 1. Licensee assumes shipping responsibility?
- 2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages

- 1. Authorized packages used [173.415, 416]?
- 2. Performance test records on file?
 - a. DOT-7A packages [173.415(a)]
 - b. Special form sources [173.476(a)]
- 3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441]?
- 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee) [172.301, 306, 310, 312, 324]?
- 5. Closed and sealed during transport [173.475(f)]?

D. Shipping Papers

- 1. Prepared and used [172.200(a)]?
- 2. Proper {Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)} [172.200-204]?
- 3. Readily accessible during transport [177.817(e)]?

21. TELETHERAPY AND GAMMA STEREOTACTIC RADIOSURGERY SERVICING

- A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.655(a)]?
- B. Licensee arranged for needed service identified during the inspection?
- C. Service performed by persons specifically authorized to do so [35.655(b)]?

22. FULL CALIBRATION-THERAPEUTIC MEDICAL DEVICES

- A. Licensee uses one of the proper protocols (TG-21, AAPM 54, TG-56, TG-40) [35.632, 633, 635]?
- B. Performed prior to first patient use [35.632(a)(1), 633(a)(1), 635(a)(1)]?
- C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding 120 days for HDR and PDR remote afterloaders [35.632(a)(3)], 633(a)(3) and (4), 635(a)(3)]?
- D. Whenever spot-checks indicate output differs from expected by $\pm 5\%$ [35.632(a)(2)(i), 633(a)(2)(i), 635(a)(2)(i)]?
- E. After source exchange, relocation, and major repair or modification [35.632(a)(2), 633(a)(2), 635(a)(2)]?
- F. Performed with properly calibrated instrument [35.632(c), 35.633(d), 35.635(c)]?
- G. Includes:

1. For teletherapy:

- a. Output measured within $\pm 3\%$ of expected for the range of field sizes, range of distances [35.632(b)(1)]?
- b. Coincidence of radiation field and field light localizer [35.632(b)(2)]?
- c. Uniformity of radiation field and beam angle dependence [35.632(b)(3)]?
- d. Timer constancy and linearity over the range of use [35.632(b)(4)]?
- e. On-off error [35.632(b)(5)]?
- f. Accuracy of all measuring and localization devices [35.632(b)(6)]?

2. For HDR and PDR remote afterloaders:

- a. Output measured within $\pm 5\%$ of expected [35.633(b)(1)]?
- b. Source positioning accuracy within ± 1 millimeter [35.633(b)(2)]?
- c. Source retraction with backup battery upon power failure [35.633(b)(3)]?
- d. Electrically assisted treatment room doors with power turned off [35.633(b)(4)]?
- e. Source guide tubes [35.633(c)(1)]?
- f. Timer accuracy and linearity over the range of use [35.633(c)(1)]?
- g. Length of the connectors [35.633(c)(1)]?
- h. Annual check of source guide tube and connector function [35.633(c)(1)]?

3. For LDR remote afterloaders:
 - a. Output measured within $\pm 5\%$ of expected [35.633(b)(1)]?
 - b. Source positioning accuracy within ± 1 millimeter [35.633(b)(2)]?
 - c. Source retraction with backup battery upon power failure [35.633(b)(3)]?
 - d. Autoradiograph of the source(s) to verify source(s) arrangement and inventory [35.633(c)(2)]?
 - e. Quarterly spot check of the absolute timer accuracy [35.633(c)(2)]?
4. For gamma stereotactic radiosurgery:
 - a. Output measured within $\pm 3\%$ of expected [35.635(b)(1)]?
 - b. Helmet factors [35.635(b)(2)]?
 - c. Isocenter coincidence [35.635(b)(3)]?
 - d. Timer accuracy and linearity over the range of use [35.635(b)(4)]?
 - e. On-off error [35.635(b)(5)]?
 - f. Trunnion centricity [35.635(b)(6)]?
- H. Output corrected mathematically [35.632(e), 35.633(f), 35.635(e)]?
- I. Records maintained [35.2632, 35.2633, 35.2635]?

23. PERIODIC SPOT CHECKS FOR THERAPEUTIC DEVICES

- A. Performed at required frequency [35.642(a), 643(a), 644(a), 645(a)]?
- B. Procedures established by medical physicist [35.642(b), 35.643(b), 35.644(c), 35.645(b)]?
- C. Procedures followed?
- D. Medical physicist reviews results within 15 days [35.642(c), 35.643(b), 35.644(c), 35.645(b)]?
- E. Performed with properly calibrated instrument [35.642(a)(5), 35.643(c)(2), 35.645(c)(2)(i)]?
- F. Output and safety spot checks include:
 1. For teletherapy:
 - a. Timer constancy and linearity over the range of use [35.642(a)(1)]?
 - b. On-off error [35.642(a)(2)]?
 - c. Coincidence of radiation field and field light localizer [35.642(a)(3)]?
 - d. Accuracy of all measuring and localization devices [35.642(a)(4)]?
 - e. The output for one typical set of operating conditions [35.642(a)(5)]?
 - f. Difference between measured and expected output [35.642(a)(6)]?
 - g. Interlock systems [35.642(d)(1)]?
 - h. Beam stops and dead-man switches [35.642(d)(2)]?
 - i. Source exposure indicator lights [35.642(d)(3)]?
 - j. Viewing and intercom systems [35.642(d)(4)]?

- k. Treatment room doors, inside and out [35.642(d)(5)]?
 - l. Electrical treatment doors with power shut off [35.642(d)(6)]?
2. For HDR and PDR remote afterloaders:
- a. Source positioning accuracy [35.643(c)(1)]?
 - b. The output [35.643(c)(2)]?
 - c. Difference between measured and expected output [35.643(c)(3)]?
 - d. Interlock systems [35.643 (d)(1)]?
 - e. Source exposure indicator lights [35.643(d)(2)]?
 - f. Viewing and intercom systems [35.643(d)(3)]?
 - g. Emergency response equipment [35.643(d)(4)]?
 - h. Radiation monitors used to indicate source position [35.643(d)(5)]?
 - i. Timer constancy [35.643(d)(6)]?
 - j. Clock (date and time) in the unit's computer [35.643(d)(7)]?
 - k. Simulated cycle of treatment [35.643(e)]?
3. For LDR remote afterloaders:
- a. Interlock systems [35.644(a)(1)]?
 - b. Source exposure indicator lights [35.644(a)(2)]?
 - c. Viewing and intercom systems [35.644(a)(3)]?
 - d. Emergency response equipment [35.644(a)(4)]?
 - e. Radiation monitors used to indicate source position [35.644(a)(5)]?
 - f. Timer constancy [35.644(a)(6)]?
 - g. Clock (date and time) in the unit's computer [35.644(a)(7)]?
 - h. Simulated cycle of treatment [35.644(b)]?
4. For gamma stereotactic radiosurgery:
- a. Treatment table retraction mechanism [35.645(c)(1)(i)]?
 - b. Helmet microswitches [35.645(c)(1)(ii)]?
 - c. Emergency timing circuits [35.645(c)(1)(iii)]?
 - d. Emergency off buttons [35.645(c)(1)(iv)]?
 - e. Stereotactic frames and localizing devices [35.645(c)(1)(v)]?
 - f. The output for one typical set of operating conditions [35.645(c)(2)(i)]?
 - g. Difference between measured and expected output [35.645(c)(2)(ii)]?
 - h. Source output compared against computer calculation of output [35.645(c)(2)(iii)]?
 - i. Timer accuracy and linearity over the range of use [35.645(c)(2)(iv)]?
 - j. On-off error [35.645(c)(2)(v)]?
 - k. Trunnion centricity [35.645(c)(2)(vi)]?
 - l. Interlock systems [35.645(d)(1)]?
 - m. Source exposure indicator lights [35.645(d)(2)]?
 - n. Viewing and intercom systems [35.645(d)(3)]?

- o. Timer termination [35.645(d)(4)]?
- p. Radiation monitors used to indicate room exposures [35.645(d)(5)]?
- q. Hydraulic cutoff mechanism [35.645(d)(6)]?

- G. . Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [35.642(e), 35.643(g), 35.644(d), 35.645(f)]?
- H. Records maintained [35.2642, 35.2643, 35.2645]?

24. INSTALLATION, MAINTENANCE, AND REPAIR OF THERAPY DEVICES

- A. Only authorized individuals perform maintenance, repair and inspection [35.605]?
Name of organization/individual: _____
- B. Records of maintenance, inspection and service maintained [35.2605]?

25. OPERATING PROCEDURES FOR THERAPY DEVICES

- A. Instructions on location of procedures and emergency response telephone numbers are posted at the device console [35.610(c)]?
- B. Copy of the entire procedures physically located at the device console [35.610(b)]?
- C. Procedures include:
 - 1. Securing the device, the console, and the console keys [35.610(a)(1)]?
 - 2. Ensuring the only the patient is in the treatment room before starting a treatment (except for LDR) [35.610(a)(2)]?
 - 3. Preventing dual operation of more than one radiation producing device in the treatment room [35.610(a)(3)]?
 - 4. Responding to emergencies or abnormal situations [35.610(a)(4)]
 - 5. Radiation survey of patient is performed to ensure source is returned to shielded position [35.604(a)]?
 - 6. Records of radiation surveys maintained for three years [35.2404]?
- D. Authorized medical physicist and authorized user:
 - 1. Physically present during initiation of patient treatment with remote afterloaders [35.615(f)(1), (2), and (3)]?
 - 2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [35.615(f)(4)]?

26. PERSONNEL RADIATION PROTECTION

- A. Exposure evaluation performed [20.1501]?
- B. ALARA program implemented [20.1101(b)]?
- C. External Dosimetry

1. Monitors workers per [20.1502(a)]?
2. External exposures account for contributions from airborne activity [20.1203]?
3. Supplier _____ Frequency _____
4. Supplier is NVLAP-approved [20.1501(c)]?
5. Dosimeters exchanged at required frequency?

D. Internal Dosimetry

1. Monitors workers per [20.1502]?
2. Briefly describe program for monitoring and controlling internal exposures [20.1701, 20.1702]?
3. Monitoring/controlling program implemented (includes bioassays) [35.315(a), 205(d)]?
4. Respiratory protection equipment [20.1703]?

E. Reports

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [20.2104]?
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organs _____
6. Maximum CEDE _____
7. Internal and external summed [20.1202]?
8. TEDEs and TODEs within limits [20.1201]?
9. NRC forms or equivalent [20.2104(d), 2106(c)]?
 - a. NRC-4 Complete:
 - b. NRC-5 Complete:
10. Worker declared her pregnancy in writing during inspection period (review records)?
If yes, in compliance with [20.1208] and records maintained [20.2106(e)]?

F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104, 2105, 2204]?

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106]?

27. CONFIRMATORY MEASUREMENTS

Detail location and results of confirmatory measurements

28. MEDICAL EVENTS

- A. If medical events [criteria in 35.3045(a)] have occurred since the last audit, evaluate the incident(s) and procedures for implementing & administering written directives using the existing guidance.

1. Event date _____ Information Source _____
2. Notifications

NRC Ops Center	Region
Referring Physician	Patient
In writing/By telephone	

If notification did not occur, why not?

3. Written Reports [35.3045]
 - a. Submitted to Region within 15 days?
 - b. Copy to patient within 15 days?

- B. Records maintained [35.2045]?

29. NOTIFICATION AND REPORTS

- A. In compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20)?
- B. In compliance with [20.2201, 30.50] (theft or loss)?
- C. In compliance with [20.2202, 30.50] (incidents)?
- D. In compliance with [20.2203, 30.50] (overexposures and high radiation levels)?
- E. Aware of NRC Ops Center phone number?
- F. In compliance with [20.2203] (Constraint on air emissions)?

30. POSTING AND LABELING

- A. NRC Form 3, "Notice to Workers" is posted [19.11]?
- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]?
- C. Other posting and labeling per [20.1902, 1904]? and not exempted by [20.1903, 20.1905]?

31. BULLETINS AND INFORMATION NOTICES

- A. Bulletins, Information Notices, NMSS Newsletters, etc., received?
- B. Appropriate action in response to Bulletins, Generic Letters, etc.?

32. SPECIAL LICENSE CONDITIONS OR ISSUES

- A. Special license conditions or issues to be reviewed:
- B. Evaluation:

33. AUDITS AND FINDINGS

- A. Summary of findings:
- B. Corrective and preventive actions:

Appendix L

**Model Procedures for an Occupational
Dose Program**

Model Procedures for an Occupational Dose Program

Dosimetry is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20.1201. The Total Effective Dose Equivalent (TEDE) is the sum of the deep-dose equivalent (external exposure) and the committed effective dose equivalent (internal exposure). To demonstrate that dosimetry is not required, the licensee needs to have available, for inspection, an evaluation to demonstrate that the workers are not likely to exceed 10% of the applicable annual limits.

If an individual is likely to receive more than 10 percent of the annual dose limits, the NRC requires the licensee to monitor the dose, to maintain records of the dose, and, at least on an annual basis, to inform the worker of his/her dose.

THE AS LOW AS REASONABLY ACHIEVABLE "ALARA" PROGRAM

10 CFR 20.1101 states that "each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities ..." and "the licensee shall use, to the extent practicable, procedures and controls based upon sound standard protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA)." Additionally, 10 CFR 20.1101 requires that licensees periodically review the content of the radiation protection program and its implementation.

EXTERNAL DOSE EXPOSURE

The mechanism by which doses to individuals from exposure to radiation is evaluated is called dosimetry. Dosimetry allows the licensee to ensure that doses are maintained ALARA. Dosimetry also allows the licensee to show compliance with the occupational dose limits required by the NRC.

Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body (5 rems or 0.05 Sv), shallow dose to the skin or extremities (50 rems or 0.5 Sv), and dose to the lens of the eye (15 rems or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the deep-dose equivalent (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm²), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm²), and eye dose equivalent at 0.3 cm (300 mg/cm²). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Monitoring an individual's external radiation exposure is required by 10 CFR 20.1502(a) if the external *occupational dose* is likely to exceed 10 percent of the dose limit appropriate for the individual (i.e., adult, minor, or declared pregnant woman). External radiation monitoring is also required by 10 CFR 20.1502(a)(3) for any individual entering a high or very high radiation area.

The use of individual monitoring devices for external dose is required for the following:

- For adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 0.5 rem (0.005 Sv) DDE
 - 1.5 rems (0.015 Sv) eye dose equivalent
 - 5 rems (0.05 Sv) shallow-dose equivalent to the skin
 - 5 rems (0.05 Sv) shallow-dose equivalent to any extremity.
- For minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 0.05 rem (0.5 mSv) DDE
 - 0.15 rem (1.5 mSv) eye dose equivalent
 - 0.5 rem (0.005 Sv) shallow-dose equivalent to the skin
 - 0.5 rem (0.005 Sv) shallow-dose equivalent to any extremity.
- For declared pregnant women who are likely to receive an annual dose from occupational exposure in excess of 0.05 rem (0.5 mSv) DDE, although the dose limit applies to the entire gestation period.
- For individuals entering a high or a very high radiation area.

If the licensee determines that monitoring the occupational exposure of some workers is not necessary, he/she must demonstrate to the NRC that these workers will not exceed 10 percent of these limits using acceptable criteria. In these cases, the licensee need not provide individual monitoring devices to these workers.

The following are examples of criteria NRC accepts:

- the licensee has previous dosimeter monitoring reports for workers in a specific work area that show that the workers are not likely to receive a dose in excess of 10 percent of the limits.
- the licensee has performed appropriate radiation level surveys (using a survey meter or area thermoluminescent dosimeter (TLD)) of the work area, and has determined the number of hours a worker will be present in that work area, and has calculated the dose to workers (including "reasonable" accident scenarios) that shows that the workers are not likely to receive a dose in excess of 10 percent of the limits.
- the licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10 percent of the limits.

External dose is determined by using individual monitoring devices, such as film badges or thermoluminescent dosimeters (DDE). These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP) approved, as required by 10 CFR 20.1501. Acceptable exchange frequencies are every 3 months for TLDs and every month for film badges.

The device for monitoring the whole body dose shall be placed near the location expected to receive the highest dose during the year (10 CFR 20.1201(c)). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly nonuniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

An acceptable alternative approach for highly nonuniform radiation fields is to use more than one dosimeter to separately track doses to different parts of the whole body. At the end of the year, each of the doses for each location would be summed. The deep-dose equivalent to be recorded would be that of the dosimeter location receiving the highest dose.

If the licensee determines that extremity monitoring is required, it may be appropriate to use an extremity dosimeter for some, but not all, radiation exposure. The licensee could supply an extremity dosimeter when exposure is nonuniform. When exposure is uniform, the shallow-dose equivalent measured by a torso dosimeter would be representative of the shallow-dose equivalent to the extremities, and separate extremity monitoring would not be needed. If protective gloves are used, it is acceptable to place the extremity dosimeter under the gloves.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC Form 5 is used to record for the calendar year doses received. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another. As long as the year begins and ends within the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees shall be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate.

INVESTIGATIONAL LEVELS - EXTERNAL DOSE MONITORING

The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," Investigational levels serve as check points above which the results are considered sufficiently important to justify investigations.

When the exposure to a radiation worker exceeds Investigational Level I in Table L.1 of the occupational exposure in a quarter (Action Level I), an investigation should take place by the RSO, and a consideration of actions that might be taken to reduce the probability of recurrence will be reviewed by the RSO. When the exposure exceeds Investigational Level II in Table L.1 of the occupational exposure in a quarter (Action Level II), an investigation should take place by the RSO, with a consideration of actions to be taken to reduce the probability of occurrence, and a report of the actions should be reviewed by management.

Table L.1

Investigational Levels

Part of Body	Investigational Level I (mrems per calendar quarter)	Investigational Level II (mrems per calendar quarter)
whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
hands and forearms; feet and ankles	1875	5625
skin of whole body	750	2250

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. The following actions should be taken at the investigational levels as stated in Table 1:

- a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

- b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual whose quarterly dose equals or exceeds Investigational Level I, a timely investigation should take place by the RSO. A consideration of actions that might be taken to reduce the probability of recurrence

should be reviewed by the RSO following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO should, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and should make a record of the review.

- c. Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation

- d. Re-establishment of Investigational Level II to a level above that listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

DECLARED PREGNANCY AND DOSE TO EMBRYO/FETUS

10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. The pregnancy is declared in writing to include the worker's estimated date of conception. If the fetal exposures have exceeded 0.5 rem (5 mSv), or are within 0.05 rem (0.5 mSv) of this dose, exposures to the fetus will not exceed 50 mrem (0.5 mSv) during the remainder of the pregnancy. The dose to an embryo/fetus shall be taken as the sum of:

- 1) the deep-dose equivalent to the declared pregnant woman; and
- 2) the dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Methods for calculating the radiation dose to the embryo/fetus can be found in Regulatory Guide 8.36, "Radiation Dose To The Embryo/Fetus."

INTERNAL DOSE EXPOSURE

With respect to internal exposure, you are required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the ALI from intakes in 1 year. 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., DAC and ALI.

Exposure to airborne radioactivity at a level of 1 DAC for 1 year (2,000 hours) would result in either a committed effective dose equivalent of 5 rems (50 mSv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route would result in a committed effective dose of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The effective dose equivalent concept described above makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR Part 20 dose methodology evaluates the doses to all major body organs, multiplies these doses by the appropriate organ weighting factors, and then sums the organ-weighted doses to obtain a whole body risk-weighted "effective dose." The ALIs and DACs in 10 CFR Part 20, Appendix B, therefore, reflect the doses to all principal organs that are irradiated. The ALI means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent (CEDE) of 5 rems or a committed dose equivalent (CDE) of 50 rems to any individual organ or tissue.

Assessment of intakes of radioactive materials by medical workers can best be determined by bioassay measurements. Bioassay services shall be available if the types and quantities of radioactive material licensed for use at your facility could, under normal operational occurrences, result in airborne levels in normally occupied areas exceeding DACs. Provisions shall be made for the collection of appropriate samples, analysis of bioassay samples, and evaluation of the results of these analyses to determine intakes.

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the NRC and provide a copy to the individual who received the dose as required by 10 CFR 20.2203 and 20.2205.

INTERNAL DOSE MONITORING (BIOASSAY PROGRAM)

For each patient or human research subject receiving radiopharmaceutical therapy, the licensee should measure the thyroid burden of each individual who prepares or administers a dosage of iodine-131 NaI within 24 to 72 hours after administering the dosage. Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Elements that shall be considered include: 1) the potential exposure of the individual; 2) the retention and excretion characteristics of the radionuclide; 3) the sensitivity of the measurement technique; and 4) the acceptable uncertainty in the estimate of intake and committed dose equivalent. Bioassay measurements used for demonstrating compliance with

the occupational dose limits shall be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI.

Two separate categories of bioassay measurements further determine the frequency and scope of measurements: *routine measurements* and *special measurements*.

1) *Routine Measurements* include *baseline measurements*, *periodic measurements*, and *termination measurements*. These measurements shall be conducted to confirm that appropriate control exists and to assess dose.

- a) *Baseline measurements* shall be conducted prior to initial work activities that involve exposure to radiation or radioactive materials, for which monitoring is required.
- b) *Periodic measurements* shall be performed on a frequency determined on an *a priori* basis, considering the likely exposure of the individual. Periodic measurements shall be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours shall be excluded from the evaluation, since external exposure is generally controlling for these radionuclides. As a minimum, periodic measurements shall be conducted annually.
- c) *Termination measurements* shall be made when an individual is no longer subject to the bioassay program because of termination of employment or change in employment status. These measurements ensure that any unknown intakes are quantified.

2) *Special Monitoring* considers abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, which shall be evaluated on a case-by-case basis.

Methods are presented for evaluating bioassay data that will result in calculated intakes acceptable to the NRC for evaluating compliance with the occupational dose limits of 10 CFR 20.1202. Examples of specific exposure situations and the physical and biochemical processes considered in the assessment of the exposures are in Appendix A of Regulatory Guide 10.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program."

ESTIMATING INTAKES - EVALUATION AND INVESTIGATION LEVELS

Licensees shall estimate the intake for any bioassay measurement that indicates internally deposited radioactive material resulting from licensed activity. The scope of the evaluation shall be commensurate with the potential magnitude of the intake. For individual exposures with an estimate of intake less than 0.02 ALI, minimum bioassay measurements are adequate to provide a reasonable approximation of intake. Repeated follow-up measurements or additional exposure data reviews are not necessary, provided a reasonable estimate of the actual intake can be made based on available data.

Evaluation Level

The Evaluation Level is the level at which an intake shall be evaluated beyond the initial bioassay measurement. The Evaluation Level is 0.02 times the annual limit on intake (ALI), which is equivalent to 40 derived air concentration (DAC) hours. For very small intakes, a single bioassay measurement is adequate to estimate intake. For intakes that represent a significant contribution to dose, other available data shall be evaluated. If initial bioassay measurements indicate that an intake is greater than an Evaluation Level of 0.02 ALI, additional available data, such as airborne measurements or additional bioassay measurements, shall be used to obtain the best estimate of actual intake.

The primary radiopharmaceutical in medical bioassay programs is I-131 sodium iodide in either solution or capsule form. Greater volatility is associated with I-131 NaI in solution. The Evaluation Level (0.02 ALI) for I-131(inhalation) is (1 μ Ci). The ALI for class D I-131 is 5E+1 μ Ci (from Appendix B to 10 CFR 20.1001-20.2401); therefore, the Evaluation Level is:

$$(0.02 \times \text{ALI } (50 \mu\text{Ci})) = 1 \mu\text{Ci } (3.7\text{E}+4 \text{ Bq})$$

Investigational Level

The Investigational Level is the level at which an intake shall be investigated. The Investigation Level is any intake greater than or equal to 0.1 times the annual limit on intake (ALI). For single intakes that are greater than 10% of the ALI, a thorough investigation of the exposure shall be made; therefore, if a potential intake exceeds an investigation level of 0.1 ALI, multiple bioassay measurements and an evaluation of available workplace monitoring data shall be conducted. If practical, daily measurements shall be made until a pattern of bodily retention and excretion can be established. Such a determination is feasible after as few as three measurements; however, physiologically related variations and uncertainties require that measurements be continued over a longer period of time in some cases. For potential intakes near or exceeding the ALIs, the bioassay data evaluations shall consider any additional data on the physical and chemical characteristics and the exposed individual's physical and biokinetic processes.

The Investigational Level for I-131 is:

$$0.1(10\%) \times \text{the ALI } (50 \mu\text{Ci}) = 5 \mu\text{Ci } (1.9\text{E}+5 \text{ Bq})$$

Table L.2

Bioassay Action Levels For I-131

I-131 Intake Level	Activity Action Level for I-131
Evaluation Level	1 μ Ci (2.22×10^6 dpm) 0.02 ALI
Investigation Level	5 μ Ci (1.11×10^7 dpm) 0.1 ALI

Actions taken by RSO if radionuclide Intake level is exceeded:

1) Evaluation Level - The RSO should collect additional available data, such as airborne measurements or additional bioassay measurements to obtain the best estimate of actual intake. A consideration of actions that might be taken to reduce the probability of recurrence should be reviewed by the RSO in a timely manner following the time when the intake was recorded. If the intake does not equal or exceed the Investigational Level, no action related specifically to the intake is required unless deemed appropriate by the RSO. The RSO should, however, review each such intake in comparison with those of others performing similar tasks as an index of ALARA program quality and should make a record of the review.

2) Investigational Level - The RSO should collect multiple bioassay measurements and should evaluate available workplace monitoring data. If practical, daily measurements shall be made until a pattern of bodily retention and excretion can be established. Such a determination is feasible after as few as three measurements. The RSO should investigate in a timely manner the causes of all personnel intakes exceeding the Investigational Level. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

If a worker receives an intake in excess of ALI, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. For I-131, the ALI is 50 uCi to the thyroid gland. ALI is the smaller value of uptake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) to the whole body or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001-20.2401.

TYPES OF MEASUREMENTS

Characteristics such as mode of intake, uptake, and excretion and mode of radioactive decay shall be considered in selecting the most effective and reliable types of measurements. For example, in vivo lung or total body measurements shortly following exposure generally provide reliable estimates of intakes for most gamma-emitting radionuclides. In vitro measurements shall be used for radionuclides that emit little or no gamma radiation; however, in vitro urine or fecal measurements for the first voiding following exposure, while providing important information for assessing potential significance, do not generally represent equilibrium conditions and thereby shall not be relied upon in evaluating intakes. ICRP Publication 54 and NCRP Report No. 87 provide guidance acceptable to the NRC for determining the types of bioassay measurements that shall be made considering the physical and biological characteristics of the radioactive material.

RECORDKEEPING

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.1204 (c), 20.2103 (b), and 20.2106 (a).

INTERPRETATION OF BIOASSAY MEASUREMENTS

The specific scope and depth of the evaluation of bioassay measurements, as discussed in the Estimating Intake - Evaluation and Investigational Levels section, depends on the potential significance of the intake. The methods presented below are acceptable to the NRC staff for correlating bioassay measurements to estimates of intakes for the purpose of demonstrating compliance with the occupational dose limits of 10 CFR 20.1201.

Time of Exposure

Accurate estimation of intake from bioassay measurements is dependent upon knowledge of time of intake. Generally, the time of intake is known considering work activities and other monitoring data, such as air sample data; therefore, the time of intake will be known for all but unusual situations. When the time of intake cannot be determined from monitoring data, it can often be determined from information provided by the individual. When information is insufficient to determine the time of intake, it is acceptable to assume that the intake occurred at the midpoint of the time period since the last bioassay measurement. This initial assumption should be refined by using any available information such as the individual's work schedule, facility operations data, historical air monitoring data, and effective half-life of the radionuclides detected (see Example 2 of Supplement A).

Acceptable Biokinetic Models

Determining a worker's intake from bioassay measurements involves comparing the measured bodily retention or excretion to a tabulated value. The models and methods used for evaluating bioassay measurements should provide a reasonable assessment of the worker's exposure. For intakes that are a small fraction of the limit, greater inaccuracy in the estimate of intake can be accepted without significant impact on the overall assessment of a worker's dose; however, for annual exposures for which monitoring is required by 10 CFR 20.1502(b), these methods should not lead to significant underestimation or overestimation of the actual intake.

Variations from predicted retention and excretion for specific individuals can be expected. Excretion of radionuclides may be influenced by the worker's diet, health condition, age, level of physical and metabolic activity, or physiological characteristics. The lung deposition and clearance of the inhaled radionuclide, the particle size distribution, and the time of the excretion also influence the excretion rate of radionuclides.

Important considerations for evaluating bioassay measurements include:

- Appropriate measurement technique (in vivo or in vitro) based on radionuclide decay characteristics (i.e., types of radiation emitted) and biokinetic characteristics (i.e., systemic uptake and retention and urine and fecal excretion fractions);
- The effects of diuretics or chelation to reduce systemic uptake and to increase excretion or excretion rates;

- Representativeness of measurements such as 24-hour or accumulated urine or fecal measurements;
- The appropriate lung clearance class (D, W, or Y), if known (see definition of class in 10 CFR 20.1003), or if no information on the biological behavior or chemical form is available, the most restrictive clearance class relevant for the particular element should be assumed (i.e., that class that gives the lowest value of ALI);
- Particle size distribution;
- Chemical toxicity, as in the case of uranium (see 10 CFR 20.1201(e)).

The metabolic models in ICRP-30 and accompanying addenda and ICRP-54 present acceptable bases for estimating intake from bioassay measurements. Other acceptable models are the tritium model developed by Johnson and Dunford and the plutonium urinary excretion model developed by Jones.

The use of computer codes that apply these models is also acceptable for evaluating bioassay measurements, provided it can be demonstrated through documented testing that the models and methods employed provide results consistent with the acceptable models. There are several commercially available computer codes for interpreting bioassay measurements; these codes may be used as long as the software application is based on acceptable models and provides results that correctly implement the models. No specific computer codes are endorsed by the NRC staff. Licensees are responsible for ensuring that computer codes are appropriate for use in their particular circumstances.

Intake Retention and Excretion Fractions for Calculating Intakes

ICRP-54 presents urinary excretion and fecal excretion equations as a function of time following intake for a number of radionuclides. By differentiating these equations, intake retention functions can be derived. The solution of these equations over a range of times allows the development of tabulated intake retention and excretion fractions. The intake retention fractions⁶ (IRFs) contained in NUREG/CR-4884 were developed in this manner and represent an acceptable basis for correlating bioassay measurements to estimates of intake. To apply the use of IRFs for calculating an individual's radionuclide intake from a single bioassay measurement, divide the total activity in 24-hour urine, 24-hour feces, accumulated urine, or accumulated feces,⁷ or the radionuclide content in the total body, systemic organs, lungs, nasal passages, or GI tract, by the appropriate IRF value in NUREG/CR-4884.

⁶For purposes of this guide and the application of the data from NUREG/CR-4884, the parameter IRF denotes both intake retention fractions and intake excretion fractions.

⁷The term "24-hour urine" means the total urine output collected over a 24-hour period, and the term "24-hour feces" means the total feces output collected over a 24-hour period. "Accumulated urine" and "accumulated feces" mean the total output since time of exposure.

Equation 1 demonstrates this method:

$$I = \frac{A(t)}{IRF(t)} \quad \text{Equation 1}$$

where:

- I = Estimate of intake with units the same as $A(t)$;
- $A(t)$ = Numerical value of the bioassay measurement obtained at time t (decay corrected to time of sampling for in vitro measurements) with appropriate units (μCi , Bq , or μg);
- $IRF(t)$ = Intake retention fraction corresponding to type of measurement for time t after estimated time of intake.

Evaluating Spot Samples

If the total urine or feces is not collected for the 24-hour period, the following equations may be used to estimate the total activity excreted or eliminated over the 24-hour period based on less frequent sampling (spot samples).

$$\Delta A_i = C_i E(t_i - t_{i-1}) \quad \text{Equation 2}$$

$$A_i = \Delta A_1 + \Delta A_2 + \dots \Delta A_i \quad \text{Equation 3}$$

where:

- ΔA_i = Activity or amount of radioactive material in sample i
- i = The sequence number of the sample
- C_i = The radionuclide concentration in urine (activity/liter) or feces (activity/gram) of sample i , decay corrected to the time of sampling
- E = Daily excretion rate (use measured rates when available, or assume values of 1.4 liters/day for urine and 135 grams/day for feces for standard man or 1.0 liter/day for urine and 110 grams/day for feces for standard woman)
- t_i = The time (days) after intake that sample i is collected
- A_i = Total activity excreted or eliminated up to time

This method is applicable only if spot samples are collected with a frequency consistent with the significance of changes in the excretion rates. In general, spot samples should be collected frequently enough that there is no more than a 30% increase in the IRFs between bioassay measurements. For example, if the IRF for accumulated urine increases at a rate of 30% per day, spot samples should be collected daily. If the rate is 10% per day, collecting spot samples once every 3 days would be adequate. Also, the rapid clearance and excretion of inhaled particles from the N-P region of the lung makes it important that at least one spot sample be collected within the first 24 hours after exposure. Otherwise, the reliability of using accumulated samples and excretion fractions for calculating intakes should be examined; calculations based on spot samples correlated to 24-hour samples may provide better estimates.

For spot samples used to estimate an equivalent 24-hour sample, correcting for abnormal conditions of high or low fluid intake or excessive loss of fluids by perspiration may be warranted. NCRP-87 presents the following method based on a relationship between the specific gravity (sp. gr.) of the sample to the average specific gravity of urine (1.024 g/ml).

$$\text{corr.conc.} = \text{meas.conc.} \frac{1.024 - 1 \text{ (g/ml)}}{\text{meas. sp. gr.} - 1 \text{ (g/ml)}} \quad \text{Equation 4}$$

An alternative to this method is a correction based on the expected creatine excretion rate of 1.7 grams/day for men and 1.0 grams/day for women. Refer to NCRP-87 for additional information.

Logarithmic interpolation should be used for interpolating retention and excretion fractions (see Example 2 in Supplement A). For example, using the NUREG/CR-4884 data, an IRF value for 2.8 days post intake should be calculated by a logarithmic interpolation between the 2-day and the 3-day IRF values.

Examples of the application of intake retention and excretion fractions based on the NUREG/CR-4884 data set are provided in Supplement A.

Evaluating Multiple Bioassay Measurements

When multiple bioassay measurements are made, a statistical evaluation of the data should be performed. Numerous statistical methods are available for evaluating multiple measurements, but the results will be no better than the reliability of the data set. Measurements that are suspect or known to be inaccurate should be excluded from the analysis. Additional measurements should be used for obtaining an appropriate data set. For the evaluation of multiple measurements, NUREG/CR-4884 recommends the use of unweighted, minimized chi-squared statistics, assuming all variances are the same (i.e., a least squares fit). This method is acceptable to the NRC staff; it is simple and straightforward for evaluating multiple bioassay measurements. The equation is as follows:

$$I = \frac{\sum_i IRF_i(t) \times A_i(t)}{\sum_i IRF_i(t)^2} \quad \text{Equation 5}$$

Other statistical analyses of the data may provide a better fit of the data, considering the particulars of the measurements. For example, a minimized chi-squared fit weighted by the inverse of the variance may be used. Several methods are available for estimating the variance of measurements. One approach, applicable to radioactivity measurements, is to assume that the variance is proportional to the value of the measurement itself. Another is the assumption that the variance is proportional to the expected value.

In selecting the statistical method to be used for evaluating multiple measurements, consideration should be given to available information, particularly observed variability of the data and reliability of individual measurements. Other statistical methods are acceptable to the NRC staff, provided it can be demonstrated that the results provide reasonable estimates of intake.

Adjusting Intake Estimates for Multiple and Continuous Intakes

In practice, a worker may receive repeated exposures to the same radionuclide over a period of time. These intakes should be treated as separate acute intakes if measurements collected through the period allow for the individual quantification of each exposure. As a general rule, if intakes are separated in time so that the retained or eliminated fraction from an earlier intake is less than 10% of the retention or excretion fraction for the next intake, each intake may be evaluated separately without regard to any previous intakes.

Continual intakes that are distributed equally in size and time may be approximated using a relationship based on time integration of the IRF. The total intake is estimated by dividing the measured activity by the appropriate time integrated retention or excretion fraction. An example using the IRF values from NUREG/CR-4884 (Ref. 4) would be to perform a numerical integration over the individual IRF values covering the time period of interest. Any one of a number of standard integration techniques, including numerical and analytical solutions, can be used. For example, using the trapezoidal rule (see example 7 in Supplement A) yields the following method:

For bioassay measurements taken during an exposure time interval, the equation is:

$$I = \frac{A(t) \times T}{\int_0^t IRF(\mu) d\mu} \quad \text{for } t < T \quad \text{Equation 6}$$

Using the trapezoidal rule to solve Equation 6 yields the following approximation:

Equation 7

$$I \approx \frac{A(t) \times T \times n}{t \times \left[\frac{IRF(t) + IRF(t=0.1 \text{ days})}{2} + IRF(\mu_1) + \dots + IRF(\mu_{n-1}) \right]}$$

For bioassay measurements taken after an exposure interval, the equation is:

$$I = \frac{A(t) \times T}{t} \quad \text{for } t \geq T$$

$$\int_{t-T}^t IRF(\mu) \, d\mu$$

Equation 8

Likewise, Equation 8 may be approximated using the trapezoidal rule, which yields Equation 9:

$$I \approx \frac{A(t) \times n}{\left[\frac{IRF(t-T) + IRF(t)}{2} + IRF(\mu_1) + \dots + IRF(\mu_{n-1}) \right]}$$

Equation 9

where:

- I = Total intake during period T
- A(t) = Amount of activity in compartment or whole body at time t following onset of intake
- T = Duration of intake (exposure time period)
- t = Time from onset of intake to time of measurement
- IRF(u) = Intake retention fraction at time u in compartment or whole body for a single intake of a radionuclide
- μ = Variable time between integration limits
- n = number of increments

The number of increments to be used for a numerical integration should be selected to minimize unnecessary errors associated with the particulars of the IRF values over which the integration is being performed. In general, errors associated with the integration technique used should be limited to less than 10%.

Correcting Intake Estimates for Particle Size Differences

The models used for deriving intake retention and excretion fractions, such as those in NUREG/CR-4884, are typically based on 1-micrometer activity median aerodynamic diameter (AMAD) particles. It is acceptable to correct intake estimates for particles of different sizes. These corrections often help explain retention or excretion rates different from those expected, such as would occur for larger particles preferentially deposited in the upper region of the respiratory tract (N-P region) with more rapid clearance times. Guidance for determining AMADs is provided in Regulatory Guide 8.25, Air Sampling in the Workplace."

Equation 10, taken from Appendix B to NUREG/CR-4884, should be used for revising the total body IRFs in NUREG/CR-4884 to particle size distributions between 0.1 to 20 μm AMAD.

Equation 10

$$\begin{aligned} IRF_{AMAD} = IRF_{1\mu m} \sum_T \left[f_{N-P,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_{N-P}(AMAD)}{D_{N-P}(1 \mu m)} \right. \\ \left. + f_{T-B,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_{T-B}(AMAD)}{D_{T-B}(1 \mu m)} \right. \\ \left. + f_{P,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_P(AMAD)}{D_P(1 \mu m)} \right] \end{aligned}$$

where:

IRF_{AMAD} = IRF for the activity median aerodynamic diameter (AMAD) of interest

$IRF_{1\mu m}$ = Total body IRF for inhalation of 1 μm AMAD aerosols (these IRFs are given in Appendix B to NUREG/CR-4884)

\sum_T = Summation over all tissues (and organs) T

N-P, T-B, P = The compartments or regions of deposition of the respiratory tract: the nasopharyngeal passage region (N-P), the tracheobronchial region (T-B), and the pulmonary region (P)

$f_{N-P,T}, f_{T-B,T}, f_{P,T}$ = The fraction of committed dose equivalent in the tissue T resulting from deposition in the N-P, T-B, and P regions, respectively. (Values for individual radionuclides are contained in the Supplements to Part 1 of

ICRP-30)

H_{50T} = Committed dose equivalent for tissue (or organ) T per unit intake

W_T = Tissue (or organ) weighting factor, from 10 CFR 20.1003

D_{N-P} , D_{T-B} , D_P = Regional deposition fractions for an aerosol entering the respiratory system. (Values presented in Table 1, below.)

Equation 10 may not provide valid corrections for time periods shortly following intakes. The time after intake for which Equation 10 begins to yield satisfactory results is less than 1 day for Class D compounds. For Class W compounds, this time is about 7 days following intake, and for Class Y compounds, it is about 9 days following intake.

Table L.3

Aerosol AMAD

	0.2 μm		0.5 μm	0.7 μm	1.0 μm
D_{N-P}	0.05	0.16	0.23	0.30	
D_{T-B}	0.08	0.08	0.08	0.08	
D_P	0.50	0.35	0.30	0.25	
Total Deposition	0.63	0.59		0.61	0.63
	2.0 μm		5.0 μm	7.0 μm	10.0 μm
D_{N-P}	0.50	0.74	0.81	0.87	
D_{T-B}	0.08	0.08	0.08	0.08	
D_P	0.17	0.09	0.07	0.05	
Total Deposition	0.75	0.91		0.96	1.00

Equation 10, for revising the IRF for different particle sizes, is applicable for the total body IRF. ICRP-54 provides graphs of IRF values for 0.1 μm , 1 μm , and 10 μm AMAD particles for other tissues and excreta. Intake retention and excretion functions are derived for other AMAD

particles based on the acceptable biokinetic modeling, as discussed in Regulatory Positions 4.2 and 4.3 of Regulatory Guide 8.9.

It is acceptable to take into account particle size distribution and its effect on lung deposition and transfer in evaluating an individual's dose. ICRP-30 (with supplements) provides data and methods for use in evaluating the lung deposition and resultant doses for particle sizes between 0.1 and 20 μm AMAD. For particles with AMADs greater than 20 μm , complete deposition in the N-P region can be assumed.

It is acceptable to compare the estimate of intake for different particle sizes with the ALIs in Appendix B to §§20.1001-20.2401 for demonstrating compliance with intake limits. The ALIs are based on a particle size of 1 micrometer; however, modifying the ALI values for different particle size distributions requires prior NRC approval (10 CFR 20.1204(c)(2)).

Use of Individual Specific Biokinetic Modeling

Individual specific retention and excretion rates may be used in developing biokinetic models that differ from the reference man modeling (10 CFR 20.1204(c)). The quality and quantity of data used for this type of individual specific modeling should be sufficient to justify the revised model. Licensees should not attempt to develop individual specific retention and excretion fractions in the absence of actual biochemical and particle size information. Individual specific modeling is not required but may be developed; the modeling as presented above is acceptable for evaluating regulatory compliance.

CALCULATING DOSE FROM ESTIMATES OF INTAKE

Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," contains additional guidance on determining doses based on calculated intakes once the intake is determined.

RECORD-KEEPING

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.1204(c), 20.2103(b), and 20.2106(a). For additional information on RECORD-KEEPING and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this appendix.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described in this appendix will be used by the NRC staff for evaluating compliance with 10 CFR 20.1001-20.2401.

INTAKE RETENTION FRACTION EXAMPLES

Examples illustrating the use of retention and excretion functions for calculating intakes based on bioassay measurements are presented in Appendix A of Regulatory Guide 8.9. The data used for these examples are taken from NUREG/CR-4884, "Interpretation of Bioassay Measurements." These examples do not illustrate the use of all possible bioassay or health physics measurements that are available (e.g., excreta and air sampling measurements) during an exposure incident. The examples demonstrate the use of retention and excretion factors to:

- Estimate intake from one or several bioassay measurements,
- Adjust intake estimates for multiple or continuous intakes, and
- Correct intake estimates for particle size differences.

Appendix M

Guidance for Demonstrating that Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating that Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

Licensees must show compliance with both portions of the regulation. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

Calculation Method*

* For ease of use, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 foot (ft) = 0.305 meter; 1 mrem = 0.01 mSv.

The calculational method takes a tiered approach, going through a four-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) licensed material is a point source; (2) typical radiation levels encountered when the source is in the shielded position are taken from the manufacturer's literature; and (3) credit is taken for any shielding found between the licensed material and the unrestricted areas.

Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine

if the distance between the licensed material and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Part 3 considers the distance, the portion of time and dose rate during source exposure, the portion of time and dose rate while the source is in the shielded position, and the portion of time that the affected member of the public is present. Part 4 considers the approach in Part 3 plus any additional shielding between the licensed material and the unrestricted area. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses that could be received.

Example 1

To better understand the calculational method, we will examine Therapy Clinic, an HDR Afterloading Device licensee. Yesterday, the clinic's president noted that the new HDR facility is close to his secretary's desk and he asked Joe, the RSO, to determine if the clinic is complying with NRC's regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked HDR room where the clinic has located its unit. Joe measures the distance from the HDR unit to the wall and assumes that the device would have the maximum dose rate when the source is exposed: 5000 mrem per hour at one meter. This is the maximum dose rate during treatment time. Figure M.1 is Joe's sketch of the areas in question, and Table M.1 summarizes the information Joe has on the HDR unit.

A Bird's Eye View of Office and HDR

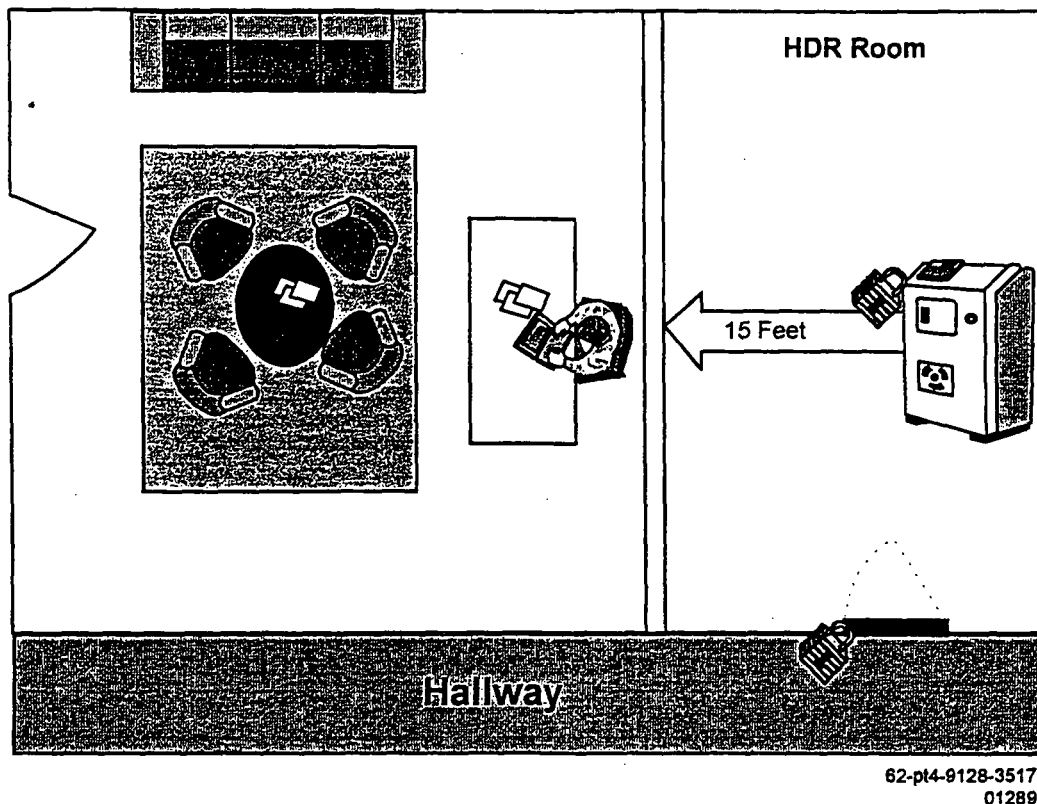


Figure M.1 Diagram of Office and HDR Facility. *This sketch shows the areas described in Examples 1 and 2.*

Table M.1 Information Known About the HDR Unit

Description of Known Information	Ir-192/HDR/10 Ci
Dose rate in mrem/hour encountered at specified distance from the HDR unit (from manufacturer)	5000 mrem/hour at 1 meter (3.28 ft)
Distance in ft to secretary's chair	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the HDR unit and the secretary's chair may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes: (1) the HDR unit is constantly present with a patient being treated; and (2) the secretary is constantly sitting in the desk chair (i.e., 24 hours/day). Joe proceeds to calculate the dose she might receive hourly and yearly from the HDR unit as shown in Table M.2 below.

Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received From the HDR Unit

Step No.	Description	Input Data	Results
1	Dose received in an hour at known distance from the HDR unit (e.g., from the manufacturer), in mrem/hour	5000	5000
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.28) ²	10.8
3	Square of the distance (ft) from the HDR unit to the secretary's desk in an unrestricted area, in ft ²	(15.0) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	5000 x 10.8	54000
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM THE HDR UNIT , in mrem in an hour	54000/225	240
6	Multiply the result of Step 5 by 24 hours/day x 366 (leap year) days/year = MAXIMUM ANNUAL DOSE RECEIVED FROM THE HDR UNIT , in mrem in a year	240 x 24 x 366	2108000

Note: The result in Step 5 does not demonstrate compliance with the 2 mrem in any one hour limit. Also, if the result in Step 6 exceeds 100 mrem/year, proceed to Part 2 of the calculational method.

At this point, Joe notes that the total dose that an individual could receive in any one hour greatly exceeds 2 mrem in an hour (i.e., 240 mrem in an hour) and notes that an individual could receive a dose of 2108000 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hours/day. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the HDR unit is constantly present and in use (i.e., 24 hours/day). He then recalculates the annual dose received.

Table M.3 Calculational Method, Part 2: Annual Dose Received From the HDR Unit

Step No.	Description	Results
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hours/day; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5.0
	B. Average number of days per week in area (e.g., secretary is part time and works 3 days/week)	3.0
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
8	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5.0 \times 3.0 \times 52$ = 780
9	Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM THE HDR UNIT CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	$240 \times 780 =$ 187000

Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the calculational method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still greatly exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that the HDR unit is not constantly in use when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table M.4 Calculational Method, Part 3: Summary of Information

Step No.	Description	Input
10	Dose rate while the source is in the shielded position, in mrem per hour at 3.28 ft from the HDR (from manufacturer)	0.02
11	Dose rate while patient is being treated, in mrem per hour at 3.28 ft from the HDR	5000
12	Maximum number of patients treated per hour	2.0
13	Maximum treatment time, in minutes	1.0
14	From Table M.1, distance from HDR to secretary, in feet	15.0
15	From Step 8, average number of hours that secretary is in area of concern, per year	780

Table M.5 Calculational Method, Part 3: Annual Dose Received from HDR

Step No.	Description	Result
16	[60 minus the input from Step 12 multiplied by (the input from Step 13)] divided by 60 = $[60 - 2 \times (1)] / 60 = [60. - 2.] / 60 =$ FRACTION OF TIME THE SOURCE IS IN THE SHIELDED POSITION	0.97
17	1.0 minus the result from Step 16 = $1 - 0.97 =$ FRACTION OF TIME THE HDR UNIT IS USED	0.03
18	(The input from Step 10 multiplied by the result from Step 16) plus (the input from Step 11 multiplied by the result from Step 17) = $(0.02 \times 0.97) + (5000 \times 0.03) = 0.02 + 150 =$ AVERAGE DOSE ENCOUNTERED AT 3.28 FEET FROM THE HDR UNIT, in mrem in an hour.	150
19	The result from Step 18 multiplied by (3.28 squared divided by the input from Step 14 squared) = $150 \times (3.28^2 / 15^2) = 150 \times (10.8 / 225) =$ AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY, in mrem per hour.	7.20
20	The result from Step 19 multiplied by the input from Step 15 = $780 \times 7.20 =$ ANNUAL DOSE RECEIVED FROM HDR UNIT CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND HDR UNIT USAGE, in mrem in a year.	5600

Note: If the result in Step 20 is greater than 100 mrem/yr, the licensee must take corrective actions. Corrective action may include shielding the HDR treatment room.

Although, Joe notes that the result in Step 20 is significantly lower, he realizes that the result still exceeds the 100 mrem in a year limit and that he must consider additional corrective actions. As he reviews the situation, he realizes that the walls of the treatment room consist of approximately 10.5 inches of concrete. He decides to take this into account.

Example 1: Part 4

Table M.6 Calculational Method, Part 4: Summary of Information

Step No.	Description	Input
21	Tenth Value Layer for Iridium 192 in concrete in inches	3.5
22	Thickness of concrete in wall	10.5
23	Annual dose received from HDR unit from Step No. 20, in mrem in a year.	5600

Table M.7 Calculational Method, Part 4: Annual Dose Received from HDR

Step No.	Description	Result
24	[Input from Step 22 divided by the input from Step 21] = [10.5/3.5] = NUMBER OF TENTH VALUE LAYERS	3.0
25	[Input from Step 23 divided by 10 raised to the result from Step 24] = $5600/10^3$ = ANNUAL DOSE RECEIVED FROM HDR UNIT CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, HDR UNIT USAGE, AND TREATMENT ROOM SHIELDING, in mrem in a year	5.6

Joe is glad to see that the results in Step 25 show compliance with the 100 mrem in a year limit. Had the result in Step 25 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions

- Calculate the effect of any additional shielding* located between the HDR unit and the secretarial workstation

* NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

- Take corrective action (e.g., move the secretarial workstation) and perform new calculations to demonstrate compliance
- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary as required by 10 CFR 19.12

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the HDR facility. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORDKEEPING: 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement - Calculational Method

This method, which allows the licensee to take credit for shielding between the HDR unit and the area in question, begins by measuring radiation levels in the areas, as opposed to using manufacturer-supplied rates at a specified distance from the unit. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation; however, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hours/week for 52 weeks/year) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs* in unrestricted areas next to the HDR unit for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/year (100 mrem/year) limit.

* TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/year (100 mrem/year) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring.

Example 2

As in Example 1, Joe is the RSO for Therapy Clinic a HDR licensee. The clinic has one HDR unit in a designated, locked area that adjoins an unrestricted area where a secretarial work station is located. See Figure M-1 and Table M-2 for information. Joe wants to see if the clinic complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 1 mSv (100 mrem).

Example 2: Part 1

Table M.8 Combination Measurement-Calculational Method

Step No.	Description	Input Data and Results
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hours/day x 30 days/month = 720
3	Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour	$100/720 = 0.14$
4	Multiply the results of Step 3 by 366 days/year [leap year] x 24 hours/day = 8760 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM THE HDR UNIT , in mrem in a year	$366 \times 24 \times 0.14 = 8784 \times 0.14 =$ 1230

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the

licensee will need to reevaluate the potential doses that could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations.

Example 2: Part 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area and the time the HDR unit was operating, as he did in Parts 2 and 3 of Example 1.

Example 2: Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the secretary's desk or adding additional shielding to the wall.

Appendix N

Emergency Procedures

Emergency Procedures

Model Spill Procedures - Low and High Dose Unsealed Sources

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Use Table N-1 as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below are considered minor.

Table N.1 Relative Hazards of Common Radionuclides

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

- 6 pairs of disposable gloves, 1 pair housekeeping gloves
- 2 disposable lab coats
- 2 paper hats
- 2 pairs shoe covers
- 1 roll absorbent paper with plastic backing
- 6 plastic trash bags with twist ties
- "Radioactive Material" labeling tape
- 1 china pencil or marking pen
- 3 pre-strung "Radioactive Material" labeling tags
- Supplies for 10 contamination wipe samples
- Instructions for "Emergency Procedures"
- Clipboard with one copy of Radioactive Spill Report Form
- Pencil

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

If AUs or other personnel involved in the surgical procedure are likely to receive exposures exceeding the nonoccupational permissible dose limits specified in 10 CFR 20.1301, we will follow the procedures below:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine, etc.) will be carefully removed and contained in a closed system.
2. The surgeon and the personnel involved in the surgical procedures will wear protective gear for the protection of the eyes from possible splashing of foreign materials, as well as from beta radiation.
3. The RSO will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

If AUs or other personnel involved in the autopsy are likely to receive exposures exceeding the nonoccupational permissible dose limits specified in 10 CFR 20.1301, we will follow the procedures below:

1. Upon the death of the therapy patient, the AU in charge and the RSO will be notified immediately.
2. An autopsy will be performed only after consultation and permission from the RSO.
3. Protective eye wear will be worn by the pathologist and his assistants for protection from possible splashing of foreign materials and exposure from beta radiation.
4. If an entire block of tissue containing the radionuclide can be removed during autopsy, this will be done first. The remainder of the autopsy can then proceed as usual.
5. The RSO will evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
6. When possible, separate organs will be promptly removed from the body, and detailed dissection will be carried out a safe distance away from the body.
7. After selected small samples have been removed, the radioactive tissues that are retained will promptly be either placed in appropriately shielded vessels for storage or disposed of according to procedures deemed appropriate by the RSO and in accordance with the regulations.
8. If an injury occurs during the autopsy which results in a cut or tear in the glove, the individual will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed on any possible radiation hazard.

Model Emergency Procedures for Teletherapy Units Containing Sealed Sources-Emergency Procedures for Beam Control Failure or Malfunction

If the light signals or beam-on monitor indicates that the beam control mechanism has failed to terminate the exposure at the end of the pre-set time (e.g., if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds), the source may still be in the exposed position. The following steps are to be carried out promptly:

- Open the door to the treatment room.
- Tell an ambulatory patient to leave the room.
- If the patient is not ambulatory, enter the treatment room but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.
- Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.
- Turn off the main switch at the control panel.
- Notify the AU and RSO at once.
- Conspicuously post a sign in the area to warn others of the problem.

Authorized User: _____

Phone No.: On Duty _____ Off Duty _____

Radiation Safety Officer _____

Phone No.: On Duty _____ Off Duty _____

Appendix O

**Model Procedures for Ordering and
Receiving Packages**

Model Procedures for Ordering and Receiving Packages

Model Guidance

- We will, through a designee (e.g., RSO), authorize each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.
- We will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:
 1. Written records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier
 2. Confirmation, through the above records, that material received was ordered through proper channels.
- For deliveries during normal working hours, we will inform carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, we will inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. We will develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of radioactive material that arrives outside normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Division, Room _____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension ____.

Name

Home Telephone

Radiation Safety Officer:

Director of Nuclear Medicine:

Nuclear Medicine Technologist Supervisor:

Nuclear Medicine Technologist on call

(call page operator at extension ____)

Nuclear Medicine Physician on call

(call page operator at extension ____)

Appendix P

**Model Procedure for Safely Opening
Packages Containing Radioactive
Material**

Model Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure for Safely Opening Packages Containing Radioactive Material

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in 49 CFR 173.433 or in Table A-1 of 10 CFR Part 71 (e.g., 13.5 curies of Mo-99, Cs-137, Ir-192; 54.1 curies of I-125; 541 curies of Xe-133, or 216 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages that are so required, monitoring for external radiation levels and surface contamination must be performed within 3 hours after receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 10 CFR 20.1906(c). The NRC Regional Office and the final delivery carrier must be notified if:

1. Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) [i.e. 22 dpm/centimeter squared (cm^2) of beta and gamma emitting photons and 2.2 dpm/ cm^2 of alpha]; and
2. External radiation levels exceed the limits of 10 CFR 71.47.

We will implement the following procedure for opening each package containing radioactive material received pursuant to our NRC license:

- a. Put on gloves to prevent hand contamination.
- b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
- c. Monitor the external surfaces of a labeled* package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4.
- d. Monitor the external surfaces of a labeled* package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.
- e. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- f. Remove the packing slip.
- g. Open the outer package, following any instructions that may be provided by the supplier.
- h. Open the inner package and verify that the contents agree with the packing slip.

- i. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
- j. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. *Note: a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.
- k. Check the user request to ensure that the material received is the material that was ordered.
- l. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
- m. Make a record of the receipt.

For packages received under the general license in Section 31.11, we will implement the following procedure for opening each package:

- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO immediately.
- b. Check to ensure that the material received is the material that was ordered.

* Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations, 49 CFR 172.403 and 172.436-440.

Appendix Q

Model Leak Test Program

Model Leak Test Program

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 0.005 microcurie of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in microcuries}} = \text{efficiency in cpm/microcurie}$$

where: cpm = counts per minute
 std = standard
 bkg = background

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcuries and record.

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/microcurie}} = \text{microcuries on wipe sample}$$

- Leak test records will be retained in accordance with 10 CFR 35.2067 for three years. The records must contain:
 1. The model number and serial number (if assigned) of each source tested,
 2. The identity of each source radionuclide and its estimated activity,
 3. The measured activity of each test sample expressed in microcuries,
 4. A description of the method used to measure each test sample,
 5. The date of the test, and
 6. The name of the individual who performed the test.
- If the wipe test activity is 0.005 microcurie or greater:
 1. Immediately withdraw the sealed source from use and either store the source, dispose of the source, or cause the source to be repaired, in accordance with the requirements in 10 CFR Parts 20 and 30.
 2. File a report within five days of the leakage test with the appropriate NRC Regional Office listed in 10 CFR 30.6.

Appendix R

Model Procedure for Area Surveys

Model Procedure for Area Surveys

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples should be analyzed in a low-background area.
- Consider using a gamma counter system with a single or multi-channel analyzer to count samples containing gamma-emitters (e.g., Cs-137, Co-60).
- Consider using either a liquid scintillation or a gas-flow proportional counting system to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

We will implement the following procedure for ambient radiation level surveys:

- Dose-rate surveys, at a minimum, will be performed in locations where:
 1. workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits, or
 2. an individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- 10 CFR 20.1301 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 10 CFR 20.1301 are met.
- Radiation level surveys will consist of measurements with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour. The following areas and frequencies will be followed:
 1. Survey at the end of each day of use for all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms should be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μ Ci).
 2. Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μ Ci at a time).

3. Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents, etc.) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
 4. Survey quarterly all sealed source and brachytherapy source storage areas.
- The RSO will be notified immediately of radiation levels that exceed trigger levels. Trigger levels for restricted and unrestricted areas are presented in Table R-1.

Table R.1 Ambient Dose Rate Trigger Levels

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.05 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

We will implement the following procedure for contamination surveys:

- Contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through use of a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.
- Contamination surveys should be performed:
 1. to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
 2. after any spill or contamination event
 3. when procedures or processes have changed
 4. to evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
 5. in unrestricted areas at frequencies consistent with the types and quantities of materials in use but not less frequently than monthly
 6. in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Personnel will survey for contamination in locations where individuals are working with an unsealed form of radioactive material, in an amount greater than or equal to 10 percent of the smallest annual limit on intake (*ALI*) (either the inhalation or ingestion *ALI*) listed for that radionuclide in 10 CFR Part 20. These surveys will be done at a frequency appropriate to the types and quantities of radioactive materials in use, but at least monthly. If amounts are used

that are greater than or equal to the smallest *ALI* listed for that radionuclide in 10 CFR Part 20, then detailed documented surveys should be performed at least weekly.

- The method for performing removable contamination surveys must be sufficiently sensitive to detect the most restrictive isotope used and listed in Table R.2 for restricted areas and R.3 for unrestricted areas (e.g., 200 dpm/100 cm² for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies will be followed:
 1. Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99m heart agents, etc.), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
 2. Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (< 200 microcuries at a time).
 3. Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity will be used to convert sample measurements (usually in cpm) to dpm.
- The area will be either decontaminated, shielded, or posted and restricted from use if unable to decontaminate.
- The RSO will be immediately notified of contamination levels in excess of the trigger levels. Trigger levels for restricted areas are presented in Table R-2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels. When it is not possible to get to background levels, we will ensure that the amounts do not exceed the contamination levels listed in Table R-3.

Table R.2 Acceptable Surface Contamination Levels in Restricted Areas in dpm/100 cm²

Area, clothing, skin if indicated	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas, skin	2000	20000

Table R.3 Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm²

Nuclide^a	Average^{b, c, f}	Maximum^{b, d, f}	Removable^{b, e, f}
I-125, I-129, Transuranics	100	300	20
I-126, I-131, I-133, Sr-90	1,000	3,000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000	15,000	1,000

- a) Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.
- b) As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- c) Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
- d) The maximum contamination level applies to an area of not more than 100 cm².
- e) The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
- f) The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 cm and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

- When equipment or facilities that are potentially contaminated are to be released to unrestricted areas, the above table provides the maximum acceptable residual levels. To the extent practicable and consistent with the ALARA principle, it is appropriate to decontaminate to below these levels. Surface contamination surveys will be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use to ensure that they meet these limits.
- A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

Alternate Survey Frequency

Classification of Laboratories:

Survey Frequency Category

<u>Group</u>	<u>Low</u>	<u>Medium</u>	<u>High</u>
1	< 1 mCi	1 mCi to 10 mCi	> 10 mCi
2	< 1 mCi	1 mCi to 100 mCi	> 100 mCi
3	< 100 mCi	100 mCi to 10 Ci	> 10 Ci
4	< 10 Ci	10 Ci to 1000 Ci	> 1000 Ci

Proportional fractions are to be used for more than one isotope.

<u>Modifying Factors</u>	<u>Factors</u>
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

Low - Not less than once a month

Medium - Not less than once per week

High - Not less than once per normal working day.

Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238 Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 (13 y) Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249
Group 3	Be-7 C-14 F-18 Na-24 Cl-38 Si-31 P-32 S-35 A-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-131m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-131 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171, Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-191 Pt-193 Pt-197 Au-196 Au-198 Au-199 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239
Group 4	H-3 O-15 A-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-91m Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat.

Survey Record Requirements

Each survey report should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe tests were taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

Appendix S

Procedures for Developing, Maintaining, and Implementing Written Directives

Procedures for Developing, Maintaining, and Implementing Written Directives

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This model does not limit you from using other guidance in developing procedures for administrations requiring a WD, e.g., information available from the Joint Commission on Accreditation of Healthcare Organizations or the American College of Radiology.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department when the AU prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an AMP, a dosimetrist, and a radiation therapist. Conducting the plan of treatment may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. In addition, 10 CFR 35.27(c) requires that licensees establish a policy for all supervised individuals to request clarification, as needed, about instructions, including procedures requiring a WD.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery, and future emerging technologies. For each modality, the licensee shall develop procedures for WDs to meet the objectives of 10 CFR 35.40 and 35.41 (as applicable to the type of medical use), outlined below:

- Have an authorized user prepare, date, and sign a written directive prior to the administration,
- Verify the patient's or human research subject's identity prior to each administration,
- Verify that the specific details of the administration are in accordance with the written directive and the treatment plan,
- Check both manual and computer-generated dose calculations,

- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices, and
- Record the radiopharmaceutical dosage or radiation dose actually administered.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μ Ci), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40. The licensee shall retain the WD in accordance with 10 CFR 35.2040.

1. SUGGESTED POLICIES AND PROCEDURES FOR ANY THERAPEUTIC DOSE OR DOSAGE OF A RADIONUCLIDE OR ANY DOSAGE OF QUANTITIES GREATER THAN 30 MICROCURIES OF SODIUM IODIDE I-131.

We will establish the following policies and procedures:

- a. An AU must prepare, date, and sign a WD prior to the administration of any dose or dosage. This is required by 10 CFR 35.40.
- b. Prior to administering a dose or dosage, the patient's or human research subject's identity will be verified as the individual named in the WD. Examples of patient identity verification include the patient's ID bracelet, hospital ID card, driver's license or social security card.
- c. Before administering the dose or dosage, the specific details of the administration will be verified in accordance with the WD or plan of treatment. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded vials or sealed sources, or using clearly marked storage locations. The verification will be performed by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist) preferably other than the individual who prepared the dose or dosage or the treatment plan.
- d. All workers will be instructed to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done, prior to administration, rather than continuing a procedure when there is any doubt.

2. ADDITIONAL SUGGESTED POLICIES AND PROCEDURES FOR SEALED THERAPEUTIC SOURCES AND DEVICES CONTAINING SEALED THERAPEUTIC SOURCES

We will establish the additional following policies and procedures:

- a. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must approve a plan of treatment that provides

sufficient information and direction to meet the objectives of the WD. Suggested guidelines for information to be included in the plan of treatment may be obtained from the American College of Radiology.

- b. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration; however, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).
- c. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. The responsibilities and conditions of supervision are contained in 10 CFR 35.27. Suggested methods for checking the calculations include the following:
 - Computer-generated dose calculations will be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).
 - The computer-generated dose calculations for input into the therapy console will be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
 - Manual dose calculations will be checked for:
 - i. Arithmetic errors,
 - ii. Appropriate transfer of data from the WD, plan of treatment, tables and graphs,
 - iii. Appropriate use of nomograms (when applicable), and
 - iv. Appropriate use of all pertinent data in the calculations

If possible, the therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations should be checked.

- d. After insertion of permanent implant brachytherapy sources, we will have an AU promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

- e. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing shall be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on our specific needs and applications. Acceptance testing will also be considered after each source replacement or when spot-check measurements indicated that the source output differed by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay.
- f. Independent checks on full calibration measurements will be performed when possible. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
 - i. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51 using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630), or
 - ii. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5 percent.
- g. Full calibration measurements will include the determination of transmission factors for trays, wedges, applicators, etc. Transmission factors for other beam-modifying devices (e.g., nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) will be determined before the first medical use of the beam-modifying device and after replacement of the source.
- h. For GSR, particular emphasis will be directed toward verifying that the stereoscopic frame coordinates on the patient's skull match those of the plan of treatment.
- i. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- j. If possible, a weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or plan of treatment.

Review of Administrations Requiring a Written Directive

The licensee should consider establishing procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery and emerging technologies. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

For example, using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate (or lot tolerance percent defective) of 2 percent:

{ }Lot Size	{ }Sample Size	{ }Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4000	115	0

In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly. If the number of errors in the sample does not exceed the acceptance number in the appropriate Sampling Table, the lot should be accepted. For each patient's case, a comparison should be made between what was administered versus what was prescribed in the WD. If the difference between what was administered and what was prescribed exceeds the criteria for either a medical event or precursor event, that comparison is unacceptable. The number of unacceptable comparisons allowed for each sample size and lot tolerance percent defective is provided in the acceptance sampling tables of 10 CFR 32.110.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The licensee or designee should regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

For each patient case reviewed, the licensee shall determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or plan of treatment, as applicable. For each patient case reviewed, the licensee should identify deviations from the WD, the cause of each deviation, and the action required to prevent recurrence.

Records of Medical Events and Precursor Events

You shall maintain a record of medical events or precursor events for three years as required by 10 CFR 35.2045. The licensee shall notify by telephone the NRC Operations Center¹ no later than the next calendar day after discovery of the medical event and shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. A licensee shall report, by telephone no later than the next calendar day, any precursor event. The licensee shall submit a written report to the appropriate NRC Regional Office listed, within 15 days after discovery of the precursor event.

¹ The commercial telephone number of the NRC Operations Center is (301) 951-0550.

Appendix T

**Model Procedures for Safe Use of
Licensed Material**

Model Procedures for Safe Use of Licensed Material

Model Procedures for Safe Use of Radionuclides

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly needle.)
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear a finger exposure monitor (TLD), if required, during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; when performing camera quality control; when holding patients during procedures; and when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Consider wipe testing unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
- Consider surveying with a radiation detection survey meter, all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70 (except when administering therapy dosages in patients' rooms).
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multidose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904, with the radionuclide, the activity, the date for which the activity is estimated, and the kinds of materials (i.e., radiopharmaceutical).
- Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904, with the radionuclide, the activity, the date for which the activity is estimated, and

the kinds of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in appendix C to Part 20, the syringe or vial need only be labeled as containing radioactive material and the radiopharmaceutical (10 CFR 35.69). Consider also labeling the syringe with the type of study and the patient's name.

- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).
- Do not use a dosage if it is greater than +20 percent off from the prescribed dosage, except for prescribed dosages of less than 30 microcuries or as approved by an authorized user.
- When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Consider checking the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Consider using a cart or wheelchair to move flood sources, waste, and other radioactive material, since sources with small amounts of radioactivity exhibit a high dose rate on contact.
- Secure all licensed material when not under the constant surveillance and immediate control of the authorized user(s).

Appendix U

Release of Patients or Human Research Subjects Administered Radioactive Materials

Release of Patients or Human Research Subjects Administered Radioactive Materials

Section 35.75, "Release of Individuals Containing Radiopharmaceuticals or permanent Implants," of 10 CFR Part 35, "Medical Use of Byproduct Material," permits licensees to "authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

RELEASE EQUATION

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients who Have Received Therapeutic Amounts of Radionuclides" (Ref. 1).

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2} \quad (\text{Equation 1})$$

Where

- $D(t)$ = Accumulated exposure at time t , in roentgens,
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44),
- Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm,
- Q_0 = Initial activity of the point source in millicuries, at the time of the release,
- T_p = Physical half-life in days,
- r = Distance from the point source to the point of interest, in centimeters,
- t = Exposure time in days.

This appendix uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693UT_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2), at a distance of 1 meter. Selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis (Ref. 2) that indicate the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2} \quad (\text{Equation 2})$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2} \quad (\text{Equation 3})$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of

the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see Section B.3, "Internal Dose," of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Regulatory Position 1.1, "Release of Patients Based on administered Activity."

REGULATORY POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using conservative assumptions of (1) administered activity, (2) physical half-life, (3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and (4) no shielding by tissue. The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Regulatory Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, a record is required by 10 CFR 35.75(c) because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table 1 are not applicable to the infant or child. In this case, it may be necessary to give

instructions as described in Regulatory Positions 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisievert (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10,000 \text{ cm}^2$.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on Dose Calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table 1. Activities and Dose Rates for Authorizing Patient Release*				
Radionuclide	COLUMN 1 Activity at or below Which Patients May Be released		COLUMN 2 Dose Rate at 1 Meter, at or below Which Patients May Be released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2

Table 1. Activities and Dose Rates for Authorizing Patient Release†

Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Table 1. Activities and Dose Rates for Authorizing Patient Release†

†The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Regulatory Position 3.1, "Records of Release," for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on the millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref. 2).

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

2. INSTRUCTIONS

2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations, the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.¹ Column 1 of Table 2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table 2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Regulatory Position 2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose that is greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation 2 or 3, as appropriate, may be used.

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.¹ The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant

or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table 3, instructions on discontinuation or on the interruption period for breast-feeding and the consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 percent of the administered activity is excreted in the breast milk (Ref. 2). The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

¹The NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to 2.3.1 and 2.3.2).

Table 2. Activities and Dose Rates Above Which Instructions Should be Given When Authorizing Patient Release¹				
Radionuclide	COLUMN 1 Activity above Which Instructions are Required		COLUMN 2 Dose Rate at 1 Meter above Which Instructions are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4

Table 2. Activities and Dose Rates Above Which Instructions Should be Given When Authorizing Patient Release*

Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Table 2. Activities and Dose Rates Above Which Instructions Should be Given When Authorizing Patient Release*

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case, because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref. 2).

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

Table 3: Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	COLUMN 1 Activity above Which Instructions are Required		COLUMN 2 Activity above Which a Record is required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding*
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hr for 370 MBq (10 mCi) 12 hr for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hr for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq(12 mCi)
Tc-99m DISIDA	1,000	30	6,000	150	
Tc-99m Glucoheptonate	1,000	30	6,000	170	
Tc-99m MIBI	1,000	30	6,000	150	
Tc-99m MDP	1,000	30	6,000	150	
Tc-99m PYP	900	25	4,000	120	
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	6 hr for 740 MBq(20 mCi)

Table 3. Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	
Tc-99m Sulphur Colloid	300	7	1,000	35	6 hr for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1,000	30	6,000	150	
Tc-99m MAG3	1,000	30	6,000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hr for 1,100 MBq (5 mCi) 12 hr for 440 MBq (2 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

Table 3: Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

NOTES: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 2).

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee. Agreement State regulations may vary.

Agreement State licensees should check with their State regulations prior to using these values.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following.

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine (Ref. 4). This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The pamphlet contains blanks, for the physician to fill in the length of time that each instruction should be followed. While this pamphlet was written for the release of patients to whom less than 1,110 mega becquerels (30 millicuries) of iodine-131 had been administered, the NRC still considers the instructions in this pamphlet to be

an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following.

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days.

- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
 - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
- Place the container with the seed or pellet in a location away from people.
- Notify _____ at telephone number _____.

RECORDS

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table 1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

(1) For Immediate Release of a Patient Based on a Patient-Specific Calculation: The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was

assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

(2) For Immediate Release of a Patient Based on Measured Dose Rate: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

(3) For Delayed Release of a Patient Based on Radioactive Decay Calculation: The time of the administration, date and time of release, and the results of the decay calculation.

(4) For Delayed Release of a Patient Based on Measured Dose Rate: The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table 3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

4. Summary Table

Table 4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table 4. Summary of Release Criteria, Required Instructions to Patients, and Records To Be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity \leq Column 1 of Table 1	Yes - if administered activity $>$ Column 1 of Table 2	No
	Retained activity	Retained activity \leq Column 1 of Table 1	Yes - if retained activity $>$ Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate \leq Column 2 of Table 1	Yes - if dose rate $>$ Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose \leq 5 mSv (0.5 rem)	Yes - if calculated dose $>$ 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		<p>Additional instructions required if: Administered activity $>$ Column 1 of Table 3 or Licensee calculated dose from breast-feeding $>$ 1 mSv (0.1 rem) to the infant or child</p>	<p>Records that instructions were provided are required if: Administered activity $>$ Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding $>$ 5 mSv (0.5 rem) to the infant or child</p>

IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

REFERENCES

1. National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)
2. S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG- 1492 (Final Report), NRC, February 1997.*
3. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, Edited by S. Treves, Springer Verlag, New York, 1995.
4. "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

SUPPLEMENT A

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide ¹	Physical Half-Life (days) ²	Exposure Rate Constant ³ (R/mCi-h at 1 cm)
Ag-111	7.45	0.150
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11 ⁴
I-131	8.04	2.2

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
In-111	2.83	3.21
Ir-192 implant	74.02	4.59 ⁴
P-32	14.29	NA ⁶
Pd-103 implant	16.96	0.86 ⁵
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2.0
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	NA ⁶
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	NA ⁶
Yb-169	32.01	1.83

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

¹ Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

² K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

³ Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Ti-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of patients Administered Radioactive Material," U.S. NRC, February 1997.

⁴ R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

⁵ A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

⁶ Not applicable (NA) because the release activity is not based on beta emissions.

SUPPLEMENT B

PROCEDURES FOR CALCULATING DOSES BASED ON PATIENT-SPECIFIC FACTORS

A licensee may release a patient who has been administered an activity higher than the values listed in Column 1 of Table 1 of this supplement, if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c). The following equation can be used to calculate doses:

(Equation B-1)

$$D(t) = \frac{34.6 \Gamma Q_0 TE (-e^{-0.693t/T_p})}{r^2}$$

Where

D(t)	=	Accumulated dose to time t, in rems
34.6	=	Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ	=	Exposure rate constant for a point source, R/mCi x hr at 1 cm
Q_0	=	Initial activity at the start of the time interval
T_p	=	Physical half-life, in days
E	=	Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient
r	=	Distance in centimeters. This value is typically 100 cm
t	=	exposure time in days

B.1 OCCUPANCY FACTOR

B.1.1 Rationale for Occupancy Factors Used to Derive Table 1

In Table 1 in this appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time.

Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table 1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B.1.2 Occupancy Factors to Consider for Patient- Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E , at 1 meter, may be used for patient-specific calculations.

- $E = 0.75$ when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- $E = 0.25$ when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
 - Maintain a prudent distance from others for at least the first 2 days,
 - Sleep alone in a room for at least the first night,
 - Do not travel by airplane or mass transportation for at least the first day,
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days,
 - Have sole use of a bathroom for at least the first 2 days,
 - Drink plenty of fluids for at least the first 2 days.
- $E = 0.125$ when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
 - Follow the instructions for $E = 0.25$ above,
 - Live alone for at least the first 2 days,
 - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient has been provided with instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{r^2}$$

Since the patient has been provided with instructions for reducing exposure as recommended for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6 (2.2 \text{ R} \cdot \text{cm}^2/\text{mCi} \cdot \text{hr})(60 \text{ mCi})(8.04 \text{ d})(0.125)}{(100 \text{ cm})^2}$$

$$D(\infty) = 4.59 \text{ millisieverts (0.459 rem)}$$

Since the dose is less than 5 millisieverts (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to 10 CFR 35.75(c), because an occupancy factor less than 0.25 at 1 meter was used.

B.2 EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p} \quad (\text{Equation B-2})$$

Where T_b = biological half-life of the radionuclide
 T_p = physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The

effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F1 and F2, respectively) can be calculated with the following equations.

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p} \quad (\text{Equation B-3})$$

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p} \quad (\text{Equation B-4})$$

Where T_{b1} = biological half-life for extrathyroidal iodide

T_{b2} = biological half-life of iodide following uptake by the thyroid

T_p = physical half-life of iodine-131.

However, simple exponential excretion models do not account for (a) the time for the iodine-131 to be absorbed from the stomach to the blood and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an under estimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8-hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80 percent. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100cm)^2} [E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff}] \quad (\text{Equation B-5})$$

F_1 = Extrathyroidal uptake fraction

F_2 = Thyroidal uptake fraction

E_1 = Occupancy factor for the first 8 hours

E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ are shown in Table B-1 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 10 CFR 35.75(c) is described in Regulatory Position 3.1 of this appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 7,400 megabecquerels (200 millicuries) of iodine-131 for the treatment of thyroid remnants and metastases.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from table A-1. The uptake fractions and effective half-lives are from Table B-1. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because (1) the effective half-life associated with the dominant component is greater than 1 day, and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for patient-Specific Calculations," of this Appendix B).

Table B-1. Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments				
Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.20 ¹	0.32 ²	0.80 ¹	5.2 ¹
Post thyroidectomy for Thyroid Cancer	0.95 ³	0.32 ²	0.05 ³	7.3 ²

Table B-1. Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

¹M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75 percent of the data points shown in Figure 1 of this *Journal of Nuclear Medicine* document.

²International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in this ICRP document.

³The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper-limit postthyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6 (2.2) (200)}{(100\text{cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693(0.33)/8.04})$$

$$+ e^{-0.693(0.33)/8.04} (0.25)(0.95)(0.32) + e^{-0.693(0.33)/8.04} (0.25)(0.05)(7.3)$$

$$D(\infty) = 4.53 \text{ millisieverts (0.453 rem)}$$

Therefore, thyroid cancer patients administered 7,400 megabecquerels (200 millicuries) of iodine-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 2,035 megabecquerels (55 millicuries) of iodine-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table A-1, and Table B-1, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6 (2.2) (55)}{(100\text{cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693(0.33)/8.04}) \\ + e^{-0.693(0.33)/8.04} (0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04} (0.25)(0.80)(5.2) \}$$

$$D(\infty) = 4.86 \text{ mSv (0.486 rem)}$$

Therefore, hyperthyroid patients administered 2,035 megabecquerels (55 millicuries) of iodine-131 would not have to remain under licensee control and could be released under 10 CFR 35.75, once the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 INTERNAL DOSE

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

$$D_i = Q (10^{-5})(DCF) \quad (\text{Equation B-6})$$

Where

- D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems
- Q = Activity administered to the patient in millicuries
- 10^{-5} = Assumed fractional intake
- DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an

individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply for cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,221 megabecquerels (33 millicuries) of iodine-131. The ingestion pathway was selected since it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rems/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

In this case, the external dose to the other person would be no greater than 5 millisieverts (0.5 rem), while the internal dose would be about 0.17 millisievert (0.017 rem). Thus, the internal dose is about 3 percent of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose, since the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

REFERENCES FOR SUPPLEMENT B

B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, NUREG-1492, February 1997.*

B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*, Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

Appendix V

Guidance for Mobile Services

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?)," Health Physics, Volume 39, Number 6, 1980.

B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients - The Contamination Hazard," British Journal of Radiology, Volume 43, 1970.

B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," American Journal of Public Health, Volume 68, Number 3, 1978.

B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

REGULATORY ANALYSIS

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997), provides the regulatory basis for this guide and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

Guidance for Mobile Services

Mobile Services

Type and Location of Use

There are three classes of mobile service. Class 1 mobile service is defined as transportation and use of byproduct material within a transport vehicle (e.g., in-van use). Class 2 mobile service is defined as transportation of byproduct material to a client's facility and use within a client's facility by the mobile service's employees (i.e., transport and use). Class 3 mobile service is defined as transportation of byproduct material to a client's facility and use of the byproduct material by the client's employees (i.e., transport only).

Class 1 and 2 mobile service providers must apply for full service authorization. Class 3 mobile service providers need only apply for authorization for possession and transport of the byproduct material. For Class 3 mobile services, the client must possess a license for medical use of the byproduct material. For Class 3 mobile services, the client is authorized to provide the patient treatments and is responsible for all aspects of the byproduct material use and patient treatments upon transfer of the byproduct material to their possession.

For all classes, list the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile services. Licensed activities must be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a), which states that we will obtain a letter signed by the management (i.e., chief executive officer or delegate) of each of our clients for which services are rendered. The letter will permit the use of byproduct material at the client's address and clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for three years after the last provision of service. Additionally, we will develop and implement survey procedures to ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed before leaving each location of use as required by 10 CFR 35.80(d).

Applicants for self-contained byproduct material services (i.e., Class 1) must provide the following facility information:

1. A detailed description and diagram(s) of the proposed use facility (e.g., van) and associated equipment, in accordance with Items 8.16 through 8.20 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), to ensure security of licensed material including controlling access to the van and storage area

keys, and to ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas. The description of the van must address radiation levels in the van driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults."

2. For therapy treatments with byproduct material, submit a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public.
3. A signed agreement that location of the device/vehicle will be on client-owned or controlled property.
4. Protection from vehicular traffic that could adversely affect patient treatment(s) must be provided. This could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
5. A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

Applicants who will provide transportable services to the client's site and use within the client's facility (i.e., Class 2) must provide the following facility information and commitment:

1. A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 8.16 through 8.20 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), to ensure security of licensed material to prevent unauthorized access, and to ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
2. A commitment to retain a record establishing that the mobile service licensee has full control of the treatment room during byproduct material use for each client. This proof may be in either the form of a signed agreement or a lease agreement with the client, establishing full control of the treatment room by the applicant during all periods of use.
3. The initial installation records of a remote afterloader device for each site of use, and function checks of the remote afterloader device.

Applicants for a Class 3 mobile service must ensure the following:

1. Each client is properly licensed for medical use of byproduct material. If applicable, ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile service licensee must not transfer the remote afterloader device to the client.
2. No signed agreement with a client may state nor imply any assumption of responsibility on the part of the mobile service for the use of byproduct material for patient treatments. This includes such activities as dosage measurements, source calibrations and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile service if specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the byproduct material for patient treatments. The responsibilities for supervision of individuals in the use of the byproduct material, set forth in 10 CFR 35.27, transfer to the client's AUs upon transfer of the device to the client by the mobile service provider.
3. The initial installation of a remote afterloader device at the client site may be performed by either the mobile service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
4. A formal record of the transfer of control of the byproduct material from the mobile service provider to the client, and from the client back to the mobile service provider, must be made for each transfer of the byproduct material. A signed receipt of each transfer must be made and retained for inspection for a period of three years.

Base Location

The base location (e.g., central radiopharmaceutical laboratory) for the mobile service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, or commercial facility. As required by 10 CFR 30.33, submit a detailed description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.16 through 8.20 of this report. The description and diagram of the proposed facility must demonstrate that the building is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), to ensure security of licensed material to prevent unauthorized access, and to ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas.

1. The applicant may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.

2. Base locations can include the use of a mobile van. In those cases in which the base facility is in the van, and there is no permanent structure for the byproduct material storage, we will have provisions for the following:
 - a. Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
 - b. Secured storage facilities will be available for storage of byproduct material and radioactive waste should the van be disabled; and
 - c. Byproduct material will be delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.
3. If a base facility is located in a residential area, we will provide the following information:
 - a. Evidence of the requirement for the private residence location is required rather than for a commercial location.
 - b. Documentation of the agreement between the residence owner and the licensee in the event of disagreements between these two entities. It is essential that the mobile service have access to the facility in the event of contamination. Included will be provisions for decontamination of the mobile service van, etc., on the client property, if necessary. Documentation from both parties will illustrate the agreement between the client and the mobile service.
 - c. A description of our program demonstrating compliance with 10 CFR 20.1301, "Dose limits for individual members of the public."
 - d. Verification that restricted areas shall not contain residential quarters.

Individuals Responsible for Radiation Safety Programs

Training And Experience

We will require the supervised individual to: 1) follow the instructions of the supervising authorized user for medical uses of byproduct material; 2) follow the written radiation protection and written directive procedures established by the licensee; and 3) comply with the regulations of 10 CFR 35.80, 10 CFR 35.647 (if applicable) and the license conditions with respect to the mobile use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

In addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable), drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures. The training records for these individuals will include (at a minimum) dates, topics discussed (e.g., DOT regulations, shielding, ALARA, basic radiation protection), attendees, and the instructor's name, and shall be maintained for 3 years for NRC review. Licensees may choose to retain records for longer periods.

Survey Instrument & Dose Measurement Instrument Checks

We will check survey instruments for proper operation with a dedicated check source before use at each address of use. We will check dose measurement instruments (e.g., dose calibrator) as described in 10 CFR 35.60 or 10 CFR 35.62, as applicable, before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material

Byproduct material will be delivered by a supplier to the base location or to the client's address, if the client is licensed to receive the type of byproduct material ordered. Delivery of byproduct material to a van that is not occupied by the mobile service personnel will not be permitted.

Alternatively, we will pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

We will develop and implement emergency procedures, in accordance with 10 CFR 20.1101, that, in part, will indicate that the RSO, AU, or a responsible designee, can be physically present at the client's address in response to incidents (e.g., accidents, spills, significant precursors, medical events) that occur at client facilities. We will indicate typical response times of the RSO and AU in the event of an incident. We will develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other events, such as, wind, water or fire damage that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile service. The transportation emergency response plan will cover both the actions to be taken by the mobile service provider's headquarters emergency response personnel and the "on scene" hazmat trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency response contacts. At a minimum, this plan will include:

1. A 24-hour emergency contact telephone number for the mobile service provider's emergency response personnel.
2. Emergency contact number for NRC's Operation Center and all appropriate state radiological protection agencies.
3. Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
4. Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created. This may require one or more emergency shielded source containers.

5. Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios.
6. Preplanned decontamination procedures including ready access to all necessary materials.
7. Procedures to ensure that, following any accident, no patient treatments will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 10 CFR 30.50, will be provided to any Class 2 or 3 clients following any accident in which there is actual or possible damage to the facility or device.
8. A calibrated, operational survey meter should be maintained in the cab of the transporting vehicle. Such a survey meter may be used at an accident scene for conducting surveys.

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills, to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

We will develop procedures to assure that:

1. Radioactive material is transported in accordance with 49 CFR Parts 170–189. Procedures will include:
 - use of approved packages
 - use of approved labeling
 - conduct of proper surveys
 - complete and accurate shipping papers
 - bracing of packages
 - security provisions
2. Management (or their designee) will perform audits (at least annually) of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
3. Licensed material is secured during transport and use at the client's facilities.
4. Radioactive waste is handled properly during transport. We will describe the method of storage and final disposal.
5. The transport vehicle including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established via prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in vans, the vans will be properly secured and posted as byproduct material storage locations. We will ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area.

We will develop and implement final waste disposal procedures in accordance with Section 8.44 of this report.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with 10 CFR 20.2003. However, excreta collected from patients in a rest room in a van with a holding tank, is not considered direct disposal into the sanitary sewerage system. If we will provide rest-room facilities on the van for patient use, we will submit the following information for NRC review:

1. A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers on the van, and the driver of the van. A description of procedures to assess the tank for possible leakage. A description, of any ventilation associated with the rest-room, will be provided if any I-131 will be held in the tank.
2. A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 10 CFR 20.1201 and 20.1301. A description of procedures ensuring that doses to the general public do not exceed 100 mrem/year, that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA. We will include considerations of external dose rates in the rest-room due to the proximity of the holding tank to the toilet.
3. A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer. Precautions taken to minimize contamination in this process will be included.

Mobile Services With Remote Afterloader Devices

In addition to the above procedures addressed in the mobile services section, we will develop and implement the following procedures regarding mobile remote afterloader service operations:

1. Since the movement of the remote afterloader device from one location to another increases the risk of electro/mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, we will develop and implement the following procedures used to determine if the device is operating properly prior to the commencement of patient treatments:
 - a. Safety checks conducted on a remote afterloader device and facility. The procedure will, as a minimum, include the periodic spot checks required by 10 CFR 35.643 (or 10 CFR 35.644) and the additional spot checks required by 10 CFR 35.647, prior to medical use following any relocation of the device. Additionally, the procedure must include provisions for prompt repair of any system identified as not operating properly.
 - b. The pretreatment operational function checks after each device move must also include a review of any device alarm/error messages and, if necessary, a resolution of problems indicated by such messages.
 - c. Such tests, as indicated above, must be established by the AMP identified on the license authorizing patient treatments. (This would be the mobile service provider in Class 1 and 2 applications and the client in Class 3 applications.)
 - d. The applicant must maintain records showing the results of the above safety checks for NRC inspection and review for a period of three years.
2. For Class 1 and 2 services, we will develop and implement a radiation survey procedure which includes results of radiation surveys conducted prior to initiation of the treatment program (baseline surveys). These baseline surveys must include the source housing, with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position. Immediately following any relocation of the remote afterloader device, and prior to patient treatments, the licensee must conduct such surveys, as necessary, with a portable, calibrated survey meter, to assure the radiation dose rates obtained are comparable to those obtained from the baseline surveys. Any significant increase in the dose rates found after relocation from the baseline survey results suggests that the shielding integrity may have been compromised and must be investigated and resolved prior to use of the remote afterloader device.

Appendix W

Transportation

Transportation

The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101, and App. A, Table 2: Hazardous materials table, list of hazardous substances, and reportable quantities
- Shipping Papers 49 CFR 172.200-204: General entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.415, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A1 and A2 . . . , table of A1 and A2 values for radionuclides, radiation level limit, requirements for USNRC-approved packages (Type B), quality control requirements prior to each shipment. . . , approval of special form radioactive materials
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Appendix X

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Model Procedure for Decay-In-Storage

10 CFR 35.92 describes the requirements for DIS. Short-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage area must be in a secure location.

1. We will consider using separate containers for different types of waste, e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.
2. When the container is full, we will seal it and attach an identification tag that includes the date sealed, and the longest-lived radionuclide in the container. The container may then be transferred to the DIS area.
3. Prior to disposal as in-house waste, we will monitor and record the monitoring of each container as follows:
 - a. Choose a survey instrument that is appropriate for the type and energy of the radiation being measured.
 - b. Check the radiation detection survey meter for proper operation.
 - c. Plan to monitor in a low-level radiation (< 0.05 millirem per hour) area away from all sources of radioactive material, if possible.
 - d. Remove any shielding from around the container or generator column.
 - e. Monitor, at contact, all surfaces of each individual container.
 - f. Remove or deface any radioactive material labels (unless the containers will be immediately incinerated and instruction has been provided to the incinerator operator regarding radioactive labels and potential hazards)*.
 - g. Discard as in-house waste only those containers that cannot be distinguished from background. Record the disposal date, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

- h. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

** Note: Contact the appropriate NRC Regional Office for guidance in this area.*

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and DOT regulations. We will perform the following when returning generators:

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415 (a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination measurements required by paragraph 173.475 (i) of 49 CFR Part 173.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
5. Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Model Procedure for Return of Licensed Material to Authorized Recipients

We will perform the following when returning licensed material to authorized recipients:

1. In accordance with 10 CFR 30.41(a)(5), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material).
2. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415 (a) of 49 CFR Part 173).
3. Assemble the package in accordance with the manufacturer's instructions.
4. Perform the dose rate and removable contamination measurements required by paragraph 173.475 (i) of 49 CFR Part 173.
5. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
6. Retain records of receipts and transfers in accordance to 10 CFR 30.51.

Appendix Y
NRC Form 314

10 CFR 30.36(c)(1)(iv)
10 CFR 40.42(c)(1)(iv)
10 CFR 70.38(c)(1)(iv)

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS MANDATORY INFORMATION COLLECTION REQUEST: 30 MINUTES. THIS SUBMITTAL IS USED BY NRC AS PART OF THE BASIS FOR ITS DETERMINATION THAT THE FACILITY HAS BEEN CLEARED OF RADIOACTIVE MATERIAL BEFORE THE FACILITY IS RELEASED FOR UNRESTRICTED USE. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0028), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503. AN AGENCY MAY NOT CONDUCT OR SPONSOR, AND A PERSON IS NOT REQUIRED TO RESPOND TO, A COLLECTION OF INFORMATION UNLESS IT DISPLAYS A CURRENTLY VALID OMB CONTROL NUMBER.

CERTIFICATE OF DISPOSITION OF MATERIALS

INSTRUCTIONS: ALL ITEMS MUST BE COMPLETED -- PRINT OR TYPE
SEND THE COMPLETED CERTIFICATE TO THE NRC OFFICE SPECIFIED ON THE REVERSE

LICENSEE NAME AND ADDRESS

LICENSE NUMBER

LICENSE EXPIRATION DATE

A. MATERIALS DATA (Check one and complete as necessary)

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT:
(Check and/or complete the appropriate item(s) below.)

- ☐ 1. NO MATERIALS HAVE EVER BEEN PROCURED OR POSSESSED BY THE LICENSEE UNDER THIS LICENSE.
OR
☐ 2. ALL ACTIVITIES AUTHORIZED BY THE LICENSE HAVE CEASED AND ALL MATERIALS PROCURED AND/OR POSSESSED BY THE LICENSE NUMBER CITED ABOVE HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (If additional space is needed, use the reverse side or provide attachments.)

Describe specific material transfer actions and, if there were radioactive wastes generated in terminating this license, the disposal actions including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

For transfers, specify the date of the transfer, the name of the license recipient, and the recipient's NRC license number or Agreement State name and license number.

If materials were disposed of directly by the licensee rather than transferred to another licensee, licensed disposal site or waste contractor, describe the specific disposal procedures (e.g., decay in storage)

B. OTHER DATA

- ☐ 1. OUR LICENSE HAS NOT YET EXPIRED; PLEASE TERMINATE IT.
2. A RADIATION SURVEY WAS CONDUCTED BY THE LICENSEE TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE. (Check one)
- ☐ NO (Attach explanation)
☐ YES, THE RESULTS (Check one)
☐ ARE ATTACHED, or
☐ WERE FORWARDED TO NRC ON (Date)
- | | | |
|---|------|---|
| 3. THE PERSON TO BE CONTACTED REGARDING THE INFORMATION PROVIDED ON THIS FORM | NAME | TELEPHONE NUMBER
(Include Area Code) |
|---|------|---|
4. MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO

CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE

SIGNATURE

DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTIONS.

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE A DISTRIBUTOR OF EXEMPT PRODUCTS, SEND TO:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHERS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE,
MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW
JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR
VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANCE SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI,
NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA,
TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI,
OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO,
HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA,
NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA,
OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA,
TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND
APPLICATIONS TO:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ATTACHMENT 5

SECY-98-054



RULEMAKING ISSUE

(Notation Vote)

March 20, 1998

SECY-98-054

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: COMMISSION RESOLUTION OF SIGNIFICANT ISSUES ASSOCIATED
WITH THE REVISION OF 10 CFR PART 35, "MEDICAL USES OF
BYPRODUCT MATERIAL"

PURPOSE:

To obtain Commission direction on: (1) retaining the current requirement for medical use licensees to notify individuals and referring physicians of a medical event,¹ pursuant to 10 CFR 35.33(a)(3) and (a)(4); and (2) capturing precursor events.

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

¹ The Part 35 Working Group has replaced the term "misadministration" with "medical event," based on SRM - COMSECY-96-057, "Materials/Medical Oversight (DSI-7)," March 20, 1997 (Attachment 1), in which the Commission said the staff should consider "... changing the nomenclature from 'misadministration' to 'medical event' or comparable terminology." However, in historical discussions, the term "misadministration" is still used.

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN
THE FINAL SRM IS MADE AVAILABLE

Marjorie Rothschild, OGC
(301) 415-1633

BACKGROUND:

The Commission, in its Staff Requirements Memorandum (SRM) of June 30, 1997, SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice," approved the staff's proposed plan for the revision of 10 CFR Part 35 (Attachment 2). The staff implemented that plan by establishing a U.S. Nuclear Regulatory Commission Working Group and Steering Group, and by actively soliciting input from the public, the medical professional societies, States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The staff has benefitted from these interactions with the regulated community and the public and has received many useful comments.

The Working Group considered the input from the public and the medical community in developing the "strawman" revision of the Part 35 rule that was placed on the INTERNET and in the Public Document Room on January 30, 1998. That "strawman" revision included: (1) the current requirements for notifying NRC, referring physicians, and individuals of medical events, because of the controversy associated with individual (patient) notification; and (2) a proposed definition of a "significant precursor" (and related recordkeeping and reporting requirements).

DISCUSSION:

Notification Following a Medical Event

The current regulations in 10 CFR 35.33(a) and (b) require, in part, that NRC medical use licensees inform NRC, the referring physician, and the individual receiving the misadministration (medical event) within 24 hours of its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual, or that, based on medical judgment, telling the individual would be harmful. Background information on 10 CFR 35.33(a) and (b) is presented in Attachment 3.

Staff is not requesting guidance on whether licensees should notify NRC of a medical event. Staff and licensees recognize that this notification is needed, at a minimum, for NRC to comply with Section 208 of the Energy Reorganization Act for reporting "Abnormal Occurrences" to Congress. However, because of medical community and public comments, staff has been evaluating whether the current regulations should be revised to require notification of NRC only, or of NRC and the referring physician.

The majority of the comments received on notification following a medical event (including those of two "patient rights advocates"²), indicated that there should not be an NRC requirement for patient and/or referring physician notification in the case of a medical event. Individuals who do not favor patient notification assert that there are no other areas of medicine in which there

² However, a patient's right advocate at the ACMUI meeting on March 2, 1998, expressed concern about the risk to the patient, if the patient or referring physician is not notified.

is a Federal requirement for patient notification and that an NRC requirement for patient notification is contrary to the 1979 Medical Policy Statement. According to some of the ACMUI members and the NRC medical consultant advising the Working Group, patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which it is the "standard of care" for a physician to provide the patient with complete and accurate information.³ Members of the medical community have pointed out that they view the "fiduciary" relationship between the patient and physician as different from that between a licensee and an individual receiving a dose in excess of the 10 CFR Part 20 limits. In addition, some members of the medical community particularly object to the requirement, in 10 CFR 35.33(a)(1)-(ii), for licensees to provide the informed individual with a copy of the licensee's report to the Commission (or a similar report), believing that the report greatly magnifies the significance of the event when, in fact, a medical event could be of minimal safety significance.

Although patient (and referring physician) notification of medical mistakes or events is the "standard of care," that practice may not be uniformly followed. Based on recent articles in a professional medical journal and the national news media (Attachment 5), the issue of whether physicians should notify patients of medical "events" is the subject of considerable debate and is not at all well-settled. Thus, reliance on physicians to follow either the "standard of care" or the AMA ethical standards,³ may result in patients not receiving information necessary for their medical care.

Those opposing and those favoring retention of the requirement to notify the individual, referring physician and NRC agree that the issue is not whether patients should be notified of medical events. Rather, the issue is whether, in light of existing medical ethical and practice standards obligating physicians to make such notifications, NRC should retain the provisions in Part 35 requiring licensees to do so.⁴

Staff has identified three possible alternatives for notification of NRC, referring physician, and individuals, in the case of a medical event. Attachment 6 provides a detailed discussion of these alternatives.

Alternative 1: Retain the current reporting requirements in Part 35, with minor changes intended to clarify the term "responsible relative."

Alternative 2: Revise the current reporting requirement to require a licensee to inform NRC and the referring physician (but not the patient) of the medical event.

³ A patient's right to receive information from physicians is an element of the patient-physician relationship and is also part of "informed consent," based on American Medical Association (AMA) "Principles of Medical Ethics." (See Attachment 4).

⁴ If there is such a requirement, the Working Group/Steering Group agree that the rule should retain the provision permitting the referring physician to inform the patient and for the licensee not to notify the patient, if, based on medical judgment, telling the patient would be harmful. 10 CFR 35.33(a)(3).

Alternative 3: Revise the current reporting requirement to require a licensee to inform only NRC of a medical event.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of notifying only NRC (Alternative 3).

Precursor Events

The Commission, in COMSECY- 96-057, directed staff to determine the best way to capture precursor events. Staff's objectives in capturing precursor events are to identify and analyze incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities.

Alternative pathways for capturing precursor events were discussed with the ACMUI at the September and March semi-annual meetings, and with the public during two facilitated public workshops (October and November 1997). In September 1997, the ACMUI recommended that NRC make reporting of precursor events voluntary. Participants in the facilitated public workshops, as well as members of the public, believe that: (1) there are already adequate mechanisms in place for identifying precursor events; (2) additional NRC requirements for notification of precursor events could result in a significant financial burden for both NRC and licensees, without an associated incremental increase in safety; (3) because of the nature of precursor events, it will be hard to precisely define a precursor event in rule language; and (4) inclusion of a requirement for reporting of precursor events could lead to an additional basis for enforcement action.

Staff believes that identification and reporting of precursor events at some level is warranted, given that a "significant precursor" may have future implications for that facility or for similar facilities (generic incidents), and thus such reporting could lead to improved radiation safety programs at licensed facilities. Therefore, staff identified three possible alternatives for capturing precursor events. Attachment 7 provides a detailed discussion of these alternatives.

Alternative 1: Revise Part 35 to require reporting of "significant precursors."

Alternative 2: Revise Part 35 to require reporting of deficiencies in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer, could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility.

Alternative 3: Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding with the Food and Drug Administration and monitor/establish a system with U. S. Pharmacopeia to review its database.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of Alternative 2.

RECOMMENDATIONS:

The staff is seeking Commission guidance on the preferred alternative for notification of individuals and referring physicians of a medical event. This guidance is necessary because of the sensitivity associated with medical event reporting, the differences of opinion that exist among the staff, patient right's advocates, and the regulated community, and the fact that this is a major policy issue.

Staff recommends that Alternative 2 be chosen as the preferred alternative for identification of precursor events because it: (1) clearly states the types of incidents and conditions that NRC needs to identify and analyze events and incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities; (2) requires licensees to submit reports of precursor events; and (3) should not significantly increase the regulatory burden on licensees and the NRC.

COORDINATION:

OGC reviewed this paper and has no legal objection. The Office of the Chief Information Officer has no objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections; resources to implement the rule will be considered in developing the FY 2000 budget.



L. Joseph Callan
Executive Director
for Operations

Attachments:

1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Background Info on 10 CFR 35.33(a) and (b)
4. AMA, "Code of Medical Ethics, Current Opinions with Annotations"
5. Journal and Media Articles
6. Notification Following a Medical Event
7. Precursor Events

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Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Tuesday, April 7, 1998.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Tuesday, March 31, 1998, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 1997

Action: Paperiello/NMSS
Morrison, RES
Cys: Callan
Thompson
Jordan
Norry
Blaha
Bangart, SP
Ross, AEOD

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations
FROM: *John C. Hoyle*
John C. Hoyle, Secretary
SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057
MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

Attachment 1

- (1) Focusing Part 35 on those procedures that pose the highest risk.
- (2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.
- (3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.
- (4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.
- (5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.
- (6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.
- (7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.
- (8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(NMSS/RES) (EDG - Program)	(SECY Suspense:	6/6/97)	9700065
(NMSS/RES) (EDG - Complete Rulemaking)	(SECY Suspense:	6/30/99)	9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
Commissioner Diaz
K. Cyr
D. Rathbun
H. Bell
A. Galante
R. Scroggins
W. Beecher



OFFICE OF THE
SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 30, 1997

Action: Paperiello, NMSS

Cys: Callan
Thompson
Jordan
Norry
Blaha
Thadani, RES
Bangart, SP
Sheiton, CIO
Meyer, ADM
CHaney, NMSS
Swoods, NMSS

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: " STAFF REQUIREMENTS - SECY-97-115 - PROGRAM -
FOR REVISION OF 10 CFR PART 35, "MEDICAL USES
OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL
REGISTER NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.
2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.
3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.

SECY NOTE: SECY-97-115 WAS RELEASED TO THE PUBLIC ON JUNE 17, 1997. THIS SRM, SECY-97-131, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.

~~(EDO)~~- (NMSS)

(SECY Suspense: 9/5/97)
8/29/97

9700065

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

BACKGROUND INFORMATION ON 10 CFR 35.33(a) and (b)

The provision for notifying patients or the patient's "responsible relative" of a misadministration has been a feature of the misadministration rule since it was first proposed in 1973. "Medical Uses of Radioisotopes (Byproduct Material)," 38 Fed. Reg. 6399, 6400 (March 9, 1973). That proposed rule would have required medical use licensees to report to a patient (or responsible relative) a misadministration that could cause "... a demonstrably adverse effect, unless in the physician's professional judgment, such notification would be contrary to the best interests of the patient or a surviving relative of the patient." 38 Fed. Reg. 6400, 6401. No explicit explanation was provided in the Statements of Consideration (SOC) of the purpose of such a requirement. However, the Commission's discussion of an exception in 10 CFR Part 20 for intentional exposure of patients to radiation for medical purposes and Part 20 requirements for reporting radiation exposures to other individuals,¹ implied as a goal, achieving consistency between reporting requirements in Parts 35 and 20.² Specifically, the Commission cited former 10 CFR 20.107 (1973), which provided that nothing in the regulations in Part 20 "... shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy." Based on former 10 CFR 20.107, notifications had not been required "... of incidents involving the exposure of patients to radiation if the patient were receiving any intentional medical exposure." 38 Fed. Reg. 6399-6400. According to the Commission, since the incidents involving medical exposure that had been brought to its attention "... generally involved accidental or erroneous exposures of patients to radiation in amounts or forms other than intended, it does not seem appropriate to continue ... not requiring reports of such misadministrations to patients." 38 Fed. Reg. 6400.

The Commission withdrew the 1973 proposed rule in 1978 (citing as a reason the passage of a five-year period) and proposed new misadministration record keeping and reporting requirements. It changed, without explanation, the threshold for reporting a diagnostic misadministration to NRC, to the patient's referring physician, and the patient's responsible relative. "Human Uses of Byproduct Material, Misadministration Reporting Requirements," 43 Fed. Reg. 29297 (May 7, 1978). The threshold of "a demonstrably adverse effect" became a "clinically detectable adverse effect." 43 Fed. Reg. at 29297-98. Noting that a purpose of the

¹10 CFR 20.405(c) (1973) required that "Any exposure of an individual to radiation which is required to be reported to the Commission shall also be reported to the individual." This provision has been carried over in current 10 CFR 20.2205, "Reports to Individuals of exceeding dose limits," under which, when a licensee is required, pursuant to 10 CFR 20.2203, 2204, or 20.2206, to report the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Commission to the individual.

²10 CFR 20.1002 states the scope of present Part 20 as not applying "... to doses due to background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with [10 CFR] § 35.75, or to exposure from voluntary participation in medical research programs."

misadministration rule “. . . is to inform the patient or a patient's responsible relative³ so that corrective action can be taken,” the Commission expressed “. . . concern about the possibility of undue intrusion into the patient-physician relationship.” 43 Fed. Reg. 29297. Consequently, the Commission specifically sought comment about “those portions of the proposed amendments which deal with the manner in which referring physicians and their patients are informed of misadministrations.” Id.

Ninety percent of the comments were opposed to the proposed rule, with most citing it as “. . . an unprecedented intrusion into medical practice.” Misadministration Reporting Requirements,” 45 Fed. Reg. 31701 (May 14, 1980). A majority of the commenters who opposed the rule were opposed to the requirement for reporting diagnostic misadministrations to patients. 45 Fed. Reg. at 31703. The Commission determined that the threshold of a “clinically detectable adverse effect” in the proposed rule for reporting a diagnostic misadministration was a “moving target” and “. . . not well understood in the medical community.” 43 Fed. Reg. at 31703. Therefore, in the final rule, although the Commission required licensees to report to NRC all diagnostic and therapeutic misadministrations, it required that only therapy misadministrations be reported to the referring physician and the patient or a responsible relative.⁴ Id.

Many of the objections to the patient notification provisions specifically addressed by the Commission (as described above) have been raised again over the years, and those objections, as well as the Commission's response, warrant discussion here. Although the Commission recognized, in promulgating the rule in 1980, that the misadministration reporting requirement may be unique to medical practice, “. . . it is necessary to protect patients.” 45 Fed. Reg. at 31702. The Commission also recognized the rule's intrusion into the physician-patient relationship “. . . in the sense that the rule does affect, to a limited degree, the nature of the physician's obligation to his or her patient.” Id. Noting that some physicians supported the rule, the Commission did not, however, believe that objections warranted abandoning the rule. Id.

³The Commission explained that:

[I]t is expected that the licensee would report to the patient's responsible relative rather than the patient when, for example, the referring physician tells the licensees that in his medical judgment informing the patient would be harmful to the patient; the patient is a minor; or the patient is unconscious and incapable of comprehending the information.

43 Fed. Reg. at 29297.

⁴The Commission also made two changes to the rule regarding patient notification of the patient or “responsible relative”: First, it added a parenthetical “(or guardian)” to “responsible relative” to cover persons who do not have relatives. 45 Fed. Reg. at 31704. Secondly, as amended, the rule would permit referring physicians, if they wish, to inform the patient of the misadministration. Id.

As explained by the Commission:

The "physician-patient" relationship is a concept that was developed to advance the needs of the patient. The relationship involves duties of reasonable care and skill, confidentiality, and good faith owed by the physician to the patient. Nothing in the rule would detract from these duties. Thus, in a strict sense, the rule would not interfere with the relationship.

Id.

As to the comment noting the lack of a similar requirement in aspects of radiation medicine not regulated by the Commission (e.g., x-rays, accelerator-produced isotopes), the Commission stated that it "... must operate under the assumption that Congress intended a disproportionate degree of Federal regulatory control be exercised over nuclear materials as opposed to ... other sources of radiation." 45 Fed. Reg. at 31702. As the Commission pointed out, the U.S. Nuclear Regulatory Commission was not the only Federal agency with requirements or policies to which the medical community objected on the ground of unwarranted interference in the physician-patient relationship. Id. According to the Commission, the Food and Drug Administration (FDA) had recently rejected an objection on that basis to its request for assistance in developing a policy on labeling of prescription drugs to promote patient understanding of drugs prescribed for them. Id. The FDA determined that patients have a right to know about a drug's benefits, risks, and directions for use. Id.

Although the Commission acknowledged possible truth to the comment that the patient notification provisions would invite unwarranted malpractice suits and thereby boost medical costs, the Commission stated that "... there is nothing in the rule that would in any way modify the legal rules governing malpractice suits arising out of misadministrations." 45 Fed. Reg. at 31703. "The requirement ... to report therapy misadministrations to patients or a responsible relative is important." 45 Fed. Reg. at 31702. "Patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them." Id. The Commission's response also cited "... parallel requirements for licensee reports to workers on occupational overexposures" and the trend at the time in Federal legislation recognizing the right of individuals to know information about themselves that is contained in the records of institutions both inside and outside of the Federal sector." Fed. Reg. at 31702-03.

In a major revision of 10 CFR Part 35 (effective in 1987), the Commission changed the misadministration rule to require a report to NRC and the referring physician for a misadministration resulting "... in a dose to a patient greater than the dose to a member of the public permitted under [former] 10 CFR § 20.105(a)." "Medical Use of Byproduct Material," 51 Fed. Reg. 36932, 36942 (October 16, 1986). The Commission responded to renewed objections to misadministration reporting by agreement with assertions that the misadministration rate for radiopharmaceuticals is much lower than that for other drugs, that there is no reporting requirement for non-Atomic Energy Act radiopharmaceuticals and other drugs, and that the risk to patients, workers, and the public is small. 51 Fed. Reg. at 36942. Nevertheless, the Commission concluded that "... the fact that there are other greater potential hazards found in the medical arena does not relieve NRC of its responsibility to assure public

health and safety as it may be affected by material under its jurisdiction." Id.

The Quality Management rulemaking retained provisions for patient notification of misadministrations, but added events of arguably lesser significance ("recordable events") for which reporting to NRC or others was not required. "Quality Management Program and Misadministrations," 56 Fed. Reg. 34104 (July 25, 1991). In proposing to retain the patient notification provisions, the Commission reaffirmed the two primary purposes of those provisions, discussed above: (1) to effectuate the rights of patients to know about misadministrations unless that information would be harmful to them, and (2) to achieve consistency with parallel requirements that NRC licensees report to an individual certain radiation exposure data pertaining to that individual. "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 Fed. Reg. 1439, 1444 (January 16, 1990).

Most recently, as part of the "wrong patient" rulemaking,⁵ the Commission amended the definition of "misadministration" in 10 CFR 35.2, and the reporting requirements in 10 CFR 35.33 to substitute the word "individual" for the phrase "patient or human research subject." 60 Fed. Reg. at 48624. (The latter term had been added in another rulemaking⁶ to reflect inclusion of research subjects in the definition of "medical use" in 10 CFR 35.2). The Commission noted that if a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician, in which case the licensee is relieved of complying with that portion of 10 CFR 35.33. Id. However, the licensee must comply with all other requirements in 10 CFR 35.33. Id.

⁵ "Medical Administration of Radiation and Radioactive Materials," 60 Fed. Reg. 48623, (September 20, 1995).

⁶ "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 59 Fed. Reg. 61767 at 61772, 61781, 61783, (December 2, 1994).

FEB. 27, 1996 1:34 PM ETHICS STANDARDS 201300 F.273

American Medical Association

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**Council on Ethical
and Judicial Affairs**

1996-1997 Edition

Code of Medical Ethics

*Current Opinions with
Annotations*

6. The patient has a basic right to have available adequate health care. Physicians, along with the rest of society, should continue to work toward this goal. Fulfillment of this right is dependent on society providing resources so that no patient is deprived of necessary care because of an inability to pay for the care. Physicians should continue their traditional assumption of a part of the responsibility for the medical care of those who cannot afford essential health care. Physicians should advocate for patients in dealing with third parties when appropriate.

Report of the Council on Ethical and Judicial Affairs of the American Medical Association.

Originally adopted June 1990. Updated June 1994.

This opinion does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans. (II)

Issued June 1992.

Updated June 1994.

8.08

Informed Consent The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk-disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forgo needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment. (I, II, III, IV, V)

Issued March 1981.

W. Va. 1995 West Virginia Board of Medicine received a complaint from patient that physician was using depossession treatment. The hearing examiner in part found that there had been a lack of informed consent for such treatment. The Board changed the examiner's report and added sanctions. In doing so, it quoted Opinion 8.08. On appeal, the circuit court reversed, finding the Board's order arbitrary and an abuse of discretion. The appellate court agreed that the Board abused its discretion, but remanded the case for consideration of the issue of informed consent for depossession treatment. *Modi v. West Virginia Board of Medicine*, 465 S.E.2d 230, 236.

Journal 1995 Observes that physicians are unable to obtain informed consent because they can not guess which treatment alternatives will best serve an individual patient's interests. Suggests that this situation would be improved if patients were paired with physicians who share their personal values. Quotes Opinion 8.08. Veatch, *Abandoning Informed Consent*, 25 *Hastings Center Rep.* 5, 6 (March/April 1995).

Journal 1994 Discusses how physicians historically have taken too much license with patients' bodies and placed greater value on longevity than on quality of life. Argues that patients should be the ultimate decisionmakers in matters that affect their lives. Suggests that greater emphasis should be given to physician disclosure obligations in order to improve the quality of patient consent. Quotes Opinion 8.07 (1981) [now Opinion 8.08]. Katz, *Informed Consent — Must It Remain a Fairy Tale?* 10 *J. Contemp. Health L. & Pol'y* 69, 80 (1994).

Journal 1994 Reviews the evolution of the physician-patient relationship. Describes legal responses to increasing awareness of the importance of ensuring patient autonomy. Examines the changing health care delivery environment. Concludes with a discussion of the impact of these changes on patient participation in medical decision making. Quotes Preamble, Principles I, II, III, IV, V, and VI, Fundamental Elements (1) and (2), and Opinions 1.02 and 8.07 (1981)

participating in capital punishment. In place of any practice of active voluntary euthanasia, recommends increased use of hospices, greater emphasis on training physicians to care for the dying patient, and further research aimed at producing symptomatic relief in dying patients. Cites Opinions 2.06, 8.10 (1986) (now Opinion 8.11), and 9.06. Shewmon, *Active Voluntary Euthanasia: A Needless Pandora's Box*, 3 *Issues in Law and Med.* 219, 220, 222, 243 (1987).

Journal 1986 Addresses the problem of "patient dumping" and explores the various reasons underlying this practice. Examines applicable common law and statutory law, emphasizing the antidumping provisions of COBRA. Weaknesses in this federal legislative scheme are highlighted and recommendations for strengthening the statute and maximizing access to emergency medical care are offered. Quotes Principle VI and Opinion 8.10 (1986) (now Opinion 8.11). Note, *Preventing Patient Dumping: Sharpening the COBRA's Fangs*, 61 *N. Y. U. L. Rev.* 1186, 1189-90 (1986).

- 8.115 Termination of the Physician-Patient Relationship.** Physicians have an obligation to support continuity of care for their patients. While physicians have the option of withdrawing from a case, they cannot do so without giving notice to the patient, the relatives, or responsible friends sufficiently long in advance of withdrawal to permit another medical attendant to be secured. (I, VI)

Issued June 1996 (formerly included in Opinion 8.11).

Mass. Super. 1993 Plaintiff sought to enjoin defendant-physician from contacting patients whom defendant treated while employed with plaintiff. The court denied the injunction, noting that under Opinion 8.11 (now Opinion 8.115) defendant has a duty to notify his patients before withdrawing from a case and an injunction would force defendant to choose between violating professional ethics or violating a court order. *Plastic Surgical Servs. of New England, P.C. v. Hall*, 1993 WL 818637.

- 8.12 Patient Information.** It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Ethical responsibility includes informing patients of changes in their diagnoses resulting from retrospective review of test results or any other information. This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.

Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient. (I, II, III, IV)

Issued March 1981.

Updated June 1994.

Minn. 1970 Defendant-physician appealed order to answer interrogatories, claiming that a medical malpractice plaintiff is prohibited from compelling expert testimony from a defendant to prove a charge of malpractice without calling other medical witnesses. In holding that a

Fundamental Elements of the Patient-Physician Relationship

From ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibility for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. Physicians can best contribute to this alliance by serving as their patients' advocates and by fostering these rights:

1. The patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives. Patients should receive guidance from their physicians as to the optimal course of action. Patients are also entitled to obtain copies or summaries of their medical records, to have their questions answered, to be advised of potential conflicts of interest that their physicians might have, and to receive independent professional opinions.
2. The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.
3. The patient has the right to courtesy, respect, dignity, responsiveness, and timely attention to his or her needs.
4. The patient has the right to confidentiality. The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest.
5. The patient has the right to continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient. The physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.

American Medical Association

Principles Of Medical Ethics

Preamble:

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.
- II. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.
- V. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.
- VII. A physician shall recognize a responsibility to participate in activities contributing to an improved community.

Doctors Urged to Admit Mistakes

By DENISE GRADY

WHEN doctors make a mistake that harms a patient, they should tell the patient what happened, apologize and do whatever it takes to repair the damage, researchers are urging. In a stance that is drawing mixed reviews from the medical community, insurance companies and lawyers.

The advice to come clean, in an article in the current issue of *The Journal of General Internal Medicine*, is offered by a team led by Dr. Albert Wu, an internist and associate professor at the Johns Hopkins School of Public Health in Baltimore.

Dr. Wu and his colleagues have been advocating greater honesty about medical errors since 1991, when they published a study showing that doctors in training at three large teaching hospitals often kept serious mistakes to themselves: only half discussed mistakes with senior doctors, and just a quarter told patients or their families what had occurred. The errors, which led to illness and even death, included missed or delayed diagnoses, incorrect drug prescriptions and surgical mistakes.

There is still great reluctance in the medical profession to admit mistakes, Dr. Wu said, even though ethics manuals have long called for disclosure. "Most medical schools do not have this sort of thing in their curriculum," he said, acknowledging that doctors, not unreasonably, may fear that taking the blame will leave them open to lawsuits and hurt their reputations and careers.

Even so, Dr. Wu said, there are compelling reasons for telling patients the truth. "It is the right thing to do," he said. The doctor-patient relationship is based on trust, he said, and morally and ethically, a doctor's first responsibility is to act in the patient's best interest. People who have been harmed have a right to know what went wrong, so they do not worry that a setback means their health is failing, when the cause was really a medical error.

In addition, Dr. Wu said, such patients may need extra treatment to remedy the mistake, as well as payment of medical expenses and, possibly, compensation for their injury.

Only in the rarest instances, as when a depressed patient could become incapacitated by bad news, might it be justifiable to withhold information about a mistake, Dr. Wu and his colleagues said.

Leveling with the patient can be good for the doctor, too, Dr. Wu said, noting that doctors who have harmed patients generally feel great guilt and distress. "In some cases, disclosure is the only way the physician can be absolved," he said. Telling the truth may also strengthen patients' faith in the doctor's integrity and inspire good will, while a cover-up that fails — as they often do — may anger patients and just make them more inclined to sue. Cover-ups may also antagonize juries.

"There's a bit of folk wisdom, that some doctors never get sued," Dr. Wu said. "Those that have really

good relationships with patients, patients wouldn't think of suing. But people who feel their trust was violated feel betrayed, and a lawsuit may seem like the only the way to get the truth."

Dr. Wu, who graduated from medical school in 1984, said he has never been sued.

One of his co-authors, Dr. Stephen McPhee, an internist and professor of medicine at the University of California at San Francisco, described a case in which his failure to order a certain blood test led to a lengthy delay in diagnosing hemochromato-



Mary Karr for The New York Times

Dr. Albert Wu says admitting medical errors is right and smart.

sis, a disorder in which prompt treatment is very important. The patient happened to be a lawyer.

"You can imagine how much I sweated before talking to him," Dr. McPhee said. "I admitted I was wrong but was very sorry, and there were consequences to him that we'd be able to deal with."

To Dr. McPhee's immense relief, the patient said, "That's O.K.," adding that he understood that the doctor could not think of everything.

Dr. McPhee said: "It's a very difficult conversation to have, no question. But medicine is a human enterprise, and errors are part of being human."

Dr. Wu said that other doctors' reactions to his advice have varied. "I get everything from total agreement to laughter, which is often a little derisive, to more cynical comments which basically imply that the world needs to change first," he said. Some, Dr. Wu said, think that "in the real world, if you were to adopt this posture, you'd have your throat ripped out by ravenous litigators."

Dr. Nancy Dickey, president-elect of the American Medical Association, said that in his call for the truth, "I believe Dr. Wu is probably at least substantially right."

"The problem is that the climate

of blame in this country, fueled by the litigation process, where we have to identify someone at fault who will then pay exorbitantly, makes it difficult to walk out and finger yourself," Dr. Dickey said. "If you do, you're playing roulette. The patient may say, 'Gee, doc, thanks, that took great courage and I won't take you to court.' But even if the patient feels that way, there will be others, family members and lawyers, who may encourage patients to change their minds."

Jack Pope, communications director for the Physician Insurers Association of America, said that urging doctors to confess their mistakes was "asking them to commit professional suicide." Without tort reform to decrease the number of malpractice suits and large settlements, he said, few doctors could risk owning up to errors.

Wayne Sinclair, general counsel for MMI Companies Inc., an insurance provider, said, "If you have a doctor out there saying, 'Oh, I did it,' it's a little hard for those of us who write the insurance."

Mark Hatlie, a lawyer and executive director of the National Patient Safety Foundation, a group founded last summer by the A.M.A., said, "If you tell the truth, apologize and reach out to a family in grief, you can defuse some of the anger and polarization that characterize a typical lawsuit. But every word you utter is an admission that can be used against you in a court of law."

Mr. Hatlie said that most malpractice insurance policies instruct doctors not to admit fault to patients without first consulting the insurance company or their hospital's lawyer. Often, he said, lawyers then order doctors to say nothing until all the facts have been determined.

But in the meantime, the patient may feel left in the dark, wondering what is going on. "They want to know why their trusted caregiver is suddenly not talking to them, and why they're seeing the hospital lawyer or risk manager," Mr. Hatlie said. "That's an incredibly divisive wedge

Is it 'professional suicide' for erring doctors to confess?

to put between a patient and a health-care provider, but sometimes there are reasons to do it."

Dr. Bernard Lo, a co-author of the article and an internist and medical ethicist at the University of California at San Francisco, said: "There are other considerations than malpractice concerns that ought to be part of this decision. If you take seriously the idea that physicians have a very strong obligation to act in the best interest of patients, we really should be focusing on the best interest of patients, not our own and not those of the institution."

PERSPECTIVES

To Tell the Truth

Ethical and Practical Issues in Disclosing Medical Mistakes to Patients

Albert W. Wu, MD, MPH, Thomas A. Cavanaugh, PhD, Stephen J. McPhee, MD,
Bernard Lo, MD, Guy P. Micco, MD

While moonlighting in an emergency room, a resident physician evaluated a 35-year-old woman who was 6 months pregnant and complaining of a headache. The physician diagnosed a "mixed tension/sinus headache." The patient returned to the ER 3 days later with an intracerebral bleed, presumably related to eclampsia, and died.

Errare humanum est: "to err is human." In medical practice, mistakes are common, expected, and understandable.^{1,2} Virtually all practicing physicians have made mistakes, but physicians often do not tell patients or families about them.^{3,4} Even when a definite mistake results in a serious injury, the patient often is not told. In one study, house officers reported telling their attending physicians about serious medical mistakes only half the time, and telling the patients or families in less than a quarter of cases.⁵ Highly publicized cases of fatal mistakes have heightened public and professional concerns about how physicians and hospitals respond to serious mistakes. When mistakes are not acknowledged in a timely manner, there may be a perception of a cover-up, and public confidence in physicians may be undermined.

The American Medical Association's (AMA's) *Principles of Medical Ethics* (1957) states that a physician must report an accident, injury, or bad result stemming from his or her treatment.⁶ However, many physicians interpret these requirements to mean that they should report to their superiors or to the hospital quality assurance or

risk management committee, rather than to the patient. More recently, the *American College of Physicians Ethics Manual* states, "physicians should disclose to patients information about procedural and judgment errors made in the course of care. If such information significantly affects the care of the patient."⁶ The AMA's Council on Ethical and Judicial Affairs states, "Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all facts necessary to ensure understanding of what has occurred."⁷

In this article, we analyze the various ethical arguments for and against disclosing serious mistakes to patients. We also provide practical suggestions for how to discuss the sensitive topic of mistakes with patients.

WHAT IS A MISTAKE?

We define a medical mistake as a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred. Independent of whether there were any negative consequences, this definition excludes the natural history of disease that does not respond to treatment and the foreseeable complications of a correctly performed procedure, as well as cases in which there is reasonable disagreement over whether a mistake occurred.

We categorize errors according to their genesis. System errors, also referred to as latent errors,² derive primarily from flaws inherent in the system of medical practice. In such errors, the system "sets up" individuals to make mistakes, i.e., through the unavailability of medical records, by confusing labeling of medications, and the like. When a system error occurs, the physician shares responsibility with other elements of the health care delivery system.

Conversely, individual errors are those deriving primarily from deficiencies in the physician's own knowledge, skill, or attentiveness. For instance, a physician mistakenly prescribed a nonsteroidal anti-inflammatory agent to a patient with renal insufficiency, resulting in permanently worsened renal failure.⁸ In such a case of individual error, the physician has primary responsibility.

Received from the Department of Health Policy and Management School of Hygiene and Public Health, and the Division of Internal Medicine, Department of Medicine, Johns Hopkins University, Baltimore, Md. (AWW); the Department of Philosophy, University of San Francisco, Calif. (TAC); and the Division of General Internal Medicine, Department of Medicine, University of California, San Francisco (SJM, BL, GPM).

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Address correspondence and reprint requests to Dr. Wu: Health Services Research and Development Center, 624 North Broadway, Baltimore, MD 21205.

The considerations in the disclosure of latent errors differ from those in the disclosure of individual errors. For example, in a latent error, the physician is often one link in a chain of causes generating the error. Accordingly, the disclosure of such an error may not be the sole responsibility of the physician. In what follows, we consider only the arguments for a physician to disclose his or her individual error to a patient. We also restrict ourselves to mistakes that cause significant harm, without regard to their detectability.

Errors causing harm can be subdivided into cases that are not medically remediable and those that are medically remediable. We argue that the physician has an obligation to disclose mistakes that cause significant harm, which in the judgment of a risk manager or malpractice insurer is likely to be remediable, mitigable, or compensable. Only in rare cases would a physician be permitted not to disclose a mistake causing harm to the patient. Specifically, physicians might be permitted not to tell if they have good reason to believe that disclosure would undermine the patient's autonomy in some way (e.g., incapacitate the already severely depressed patient). Or the patient might have told the doctor explicitly, "Doctor, if anything goes wrong, I don't want to know about it."

Two ethical theories assist in thinking about the disclosing of a mistake: consequentialism and deontology. A consequentialist ethical theory holds that one ought to do that act which will realize the best overall consequences. A deontological theory maintains that one ought to do that act by which one fulfills one's duties or obligations. Both consequentialist and deontological theories ground arguments for disclosure. In what follows, we first consider arguments based on consequences; then, we attend to arguments based on a physician's duties.

POTENTIAL BENEFITS AND HARMS OF DISCLOSURE

Potential Benefits of Disclosure to the Patient

The patient could benefit in many ways from knowing that a mistake had occurred. Such knowledge would allow the patient to obtain timely and appropriate treatment to correct problems resulting from the mistake. Disclosure therefore can prevent further harm to the patient. In some situations, close monitoring or a medical procedure may be necessary to mitigate the consequences of a mistake. Patients may be unwilling to permit or cooperate with necessary measures if they are unaware of the reason for doing so.⁸ When further treatment is indicated, disclosure is essential for informed consent. Otherwise, the uninformed patient is placed at risk of subsequent misdiagnosis and improper or inadequate treatment.

Disclosure of a mistake may also prevent the patient from worrying needlessly about the etiology of a medical problem. For example, a patient who was prescribed too much warfarin resulting in excessive anticoagulation suf-

fered a gastrointestinal bleed. Telling patients about such mistakes may resolve their uncertainty about the cause of their condition, possibly allowing them to feel better by explaining that recurrence would be unlikely.

Disclosure of a mistake also provides patients with information needed to make informed decisions. Patients may develop more realistic expectations about their doctors' interventions.⁹ Acknowledgment of fallibility brings uncertainties into the open, reduces the possibility of misunderstandings, and encourages the patient to take greater responsibility for his or her own care.

In the case of an injury, knowing about a mistake may allow the patient to obtain compensation for lost earnings or to pay for care necessitated by the injury,¹⁰ or to at least get a bill written off. Such compensation might be obtained through settlement rather than lawsuit; under the current system, obtaining such compensation would be difficult or impossible without disclosure of the mistake.

Finally, disclosure of a mistake can promote trust in physicians. Patients have a presumption of truth-telling.¹¹ Thus, a patient who is not informed of a mistake may feel angry and betrayed¹¹; the patient may think that a privileged relationship has been violated.¹²

Potential Harms of Disclosure to the Patient

Patients may be harmed by learning that a mistake was made in their care. The knowledge may cause alarm, anxiety, and discouragement. It may destroy patients' faith and confidence in the physician's ability to help them. Patients may become disillusioned with the medical profession in general. This may cause them to decline beneficial treatments, or decrease their adherence to beneficial treatment regimens or habits.¹³

Not all patients want to know everything about their medical care. Some would rather not be burdened with the complexities of their illness. The well-meaning disclosure of potentially serious, but inconsequential mistakes may cause unwelcome confusion. In such cases, patients may feel they would be better off not knowing that a mistake had been made in their care. As the *American College of Physicians Ethics Manual* states, "society recognizes the 'therapeutic privilege,' which is an exemption from detailed disclosure when such disclosure has a high likelihood of causing serious and irreversible harm to the patient." However, the American College of Physicians offers the following caution: "On balance, this privilege should be interpreted narrowly; invoking it too broadly can undermine the entire concept of informed consent."¹⁴

Potential Benefits of Disclosure to the Physician

The physician might also benefit from disclosing a mistake to the patient or family. The knowledge of making a mistake that harmed a patient can cause the physician to experience great emotional distress.^{15,16,17} The physi-

cian may be relieved to admit the mistake. In the case of a serious mistake, the patient or family member may be the only person able to forgive the physician for making the mistake. This may be the only way for the physician to gain absolution for the mistake.¹³ Many patients appreciate the physician's honesty, and disclosure of a mistake actually may strengthen the doctor-patient relationship. For example, when one of the authors failed to obtain a serum ferritin test during the evaluation of a patient referred for an enlarged liver, the diagnosis of hemochromatosis was delayed significantly. When the patient was told about the omission, he responded, "That's O.K. After all, doctor, you can't think of everything."

Candid disclosure of a mistake may decrease the likelihood of legal liability.¹⁵ Some have suggested that a strong doctor-patient relationship makes patients less likely to bring suit.¹⁶ Furthermore, if the patient learns about a mistake and brings a lawsuit, failure to disclose may place the physician in greater jeopardy.¹⁷

Disclosing mistakes may help physicians to learn and improve their practice.¹⁸ In a survey by Quill and Williamson, responding physicians reported that sharing errors with colleagues, students, friends, and sometimes patients prevented isolation, and marked the beginning of grieving about and learning from the mistake.¹⁹ Admitting a mistake may also help the physician accept responsibility for it, and may help the physician make constructive changes in practice.³ Physicians may also learn vicariously from mistakes made by others, and be able to avoid making similar mistakes themselves.

Potential Harms of Disclosure to the Physician

Revealing a medical mistake to a patient is often difficult and painful for the physician. The patient may become angry and upset, and such reactions can be highly stressful to doctors.⁴

Many physicians fear that disclosing a serious medical mistake will expose them to the risk of a malpractice suit. If a lawsuit ensues, the physician may be subjected to increased malpractice premiums as well as psychological stress.²⁰

Disclosure of a mistake may harm the physician through loss of referrals, hospital admitting privileges, preferred provider status, credentials, and even licensure. Selective contracting and physician profiling by managed care organizations create more tangible threats to the physician's livelihood. The development of the National Practitioner Data Bank²¹ adds the possibility that an incident will leave a permanent mark on the physician's record. Disclosure of mistakes may also damage the physician's reputation through the loss of respect or status among colleagues. In small communities, the physician's public reputation may also suffer.

Following disclosure of a serious error, the career of a physician-in-training may be harmed by poor evaluations or letters of recommendation, or even dismissal. Even

without the expectation of overt punishment, it is difficult to admit wrongdoing.

A consequentialist argument for the disclosure of mistakes to patients would be framed in terms of the above-noted benefits and harms to individual patients and physicians. In the doctor-patient relationship, a physician is to act for the sake of the patient; therefore, in weighing the benefits and harms of disclosure, the benefits and harms to the patient should have greater weight than those to the physician. There are also duty-based grounds for holding that, in certain cases, a physician should disclose medical error to a patient. We now turn to such arguments.

THE PHYSICIAN'S DUTIES

In what follows, we argue that a physician's responsibility to disclose a mistake to a patient can be derived from the fiduciary character of the doctor-patient relationship (that is, the fact that this relationship is based on trust).²² The fiduciary character of this relationship can be further articulated in accordance with the principles of nonmaleficence, beneficence, respect for patient autonomy, and justice.²³

Primum non nocere, "first, do no harm," states the principle of nonmaleficence: a caregiver has a grave responsibility to avoid harming the patient.^{24,25} The principle of beneficence enjoins physicians to act for the best interests of their patients' health even if the physician's own financial or professional well-being is not benefited by so acting.²¹ In cases in which harm resulting from a mistake can be reversed or ameliorated, the physician is obligated to do so. For example, if a sponge has been left in a patient after surgery, the sponge can be removed and infection can be prevented. In such cases, remedying or mitigating the harms caused by a mistake often requires the physician to disclose the mistake to the patient.

Respect for patient autonomy enjoins physicians to disclose a mistake that seriously harmed a patient.¹⁷ This is the case when full disclosure frees patients of mistaken beliefs concerning their past, present, or future medical conditions, thus enabling them to make informed decisions about future medical care.^{6,7} It may also be the case even if the patient does not need to know of the error in order to make future decisions about medical care. This is because patients have a claim to know their own history and to be free of mistaken beliefs concerning their past, present, or future medical condition.^{7,11} In short, a physician's obligation to respect patient autonomy indicates that a doctor has an ethical obligation to disclose mistakes to patients.⁷

When a nonremediable mistake has been made, the doctor may have an ethical duty to disclose it to the patient so that the patient can be compensated. Justice requires that people be given what is due to them. It would be unfair not to compensate a patient who was seriously harmed by mistake, e.g., for further medical care necessi-

tated by the mistake, for income lost due to the mistake, for pain and suffering, or for loss of function. The more serious the harm and the greater the need of the patient for compensation, the greater the physician's responsibility to make amends.

Physicians may be less obligated or not obligated at all to disclose a mistake that had little marginal impact, such as a serious medication error involving a moribund patient or the failure to recognize a pneumothorax caused during a failed attempt at cardiopulmonary resuscitation. Although it can be argued that disclosure is discretionary in these cases, the counter-argument can be advanced that even these mistakes should generally be disclosed. The physician has little to lose by so doing. These cases may provide a good opportunity for open and honest discussion and may strengthen the relationship with the patient or family.

In summary, the fiduciary character of the doctor-patient relationship indicates that a physician has the ethical duty to disclose error to a patient when disclosure furthers the patient's health, respects the patient's autonomy, or enables the patient to be compensated for serious, irreparable harm.

Practical Issues in Disclosure of Mistakes

Accepting the physician's obligation to disclose mistakes, there are practical issues concerning whether, when, who, and how to tell about the mistake. For uncertain cases, who should decide whether or not to tell? Is there an ideal time to tell the patient? What should be done in the case of the incompetent patient? When more than one physician was involved, who should tell the patient? What should be the role of hospital quality assurance and risk management personnel?

Deciding Whether to Disclose a Mistake. In cases in which disclosing a mistake seems controversial, who should decide whether or not to tell? The individual physician is biased against disclosure, and can easily rationalize the decision not to tell. The burden of proof should be on the physician to justify not disclosing a mistake. However, the decision should not be left to the individual physician's judgment. It would be important to obtain a second opinion to represent what a reasonable physician would do and be willing to defend in public. This second opinion would be particularly important in cases in which there was an adverse outcome, and the physician is inclined not to tell. A formal body such as an institution's ethics committee or quality review board seems preferable to informal consultation with peers, who might be similarly reticent.

Timing of Disclosure. The timing of disclosure should be considered. Although the patient might benefit from learning about a mistake as soon as possible after it occurred, disclosure should be made at a time when the patient is physically and emotionally stable. For example,

disclosure of a surgical error should be delayed, if possible, until the patient has recovered sufficiently to be able to understand and deal with the information.

Who Should Disclose the Mistake? When a mistake is made by a physician in training, responsibility is shared with the attending physician of record. It may be most appropriate for the attending physician and house officer to disclose the mistake to the patient together.¹⁴ Sometimes it may be appropriate to involve an institutional representative, such as a hospital administrator, risk manager, or quality assurance representative, in the disclosure.

The Incompetent Patient. Many patients with impaired decision-making capacity can still appreciate an apology. However, some patients lack the mental capacity to understand and appreciate what the physician tells them about medical errors, even if the discussion is simplified. There is no need to inform an incompetent patient. However, if there is a family member or other effective decision maker, this surrogate should be informed. The physician who will be taking care of the patient in the ambulatory setting should also be informed.

What to Say? Disclosure is often difficult, for several reasons. The facts of the case may be too complicated to be explained easily, and may not be known precisely. The physician may be tempted to frame the disclosure in a way that obscures that a mistake was made.

Disclosure of a mistake is an instance of "breaking bad news" to patients.²⁰⁻²² There is need for medical education about conducting these discussions. The upsetting news that a mistake has occurred and information regarding the consequences should be presented to the patient in a way that minimizes distress. The *American College of Physicians Ethics Manual* offers the following guidance, which could be applied to the disclosure of a mistake: "Information should be given in terms the patient can understand. The physician should be sensitive to the patient's responses in setting the pace of disclosure. . . . Disclosure should never be a mechanical or perfunctory process."²³ The physician should recognize that patients or families may become upset or angry, and accept this as a natural response, taking care not to react defensively.

In telling the patient about an error, the physician should begin by stating simply that he or she has made a mistake. It may be helpful to describe the decisions that were made, including those in which the patient participated. The course of events should then be described in detail, using nontechnical language. The nature of the mistake, consequences, and corrective action taken or to be undertaken should be stated. The physician should then express personal regret and apologize for the mistake. Finally, the physician should elicit questions or concerns from the patient and address them.

The harm of disclosing a mistake may be minimized if disclosure is made promptly and openly, if apologies are

offered, and if charges for associated care are forgone. When the mistake had a major adverse impact on the patient, an offer should be made to cancel charges for subsequent care needed to remedy the mistake and to provide the necessary supportive services.

Financial amends should include all extra expenses incurred, such as physician services, error-generated laboratory fees, hospital expenses, and drug costs. Hospital risk management teams sometimes adopt and malpractice insurers sometimes encourage such an approach, which may reduce the number and size of malpractice suits. The physician rarely if ever pays for any of these services out of pocket. Under capitated payment, the hospital or group absorbs the costs (if individual physicians are capitated for pharmacy services they may also share the costs). If health insurance is available to pay for medical care, a decision should be made whether or not to bill the insurer for the services. It can be argued that the insurance company bears some co-equal responsibility because it insures the patient for all outcomes. However, companies may want recourse to reclaim some of the money. In all cases, it is important that hospital administration and risk management be involved in decisions and negotiations about billing.

A physician who had prescribed a sulfonamide to a patient known to be allergic to sulfa, causing an anaphylactoid reaction, might say, "Mrs. Smith, I have discovered what has caused you to become so ill. I regret to say that I made a mistake. Before prescribing the medication for your infection, I failed to check whether you were allergic to it. You are. The itchy rash, joint pains, and fever you now have are due to the allergy. I am giving you ibuprofen and diphenhydramine to help you feel better, and I expect you will gradually improve over the next several days. I feel very badly that my not checking has caused you to have this reaction. I am sorry. Of course, there will be no charges for the antibiotic or the medications I am now prescribing to remedy my mistake. Do you have any questions for me?"

Overcoming Barriers to Disclosure

From a pragmatic point of view, physicians are often most concerned about the potentially harmful personal consequences of disclosing a mistake. In blunt terms, physicians may question whether any possible benefits to the patient are worth the possible risks of a lawsuit to their career or livelihood. This clash between ethical ideals and pragmatic reality is a difficult one. It may sound encouraging to advise physicians to do what is best for the patient. However, the AMA's Council on Ethical and Judicial Affairs states, "Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient."⁷

We would make several responses to physicians who hesitate to disclose mistakes that cause significant harm to patients because of fears of litigation. First, disclosing

mistakes may reduce the risk of litigation. If patients appreciate physicians' honesty and fallibility.¹⁵ Second, serious mistakes may come to light, even if physicians do not disclose them. Patients may wonder about the cause of their changed condition, ask other caregivers, or even ask their physicians directly. Any perception that the physician tried to cover up a mistake might make a patient more angry and more litigious.¹⁷ Third, in disclosing mistakes physicians can take steps to mitigate any harms that may occur to them. Physicians can learn how to disclose mistakes in a manner that diffuses patient anger. Furthermore, when mistakes have caused serious harm to patients, physicians can take the initiative in recommending to institutional risk management personnel or malpractice insurers that a prompt and fair settlement is made out of court.

For an injured patient to obtain compensation through the tort system requires proof of negligence, defined as violation of professional standards. This creates an untenable conflict for physicians, for whom compensation to the patient demands the demonstration of malpractice. Acts of negligence constituted only a small proportion of the errors in the Harvard Medical Practice Study,¹ and only a small proportion of injuries resulted in compensation for the patient. Thus, the current system obstructs detection and just compensation for errors and inhibits disclosure. The need to report and reduce errors constitutes a major ethical impetus for reform to a system of no-fault, nonadversarial patient compensation. Such a system would facilitate a move to a systems approach incorporating human factors research to reduce errors.^{2,30}

The fear of damage to reputation and loss of respect from peers may also inhibit physicians from disclosing mistakes. To overcome this barrier will require increased recognition and acceptance of mistakes as part of clinical practice. Guidelines should be created to describe what physicians should do when they make a mistake. Such guidelines should also describe what to do when a colleague tells you about a mistake you have made or a mistake he or she has made. The importance of providing emotional support needs to be emphasized. It is particularly important to help physicians-in-training cope with their mistakes in such a way as to help them maintain their confidence and develop professionally.¹⁴

Disclosure of Mistakes Made by Other Physicians

A physician who, in the care of one of his or her own patients, learns of or witnesses a major error (e.g., a surgical misnomer) made by another physician, has several options. These include waiting for the other physician to disclose the mistake, advising the other physician to disclose the mistake, arranging a joint meeting to discuss the mistake, or telling the patient directly.¹⁶ Insofar as the doctor-patient relationship obtains in such a case, physicians have an obligation to facilitate disclosure. However, they may be reluctant to say anything because of lack of defin-

NOTIFICATION FOLLOWING A MEDICAL EVENT

The January 30, 1998, "strawman" version of the proposed revision of 10 CFR Part 35, which was put on the Internet for public comment, included the following draft rule text for reporting medical events:

- (a) A licensee shall report any administration of byproduct material or radiation therefrom that:
 - (1) Results in a dose that is greater than 5 rem effective dose equivalent or 50 rem to an organ, and
 - (2) Represents either:
 - (i) A total dose or dosage that differs by at least 20 percent from that prescribed in a written directive;
 - (ii) A fractioned dose that differs by at least 30 percent from that prescribed in a written directive; or
 - (iii) A prescribed dose or dosage that is the wrong pharmaceutical; delivered to the wrong patient; delivered by the wrong route of administration; delivered to the wrong treatment site;
 - (iv) delivered by the wrong treatment mode; or from a leaking source(s); and
 - (3) Is not the direct result of patient intervention that could have been reasonably prevented by the licensee.

That version stated that the issue of whom should be notified following a medical event was still under discussion, and therefore, the current notification requirements were included. As noted in the Commission paper, staff has identified three possible alternatives for notification of the U.S. Nuclear Regulatory Commission, the referring physician, and individuals in the case of a medical event.

Alternative 1 Retain the current reporting requirements in 10 CFR Part 35 with minor changes intended to clarify the term "responsible relative."

The requirement to inform individuals about a medical event is consistent with other NRC requirements (e.g., 10 CFR 19.13(d) and 20.2205) for licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC. As articulated by the Commission at the time the misadministration rule was promulgated (and later modified), patient notification "... recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector." "Misadministration Reporting Requirements," 45 Federal Register 31701, at 31702 (May 16, 1980) and "Basic Quality Assurance Program, Records, and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 Federal Register 1439, at 1444 (January 11, 1990). This alternative recognizes physician discretion to withhold information from the patient if, based on medical judgment, such information would be "harmful" to the patient. Patient notification also enables patients, in consultation with their personal physicians, to make timely decisions regarding their remedial and prospective medical care. "Quality Management Program and Misadministrations," 56 Federal Register 34104, at 34117 (July 25, 1991). In addition, this alternative codifies existing industry standards [American Medical

Association (AMA) Principles of Medical Ethics]¹ obligating physicians to provide complete and accurate information to their patients.

As stated on numerous occasions, the medical community perceives the current requirements to be an unnecessary intrusion into the practice of medicine and asserts that this is the only area of medicine where there are Federal Government requirements for notifying individuals of medical errors.

If the Commission prefers this alternative, staff recommends that the current rule text be revised to clarify the provision for notifying the individual's "responsible relative," in lieu of the individual, in certain circumstances (e.g., the individual is a minor or unconscious) because that term is not defined legally, and therefore may be subject to different interpretations by the medical community.

The 1996 OMB submittal estimated that the regulatory burden: for NRC and Agreement State licensees to report misadministrations (medical events) to NRC or the appropriate Agreement State, the referring physician, and the individual is approximately \$214,200/year (based on 105 misadministrations/year); and for NRC to respond to and follow-up on the events, and to review the written reports is approximately \$288,000/year. Staff does not anticipate any change in the regulatory burden for licensees and the NRC if this alternative is pursued.

ALTERNATIVE 2: Revise the current reporting requirement to require a licensee to inform only NRC and the referring physician (but not the patient) of the medical event.

This alternative would rely on the authorized user or referring physician's voluntary compliance with "ethical principles" and "standards of care" to present complete and accurate medical facts to patients. This approach, as compared with Alternative 1, could be viewed as intruding less into the practice of medicine. Staff believes that requiring licensees to inform the referring physician of the medical event would help to assure that individuals, in consultation with their personal physicians (referring physicians), will have the needed information to make timely decisions about their remedial and prospective medical care. Staff does recognize that in some cases there will be not be a referring physician and the responsibility to inform the individual will fall to the authorized user physician.

This alternative does not ensure that individuals will be informed of a medical event and, therefore, might not receive information, viewed necessary by NRC, to make informed medical care decisions. This alternative is not consistent with other NRC requirements, in 10 CFR Parts 19 and 20, regarding reporting radiation exposures to individuals when such reports are

¹ Although AMA discusses patients' rights to receive information from physicians as "Fundamental Elements of the Patient-Physician Relationship" and to effectuate "informed consent," AMA ethical standards for informing patients of physicians' mistakes reflect a threshold of "significant complications" to the patient that may have resulted from the physician's mistake or judgment. "AMA Council on Ethical and Judicial Affairs, Code of Medical Ethics," Current Opinions with Annotations at xxxix, 120, 125 (§8.12), 1996-1997.

made to NRC. Also, if the referring physician does not follow the "ethical principles," this approach would not effectuate the specific Commission determination that individuals have a right to know when they have been involved in a misadministration. 45 Fed. Reg. at 31702.

Regulatory burden would be approximately the same as Alternative 1 if this alternative is pursued. Although the Federal government would no longer require licensees to provide information to individuals or responsible relatives, there would still be a requirement for licensees to report to NRC, notify the referring physician, and document the event.

ALTERNATIVE 3: Revise the current reporting requirement to require a licensee to inform only NRC of a medical event.

This alternative has many of the benefits previously discussed under Alternative 2: (1) it is consistent with NRC's policy of recognizing that physicians have the primary responsibility for the protection of patients and that they will act in the best interest of their patients, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," 44 Fed. Reg. 8242, at 8244 (February 9, 1979); (2) it would not require that the referring physician be informed of a medical event; and (3) it reflects the viewpoint of the medical community members noted in the Commission paper under the general discussion of patient notification.

This alternative does not contain a Federal requirement that would ensure that patients are informed of a medical event; therefore, individuals may not have information necessary for making informed medical care decisions. In addition, individuals who are the subject of medical events would not be accorded the same protection as occupational workers and members of the public, in terms of the requirements to be informed of radiation exposures when licensees are required to report such exposures to NRC (see discussion following Alternative 1 above). Also, this alternative does not effectuate a specific Commission determination that patients have a right to know when they have been involved in a misadministration.

The regulatory burden on licensees would be decreased if this alternative is pursued. Licensees would no longer be required, by the Federal government, to provide information to individuals or responsible relatives and the referring physician. No change in burden on staff is anticipated.

PRECURSOR EVENTS

The staff has identified three possible alternatives for capturing precursor events.

Alternative 1: Revise 10 CFR Part 35 to require reporting of "significant precursors."

Part 35 would be revised to: (1) define "significant precursor" in 10 CFR 35.2; (2) require that licensees report "significant precursors" to the U.S. Nuclear Regulatory Commission; and (3) require that licensees keep records of significant precursors. In addition, the statements of consideration for the revised rule would contain examples of conditions and incidents that staff would consider to be "significant precursors" [e.g., failure of computer hardware or software, interlock systems, or source containment systems (afterloaders)]; malfunction of a treatment timer system; or mislabeling of a therapeutic radiopharmaceutical).

This alternative was included in the "strawman rule" that was made publicly available January 1998 and was based on the definitions used by the Food and Drug Administration (FDA) in the medical device reporting area. A significant precursor was defined as "a condition or incident, except for a medical event, related to the use of radionuclides in medicine that caused or could cause serious injury to a patient, human research subject, worker, or the public." Although "serious injury" was not defined in the January 1998 version, subsequent versions of the draft rule text have defined it to mean an injury or illness that: (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

This alternative would capture a range of precursor events and, therefore, would fully meet the objective of the Staff Requirements Memorandum (SRM) COM-SECY-96-057, "Materials/Medical Oversight," March 20, 1997, to "capture" precursor events. However, if the intent of identifying precursor events is to improve licensees' radiation protection programs, then this alternative could potentially go beyond the intended objective (e.g., NRC would receive reports involving certain human errors that could not be applied to improvements in other licensees' programs). This alternative is risk-based, in that a reporting threshold is set, for significant precursors, that is similar to the FDA's threshold for medical device reporting.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, staff did attempt to limit reporting of precursors to only those events that could have a significant impact on public health and safety, and, consequently limit the increase in regulatory burden. Licensees may need to revise operating procedures and would need to report and record "significant precursors." NRC resources would be needed to process, review, and investigate reported precursor events. (NOTE: If Alternative 1 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

Alternative 2: Revise Part 35 to require reporting of deficiencies in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer (RSO), could lead to a medical event at that facility or could have detrimental health and safety

implications beyond the licensee's facility.

Part 35 would be revised to require reporting of deficiencies in equipment (e.g., hardware and/or software failures), byproduct material (e.g., the wrong material in a container), or procedures supplied by a manufacturer or vendor (e.g., vendor-supplied operating procedures that could result in a source being exposed for a time period beyond that anticipated by the licensee) that, in the opinion of the licensee, could lead to a medical event at that facility or could have implications beyond the licensee's facility. Licensees would be required to keep records of incidents reported to NRC.

This alternative would limit the number of precursor events reported to NRC, but would still meet the objective of capturing precursor incidents or conditions that could improve licensees' radiation protection programs.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, it is expected that the increase for licensees and NRC will be about the same as that associated with Alternative 1 because, although the types of reports to be submitted in Alternative 2 are more limiting, the threshold for reporting events is set lower than the level in Alternative 1, i.e., NRC would receive approximately the same number of reports under Alternatives 1 and 2. (NOTE: If Alternative 2 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

Enforcement action under Alternative 2 would only occur if it is demonstrated that the RSO concluded that the requisite standard was met. Where individual licensee employees believed the standard was met, investigations might be needed to determine if the RSO had reached the same conclusion and did not report it. This would be similar to enforcement of 10 CFR 30.9(b).

Alternative 3 Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding (MOU) with the FDA and monitor/establish system with U.S. Pharmacopeia (USP) to review its database.

This alternative relies on the existing regulatory framework in Parts 20, 21, and 30 and 21 CFR Part 803 to capture precursor events. Staff recognizes that all precursor events may not be captured under this alternative. This alternative captures: (1) precursors that would have significant implications for public health and safety or common defense and security, pursuant to 10 CFR 30.9; (2) events that prevent taking immediate protective actions necessary to avoid exceeding the regulatory limits because of exposures to radiation or radioactive materials, and certain other events involving licensed material pursuant to 10 CFR 30.50; (3) information provided to the FDA, which is currently available to NRC via the FDA/NRC MOU, pursuant to 21 CFR Part 803, "Medical Device Reporting"; and (4) reporting requirements pursuant to Parts 20 and 21. In addition, staff would recommend that NRC monitor, on an ongoing basis, information errors that are available via voluntary reporting systems, such as the voluntary Medication Errors Reporting Program at USP (see Enclosure for information on USP). Note, staff discussions with both USP and the medical community have noted that voluntary reporting systems do not capture all events.

There is no increased burden on licensees associated with this alternative. NRC medical use

licensees are already required to report specified events to NRC and the FDA, and many of them already participate in the USP voluntary reporting system. It is not anticipated that this approach would result in a significant increase in expenditure of NRC resources. Some minor resources (less than 0.1 full time equivalent) would be required to monitor information provided by USP. If this alternative is pursued, staff believes that an Information Notice should be issued describing the NRC position on capturing precursor events, using existing mechanisms.

Enclosure:

1. Information on USP and Its Initiatives and Programs

F · Y · I

Information on USP and its
Initiatives and Programs

U. S. Pharmacopeia

12601 Twinbrook Parkway
Rockville, MD 20852

(301) 816-8223
FAX (301) 770-5193

USP (U.S. Pharmacopeia)

What is the USP?

USP, established in 1820, is a voluntary, not-for-profit organization that promotes the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and health care technologies by health professionals, patients, and consumers.

Who is involved with USP?

More than 1,000 pharmaceutical scientists, academicians, health care professionals, government officials, and consumers serve as USP volunteers to assure the accuracy and current relevance of USP product quality standards and medical information. A staff of more than 250 supports the activities of the volunteers.

What are USP's primary activities?

▪ Product Quality Standards for Drugs and Other Health-related Articles

USP is responsible for establishing legally recognized product quality standards for drugs and other health-related articles in the United States. The *United States Pharmacopeia* and the *National Formulary (USP-NF)* contain product quality standards for more than 3,400 drug substances and 250 pharmaceutical ingredients used in making drugs.

Many state and federal statutes, including the 1938 federal Food, Drug, and Cosmetic Act, make *USP-NF* standards legally enforceable. In a unique public/private relationship, the Food and Drug Administration (FDA) is responsible for new drug approval and USP establishes public standards of strength, quality, purity, packaging, and labeling. Once the standards are published in the *USP-NF*, they are enforced by FDA.

▪ Authoritative Drug Information

The USP DI[®] database includes clinically relevant, consensus-based medical and therapeutic drug information for health care professionals, patients, and consumers. The printed *USP DI* comprises three volumes, *Drug Information for the Health Care Professional*, *Advice for the Patient[®]*, and *Approved Drug Products and Legal Requirements*. *USP DI* is recognized as a source of medically accepted indications, including off-label-uses, drug utilization review, and patient counseling in the Omnibus Budget Reconciliation Acts of 1990 and 1993. In 1994, a strategic alliance was formed between the USP and the American Medical Association to combine the USP DI and AMA Drug Evaluations databases.

▪ Learning from Practitioner Experience

USP initiated the USP Practitioners' Reporting NetworkSM (USP PRN) to help USP learn from practitioner experience through a network of four separate reporting programs for drugs, medication errors, radiopharmaceuticals, and veterinary medicine products. Once a report is received by USP PRN, the manufacturer and the Food and Drug Administration are alerted to drug product problems or medication errors. The information assists in the development and revision of the *USP-NF* and the USP DI database, and is disseminated to health care professionals who report to the program, and to pharmacy, medicine, and nursing organizations through USP's publication, the *Drug Product Quality Review*.

ATTACHMENT 6

Memorandum Dated May 27, 1998

Dr. M. Pollycove to H. Thompson



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

May 27, 1998

NOTE TO: Hugh L. Thompson, Jr., DEDR

FROM: Myron Pollycove, M.D. *MP*

SUBJECT: REVISION OF 10 CFR PART 35 REQUIREMENTS FOR NOTIFICATION
FOLLOWING A MEDICAL EVENT

ACMUI, Barry Siegel and I agree that the current reporting requirement should be revised to require a licensee to inform only NRC of a medical event. The March 20, 1998 paper for the Commissioners from L. Joseph Callan includes the discussion that supports this revision:

"The majority of the comments received on notification following a medical event (including those of two "patient rights advocates"), indicated that there should not be an NRC requirement for patient and/or referring physician notification in the case of a medical event. Individuals who do not favor patient notification assert that there are no other areas of medicine in which there is a Federal requirement for patient notification and that an NRC requirement for patient notification is contrary to the 1979 Medical Policy Statement [by intruding into the practice of medicine]. According to some of the ACMUI members and the NRC medical consultant advising the Working Group, patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which it is the "standard of care" for a physician to provide the patient with complete and accurate information. Members of the medical community have pointed out that they view the "fiduciary" relationship between the patient and physician as different from that between a licensee and an individual receiving a dose in excess of the 10 CFR Part 20 limits. In addition, some members of the medical community particularly object to the requirement, in 10 CFR 35.33(a)(4)(i)-(ii), for licensee to provide the informed individual with a copy of the licensee's report to the Commission (or a similar report,) believing that the report greatly magnifies the significance of the event when, in fact, a medical event could be of minimal safety significance."

The next paragraph of the paper cites Attachment 5 (enclosed) as supporting current requirements for patient notification. However, all examples cited in Attachment 5 are mistakes that harm the patient. Part 35, on the other hand, does not restrict "medical events" to mistakes that harm patients. The majority of previous "misadministrations" reported to the NRC did not harm the patient. The question to be considered carefully is whether more harm than benefit would result from retaining current reporting requirements in Part 35. In Attachment 5, Wu, et.al., "To Tell the Truth", JGIM:12, p.771 lists potential harms of disclosure to the patient:

"Patients may be harmed by learning that a mistake was made in their care. The knowledge may cause alarm, anxiety, and discouragement. It may destroy patients' faith and confidence in the physician's ability to help them. Patients may become disillusioned with the medical profession in general. This may cause them to decline beneficial treatments, or decrease their adherence to beneficial treatments, or decrease their adherence to beneficial treatment regimens or habits.

Not all patients want to know everything about their medical care. Some would rather not be burdened with the complexities of their illness. The well-meaning disclosure of potentially serious, but inconsequential mistakes may cause unwelcome confusion. In some cases, patients may feel they would be better off not knowing that a mistake had been made in their care. As the *American College of Physicians Ethics Manual* states, "society recognizes the 'therapeutic privilege' which is an exemption from detailed disclosure when such disclosure has a high likelihood of causing serious and irreversible harm to the patient." However, the American College of Physicians offers the following caution: "On balance, this privilege should be interpreted narrowly: invoking it too broadly can undermine the entire concept of informed consent."

There are many potential benefits of disclosing *harmful* mistakes to the patient. There is widespread agreement among physicians that this is necessary. Regrettably, even current requirements for notification have not ensured patient notification of harmful mistakes. I believe that current NRC requirements for notification would not increase such disclosures sufficiently to offset the harm noted above, particularly since the majority of "medical events" are harmless.

Enclosure: As stated

Doctors Urged to Admit Mistakes

By DENISE GRADY

WHEN doctors make a mistake that harms a patient, they should tell the patient what happened, apologize and do whatever it takes to repair the damage, researchers are urging, in a stance that is drawing mixed reviews from the medical community, insurance companies and lawyers.

The advice to come clean, in an article in the current issue of *The Journal of General Internal Medicine*, is offered by a team led by Dr. Albert Wu, an internist and associate professor at the Johns Hopkins School of Public Health in Baltimore.

Dr. Wu and his colleagues have been advocating greater honesty about medical errors since 1991, when they published a study showing that doctors in training at three large teaching hospitals often kept serious mistakes to themselves: only half discussed mistakes with senior doctors, and just a quarter told patients or their families what had occurred. The errors, which led to illness and even death, included missed or delayed diagnoses, incorrect drug prescriptions and surgical mistakes.

There is still great reluctance in the medical profession to admit mistakes, Dr. Wu said, even though ethics manuals have long called for disclosure. "Most medical schools do not have this sort of thing in their curriculum," he said, acknowledging that doctors, not unreasonably, may fear that taking the blame will leave them open to lawsuits and hurt their reputations and careers.

Even so, Dr. Wu said, there are compelling reasons for telling patients the truth. "It is the right thing to do," he said. The doctor-patient relationship is based on trust, he said, and morally and ethically, a doctor's first responsibility is to act in the patient's best interest. People who have been harmed have a right to know what went wrong, so they do not worry that a setback means their health is failing, when the cause was really a medical error.

In addition, Dr. Wu said, such patients may need extra treatment to remedy the mistake, as well as payment of medical expenses and, possibly, compensation for their injury.

Only in the rarest instances, as when a depressed patient could become incapacitated by bad news, might it be justifiable to withhold information about a mistake, Dr. Wu and his colleagues said.

Leveling with the patient can be good for the doctor, too, Dr. Wu said, noting that doctors who have harmed patients generally feel great guilt and distress. "In some cases, disclosure is the only way the physician can be absolved," he said. Telling the truth may also strengthen patients' faith in the doctor's integrity and inspire good will, while a cover-up that fails — as they often do — may anger patients and just make them more inclined to sue. Cover-ups may also antagonize juries.

"There's a bit of folk wisdom, that some doctors never get sued," Dr. Wu said. "Those that have really

good relationships with patients, patients wouldn't think of suing. But people who feel their trust was violated, feel betrayed, and a lawsuit may seem like the only way to get the truth."

Dr. Wu, who graduated from medical school in 1984, said he has never been sued.

One of his co-authors, Dr. Stephen McPhee, an internist and professor of medicine at the University of California at San Francisco, described a case in which his failure to order a certain blood test led to a lengthy delay in diagnosing hemochromatosis, a disorder in which prompt treatment is very important. The patient happened to be a lawyer.



Merry Kats for The New York Times

Dr. Albert Wu says admitting medical errors is right and smart.

"You can imagine how much I sweated before talking to him," Dr. McPhee said. "I admitted I was wrong but was very sorry, and there were consequences to him that we'd be able to deal with."

To Dr. McPhee's immense relief, the patient said, "That's O.K.," adding that he understood that the doctor could not think of everything.

Dr. McPhee said: "It's a very difficult conversation to have, no question. But medicine is a human enterprise, and errors are part of being human."

Dr. Wu said that other doctors' reactions to his advice have varied. "I get everything from total agreement to laughter, which is often a little derisive, so more cynical comments which basically imply that the world needs to change first," he said. Some, Dr. Wu said, think that "in the real world, if you were to adopt this posture, you'd have your throat ripped out by ravenous litigators."

Dr. Nancy Dickey, president-elect of the American Medical Association, said that in his call for the truth, "I believe Dr. Wu is probably at least substantially right."

"The problem is that the climate

of blame in this country, fueled by the litigation process, where we have to identify someone at fault who will then pay exorbitantly, makes it difficult to walk out and finger yourself," Dr. Dickey said. "If you do, you're playing roulette. The patient may say, 'Gee, doc, thanks, that took great courage and I won't take you to court.' But even if the patient feels that way, there will be others, family members and lawyers, who may encourage patients to change their minds."

Jack Pope, communications director for the Physician Insurers Association of America, said that urging doctors to confess their mistakes was "asking them to commit professional suicide." Without tort reform to decrease the number of malpractice suits and large settlements, he said, few doctors could risk owing up to errors.

Wayne Sinclair, general counsel for MMI Companies Inc., an insurance provider, said, "If you have a doctor out there saying, 'Oh, I did it,' it's a little hard for those of us who write the insurance."

Mark Hatlie, a lawyer and executive director of the National Patient Safety Foundation, a group founded last summer by the A.M.A., said: "If you tell the truth, apologize and reach out to a family in grief, you can defuse some of the anger and polarization that characterize a typical lawsuit. But every word you utter is an admission that can be used against you in a court of law."

Mr. Hatlie said that most malpractice insurance policies instruct doctors not to admit fault to patients without first consulting the insurance company or their hospital's lawyer. Often, he said, lawyers then order doctors to say nothing until all the facts have been determined.

But in the meantime, the patient may feel left in the dark, wondering what is going on. "They want to know why their trusted caregiver is suddenly not talking to them, and why they're seeing the hospital lawyer or risk manager," Mr. Hatlie said. "That's an incredibly divisive wedge

Is it 'professional suicide' for erring doctors to confess?

to put between a patient and a health-care provider, but sometimes there are reasons to do it."

Dr. Bernard Lo, a co-author of the article and an internist and medical ethicist at the University of California at San Francisco, said: "There are other considerations than malpractice concerns that ought to be part of this decision. If you take seriously the idea that physicians have a very strong obligation to act in the best interest of patients, we really should be focusing on the best interest of patients, not our own and not those of the institution."

PERSPECTIVES

To Tell the Truth

Ethical and Practical Issues in Disclosing Medical Mistakes to Patients

Albert W. Wu, MD, MPH, Thomas A. Cavanaugh, PhD, Stephen J. McPhee, MD,
Bernard Lo, MD, Guy P. Micco, MD

While moonlighting in an emergency room, a resident physician evaluated a 35-year-old woman who was 6 months pregnant and complaining of a headache. The physician diagnosed a "mixed tension/sinus headache." The patient returned to the ER 3 days later with an intracerebral bleed, presumably related to eclampsia, and died.

Errare humanum est: "to err is human." In medical practice, mistakes are common, expected, and understandable.^{1,2} Virtually all practicing physicians have made mistakes, but physicians often do not tell patients or families about them.^{3,4} Even when a definite mistake results in a serious injury, the patient often is not told. In one study, house officers reported telling their attending physicians about serious medical mistakes only half the time, and telling the patients or families in less than a quarter of cases.⁵ Highly publicized cases of fatal mistakes have heightened public and professional concerns about how physicians and hospitals respond to serious mistakes. When mistakes are not acknowledged in a timely manner, there may be a perception of a cover-up, and public confidence in physicians may be undermined.

The American Medical Association's (AMA's) *Principles of Medical Ethics* (1957) states that a physician must report an accident, injury, or bad result stemming from his or her treatment.⁶ However, many physicians interpret these requirements to mean that they should report to their superiors or to the hospital quality assurance or

risk management committee, rather than to the patient. More recently, the *American College of Physicians Ethics Manual* states, "physicians should disclose to patients information about procedural and judgment errors made in the course of care. If such information significantly affects the care of the patient."⁸ The AMA's Council on Ethical and Judicial Affairs states, "Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all facts necessary to ensure understanding of what has occurred."⁷

In this article, we analyze the various ethical arguments for and against disclosing serious mistakes to patients. We also provide practical suggestions for how to discuss the sensitive topic of mistakes with patients.

WHAT IS A MISTAKE?

We define a medical mistake as a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred. Independent of whether there were any negative consequences, this definition excludes the natural history of disease that does not respond to treatment and the foreseeable complications of a correctly performed procedure, as well as cases in which there is reasonable disagreement over whether a mistake occurred.

We categorize errors according to their genesis. System errors, also referred to as latent errors,² derive primarily from flaws inherent in the system of medical practice. In such errors, the system "sets up" individuals to make mistakes, i.e., through the unavailability of medical records, by confusing labeling of medications, and the like. When a system error occurs, the physician shares responsibility with other elements of the health care delivery system.

Conversely, individual errors are those deriving primarily from deficiencies in the physician's own knowledge, skill, or attentiveness. For instance, a physician mistakenly prescribed a nonsteroidal anti-inflammatory agent to a patient with renal insufficiency, resulting in permanently worsened renal failure.³ In such a case of individual error, the physician has primary responsibility.

Received from the Department of Health Policy and Management School of Hygiene and Public Health, and the Division of Internal Medicine, Department of Medicine, Johns Hopkins University, Baltimore, Md. (AWW); the Department of Philosophy, University of San Francisco, Calif. (TAC); and the Division of General Internal Medicine, Department of Medicine, University of California, San Francisco (SJM, BL, GPM).

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Address correspondence and reprint requests to Dr. Wu: Health Services Research and Development Center, 624 North Broadway, Baltimore, MD 21205.

The considerations in the disclosure of latent errors differ from those in the disclosure of individual errors. For example, in a latent error, the physician is often one link in a chain of causes generating the error. Accordingly, the disclosure of such an error may not be the sole responsibility of the physician. In what follows, we consider only the arguments for a physician to disclose his or her individual error to a patient. We also restrict ourselves to mistakes that cause significant harm, without regard to their detectability.

Errors causing harm can be subdivided into cases that are not medically remediable and those that are medically remediable. We argue that the physician has an obligation to disclose mistakes that cause significant harm, which in the judgment of a risk manager or malpractice insurer is likely to be remediable, mitigable, or compensable. Only in rare cases would a physician be permitted not to disclose a mistake causing harm to the patient. Specifically, physicians might be permitted not to tell if they have good reason to believe that disclosure would undermine the patient's autonomy in some way (e.g., incapacitate the already severely depressed patient). Or the patient might have told the doctor explicitly, "Doctor, if anything goes wrong, I don't want to know about it."

Two ethical theories assist in thinking about the disclosing of a mistake: consequentialism and deontology. A consequentialist ethical theory holds that one ought to do that act which will realize the best overall consequences. A deontological theory maintains that one ought to do that act by which one fulfills one's duties or obligations. Both consequentialist and deontological theories ground arguments for disclosure. In what follows, we first consider arguments based on consequences; then, we attend to arguments based on a physician's duties.

POTENTIAL BENEFITS AND HARMS OF DISCLOSURE

Potential Benefits of Disclosure to the Patient

The patient could benefit in many ways from knowing that a mistake had occurred. Such knowledge would allow the patient to obtain timely and appropriate treatment to correct problems resulting from the mistake. Disclosure therefore can prevent further harm to the patient. In some situations, close monitoring or a medical procedure may be necessary to mitigate the consequences of a mistake. Patients may be unwilling to permit or cooperate with necessary measures if they are unaware of the reason for doing so.³ When further treatment is indicated, disclosure is essential for informed consent. Otherwise, the uninformed patient is placed at risk of subsequent misdiagnosis and improper or inadequate treatment.

Disclosure of a mistake may also prevent the patient from worrying needlessly about the etiology of a medical problem. For example, a patient who was prescribed too much warfarin resulting in excessive anticoagulation suf-

fered a gastrointestinal bleed. Telling patients about such mistakes may resolve their uncertainty about the cause of their condition, possibly allowing them to feel better by explaining that recurrence would be unlikely.

Disclosure of a mistake also provides patients with information needed to make informed decisions. Patients may develop more realistic expectations about their doctors' interventions.⁹ Acknowledgment of fallibility brings uncertainties into the open, reduces the possibility of misunderstandings, and encourages the patient to take greater responsibility for his or her own care.

In the case of an injury, knowing about a mistake may allow the patient to obtain compensation for lost earnings or to pay for care necessitated by the injury,¹⁰ or to at least get a bill written off. Such compensation might be obtained through settlement rather than lawsuit; under the current system, obtaining such compensation would be difficult or impossible without disclosure of the mistake.

Finally, disclosure of a mistake can promote trust in physicians. Patients have a presumption of truth-telling.¹¹ Thus, a patient who is not informed of a mistake may feel angry and betrayed¹¹; the patient may think that a privileged relationship has been violated.¹²

Potential Harms of Disclosure to the Patient

Patients may be harmed by learning that a mistake was made in their care. The knowledge may cause alarm, anxiety, and discouragement. It may destroy patients' faith and confidence in the physician's ability to help them. Patients may become disillusioned with the medical profession in general. This may cause them to decline beneficial treatments, or decrease their adherence to beneficial treatment regimens or habits.¹³

Not all patients want to know everything about their medical care. Some would rather not be burdened with the complexities of their illness. The well-meaning disclosure of potentially serious, but inconsequential mistakes may cause unwelcome confusion. In such cases, patients may feel they would be better off not knowing that a mistake had been made in their care. As the *American College of Physicians Ethics Manual* states, "society recognizes the 'therapeutic privilege,' which is an exemption from detailed disclosure when such disclosure has a high likelihood of causing serious and irreversible harm to the patient." However, the American College of Physicians offers the following caution: "On balance, this privilege should be interpreted narrowly; invoking it too broadly can undermine the entire concept of informed consent."¹⁴

Potential Benefits of Disclosure to the Physician

The physician might also benefit from disclosing a mistake to the patient or family. The knowledge of making a mistake that harmed a patient can cause the physician to experience great emotional distress.^{15,16,17} The physi-

cian may be relieved to admit the mistake. In the case of a serious mistake, the patient or family member may be the only person able to forgive the physician for making the mistake. This may be the only way for the physician to gain absolution for the mistake.¹³ Many patients appreciate the physician's honesty, and disclosure of a mistake actually may strengthen the doctor-patient relationship. For example, when one of the authors failed to obtain a serum ferritin test during the evaluation of a patient referred for an enlarged liver, the diagnosis of hemochromatosis was delayed significantly. When the patient was told about the omission, he responded, "That's O.K. After all, doctor, you can't think of everything."

Candid disclosure of a mistake may decrease the likelihood of legal liability.¹⁵ Some have suggested that a strong doctor-patient relationship makes patients less likely to bring suit.¹⁶ Furthermore, if the patient learns about a mistake and brings a lawsuit, failure to disclose may place the physician in greater jeopardy.¹⁷

Disclosing mistakes may help physicians to learn and improve their practice.¹⁸ In a survey by Quill and Williamson, responding physicians reported that sharing errors with colleagues, students, friends, and sometimes patients prevented isolation, and marked the beginning of grieving about and learning from the mistake.¹⁸ Admitting a mistake may also help the physician accept responsibility for it, and may help the physician make constructive changes in practice.³ Physicians may also learn vicariously from mistakes made by others, and be able to avoid making similar mistakes themselves.

Potential Harms of Disclosure to the Physician

Revealing a medical mistake to a patient is often difficult and painful for the physician. The patient may become angry and upset, and such reactions can be highly stressful to doctors.⁴

Many physicians fear that disclosing a serious medical mistake will expose them to the risk of a malpractice suit. If a lawsuit ensues, the physician may be subjected to increased malpractice premiums as well as psychological stress.²⁰

Disclosure of a mistake may harm the physician through loss of referrals, hospital admitting privileges, preferred provider status, credentials, and even licensure. Selective contracting and physician profiling by managed care organizations create more tangible threats to the physician's livelihood. The development of the National Practitioner Data Bank²¹ adds the possibility that an incident will leave a permanent mark on the physician's record. Disclosure of mistakes may also damage the physician's reputation through the loss of respect or status among colleagues. In small communities, the physician's public reputation may also suffer.

Following disclosure of a serious error, the career of a physician-in-training may be harmed by poor evaluations or letters of recommendation, or even dismissal. Even

without the expectation of overt punishment, it is difficult to admit wrongdoing.

A consequentialist argument for the disclosure of mistakes to patients would be framed in terms of the above-noted benefits and harms to individual patients and physicians. In the doctor-patient relationship, a physician is to act for the sake of the patient; therefore, in weighing the benefits and harms of disclosure, the benefits and harms to the patient should have greater weight than those to the physician. There are also duty-based grounds for holding that, in certain cases, a physician should disclose medical error to a patient. We now turn to such arguments.

THE PHYSICIAN'S DUTIES

In what follows, we argue that a physician's responsibility to disclose a mistake to a patient can be derived from the fiduciary character of the doctor-patient relationship (that is, the fact that this relationship is based in trust).²² The fiduciary character of this relationship can be further articulated in accordance with the principles of nonmaleficence, beneficence, respect for patient autonomy, and justice.²³

Primum non nocere, "first, do no harm," states the principle of nonmaleficence: a caregiver has a grave responsibility to avoid harming the patient.^{24,25} The principle of beneficence enjoins physicians to act for the best interests of their patients' health even if the physician's own financial or professional well-being is not benefited by so acting.²¹ In cases in which harm resulting from a mistake can be reversed or ameliorated, the physician is obligated to do so. For example, if a sponge has been left in a patient after surgery, the sponge can be removed and infection can be prevented. In such cases, remedying or mitigating the harms caused by a mistake often requires the physician to disclose the mistake to the patient.

Respect for patient autonomy enjoins physicians to disclose a mistake that seriously harmed a patient.¹⁷ This is the case when full disclosure frees patients of mistaken beliefs concerning their past, present, or future medical conditions, thus enabling them to make informed decisions about future medical care.^{6,7} It may also be the case even if the patient does not need to know of the error in order to make future decisions about medical care. This is because patients have a claim to know their own history and to be free of mistaken beliefs concerning their past, present, or future medical condition.^{7,11} In short, a physician's obligation to respect patient autonomy indicates that a doctor has an ethical obligation to disclose mistakes to patients.⁷

When a nonremediable mistake has been made, the doctor may have an ethical duty to disclose it to the patient so that the patient can be compensated. Justice requires that people be given what is due to them. It would be unfair not to compensate a patient who was seriously harmed by mistake, e.g., for further medical care necessi-

lated by the mistake, for income lost due to the mistake, for pain and suffering, or for loss of function. The more serious the harm and the greater the need of the patient for compensation, the greater the physician's responsibility to make amends.

Physicians may be less obligated or not obligated at all to disclose a mistake that had little marginal impact, such as a serious medication error involving a moribund patient or the failure to recognize a pneumothorax caused during a failed attempt at cardiopulmonary resuscitation. Although it can be argued that disclosure is discretionary in these cases, the counter-argument can be advanced that even these mistakes should generally be disclosed. The physician has little to lose by so doing. These cases may provide a good opportunity for open and honest discussion and may strengthen the relationship with the patient or family.

In summary, the fiduciary character of the doctor-patient relationship indicates that a physician has the ethical duty to disclose error to a patient when disclosure furthers the patient's health, respects the patient's autonomy, or enables the patient to be compensated for serious, irreparable harm.

Practical Issues in Disclosure of Mistakes

Accepting the physician's obligation to disclose mistakes, there are practical issues concerning whether, when, who, and how to tell about the mistake. For uncertain cases, who should decide whether or not to tell? Is there an ideal time to tell the patient? What should be done in the case of the incompetent patient? When more than one physician was involved, who should tell the patient? What should be the role of hospital quality assurance and risk management personnel?

Deciding Whether to Disclose a Mistake. In cases in which disclosing a mistake seems controversial, who should decide whether or not to tell? The individual physician is biased against disclosure, and can easily rationalize the decision not to tell. The burden of proof should be on the physician to justify not disclosing a mistake. However, the decision should not be left to the individual physician's judgment. It would be important to obtain a second opinion to represent what a reasonable physician would do and be willing to defend in public. This second opinion would be particularly important in cases in which there was an adverse outcome, and the physician is inclined not to tell. A formal body such as an institution's ethics committee or quality review board seems preferable to informal consultation with peers, who might be similarly reticent.

Timing of Disclosure. The timing of disclosure should be considered. Although the patient might benefit from learning about a mistake as soon as possible after it occurred, disclosure should be made at a time when the patient is physically and emotionally stable. For example,

disclosure of a surgical error should be delayed. If possible, until the patient has recovered sufficiently to be able to understand and deal with the information.

Who Should Disclose the Mistake? When a mistake is made by a physician in training, responsibility is shared with the attending physician of record. It may be most appropriate for the attending physician and house officer to disclose the mistake to the patient together.¹⁴ Sometimes it may be appropriate to involve an institutional representative, such as a hospital administrator, risk manager, or quality assurance representative, in the disclosure.

The Incompetent Patient. Many patients with impaired decision-making capacity can still appreciate an apology. However, some patients lack the mental capacity to understand and appreciate what the physician tells them about medical errors, even if the discussion is simplified. There is no need to inform an incompetent patient. However, if there is a family member or other effective decision maker, this surrogate should be informed. The physician who will be taking care of the patient in the ambulatory setting should also be informed.

What to Say? Disclosure is often difficult, for several reasons. The facts of the case may be too complicated to be explained easily, and may not be known precisely. The physician may be tempted to frame the disclosure in a way that obscures that a mistake was made.

Disclosure of a mistake is an instance of "breaking bad news" to patients.²⁰⁻²² There is need for medical education about conducting these discussions. The upsetting news that a mistake has occurred and information regarding the consequences should be presented to the patient in a way that minimizes distress. The American College of Physicians *Guidelines Manual* offers the following guidance, which could be applied to the disclosure of a mistake: "Information should be given in terms the patient can understand. The physician should be sensitive to the patient's responses in setting the pace of disclosure. . . . Disclosure should never be a mechanical or perfunctory process."²³ The physician should recognize that patients or families may become upset or angry, and accept this as a natural response, taking care not to react defensively.

In telling the patient about an error, the physician should begin by stating simply that he or she has made a mistake. It may be helpful to describe the decisions that were made, including those in which the patient participated. The course of events should then be described in detail, using nontechnical language. The nature of the mistake, consequences, and corrective action taken or to be undertaken should be stated. The physician should then express personal regret and apologize for the mistake. Finally, the physician should elicit questions or concerns from the patient and address them.

The harm of disclosing a mistake may be minimized if disclosure is made promptly and openly, if apologies are

offered, and if charges for associated care are forgone. When the mistake had a major adverse impact on the patient, an offer should be made to cancel charges for subsequent care needed to remedy the mistake and to provide the necessary supportive services.

Financial amends should include all extra expenses incurred, such as physician services, error-generated laboratory fees, hospital expenses, and drug costs. Hospital risk management teams sometimes adopt and malpractice insurers sometimes encourage such an approach, which may reduce the number and size of malpractice suits. The physician rarely if ever pays for any of these services out of pocket. Under capitated payment, the hospital or group absorbs the costs (if individual physicians are capitated for pharmacy services they may also share the costs). If health insurance is available to pay for medical care, a decision should be made whether or not to bill the insurer for the services. It can be argued that the insurance company bears some co-equal responsibility because it insures the patient for all outcomes. However, companies may want recourse to reclaim some of the money. In all cases, it is important that hospital administration and risk management be involved in decisions and negotiations about billing.

A physician who had prescribed a sulfonamide to a patient known to be allergic to sulfa, causing an anaphylactoid reaction, might say, "Mrs. Smith, I have discovered what has caused you to become so ill. I regret to say that I made a mistake. Before prescribing the medication for your infection, I failed to check whether you were allergic to it. You are. The itchy rash, joint pains, and fever you now have are due to the allergy. I am giving you ibuprofen and diphenhydramine to help you feel better, and I expect you will gradually improve over the next several days. I feel very badly that my not checking has caused you to have this reaction. I am sorry. Of course, there will be no charges for the antibiotic or the medications I am now prescribing to remedy my mistake. Do you have any questions for me?"

Overcoming Barriers to Disclosure

From a pragmatic point of view, physicians are often most concerned about the potentially harmful personal consequences of disclosing a mistake. In blunt terms, physicians may question whether any possible benefits to the patient are worth the possible risks of a lawsuit to their career or livelihood. This clash between ethical ideals and pragmatic reality is a difficult one. It may sound encouraging to remind physicians to do what is best for the patient. However, the AMA's Council on Ethical and Judicial Affairs states, "Concern regarding legal liability might inhibit following truthful disclosure should not affect the physician's honesty with a patient."⁷

We would make several responses to physicians who hesitate to disclose mistakes that cause significant harm to patients because of fears of litigation. First, disclosing

mistakes may reduce the risk of litigation. If patients appreciate physicians' honesty and fallibility.¹⁵ Second, serious mistakes may come to light, even if physicians do not disclose them. Patients may wonder about the cause of their changed condition, ask other caregivers, or even ask their physicians directly. Any perception that the physician tried to cover up a mistake might make a patient more angry and more litigious.¹⁷ Third, in disclosing mistakes physicians can take steps to mitigate any harms that may occur to them. Physicians can learn how to disclose mistakes in a manner that diffuses patient anger. Furthermore, when mistakes have caused serious harm to patients, physicians can take the initiative in recommending to institutional risk management personnel or malpractice insurers that a prompt and fair settlement is made out of court.

For an injured patient to obtain compensation through the tort system requires proof of negligence, defined as violation of professional standards. This creates an untenable conflict for physicians, for whom compensation to the patient demands the demonstration of malpractice. Acts of negligence constituted only a small proportion of the errors in the Harvard Medical Practice Study,¹ and only a small proportion of injuries resulted in compensation for the patient. Thus, the current system obstructs detection and just compensation for errors and inhibits disclosure. The need to report and reduce errors constitutes a major ethical impetus for reform to a system of no-fault, nonadversarial patient compensation. Such a system would facilitate a move to a systems approach incorporating human factors research to reduce errors.^{2,10}

The fear of damage to reputation and loss of respect from peers may also inhibit physicians from disclosing mistakes. To overcome this barrier will require increased recognition and acceptance of mistakes as part of clinical practice. Guidelines should be created to describe what physicians should do when they make a mistake. Such guidelines should also describe what to do when a colleague tells you about a mistake you have made or a mistake he or she has made. The importance of providing emotional support needs to be emphasized. It is particularly important to help physicians-in-training cope with their mistakes in such a way as to help them maintain their confidence and develop professionally.¹⁴

Disclosure of Mistakes Made by Other Physicians

A physician who, in the care of one of his or her own patients, learns of or witnesses a major error (e.g., a surgical misap) made by another physician, has several options. These include waiting for the other physician to disclose the mistake, advising the other physician to disclose the mistake, arranging a joint meeting to discuss the mistake, or telling the patient directly.¹⁶ Insofar as the doctor-patient relationship obtains in such a case, physicians have an obligation to facilitate disclosure. However, they may be reluctant to say anything because of lack of defin-

ATTACHMENT 7

SRM-SECY-92-171

OFFICE OF THE
SECRETARY

NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20545

Thompson
Blaha
Bennett, RM
Hammerer, OF
Jordan, AEOB
SJones, RES
Scroggins, OC

June 25, 1992

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

Barry A. Siegel, Chairman
Advisory Committee on the Medical Uses of
Isotopes

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-92-171 - ADMINISTRATION OF BYPRODUCT
MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL
TO PATIENTS WHO MAY BE PREGNANT OR NURSING

The Commission (with all Commissioners agreeing) has approved the development of a performance-based rule and a modified regulatory guide which addresses the administration of byproduct material or radiation from byproduct material to patients who may be pregnant or nursing.

~~(EDD)~~ (RES)

(SECY Suspense: 12/24/92) 9100129

In preparing the rulemaking package, the staff should consider the following:

- 1) the precautions which are already in use to guard against improper administration of nonradiological drugs, chemicals or other procedures to patients who are pregnant or nursing and the feasibility of simply mandating their use for radiological procedures,
- 2) the philosophies espoused by NCRP and ICRP for addressing the radiation safety concerns associated with administration of radiation or radioactive materials to patients who may be pregnant or nursing,
- 3) consistency with the information on radioactive drugs available from the U.S. Pharmacopeia for the health professional and for the patient,

SECY NOTE: THIS SRM, SECY-92-171 (WITHOUT COPYRIGHTED MATERIAL CONTAINED IN ENCLOSURE 8), AND THE VOTE SHEETS OF THE CHAIRMAN, AND COMMISSIONERS ROGERS, CURTISS AND de PLANQUE WILL BE MADE PUBLICLY AVAILABLE 10 WORKING DAYS FROM THE DATE OF THIS SRM

Rec'd Off. EDO

Date 6-29-92

Time 11:30

- 4) consultation with Oak Ridge-Associated Universities to establish an appropriate dose threshold for reporting unintended exposures to embryos, fetuses, and nursing infants from diagnostic administrations,
- 5) a second independent study to be done by a qualified, disinterested party to assist in preparing the regulatory analysis, and
- 6) developing a sound regulatory analysis that quantifies, to the extent available data permits, the risks and benefits, in order to have confidence that the solution being recommended is consistent with the problem being addressed.

The staff should continue to interact closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the development of the proposed rule and regulatory guide.

The Commission (with all Commissioners agreeing) requests that the ACMUI formulate recommendations on how the ACMUI could develop and document its views for the staff and Commission on major policy issues and provide an estimate of the resources required to carry out the recommendations. The staff should advise the ACMUI to present its recommendations at the July 31, 1992 briefing.

(ACMUI)

(SECY Suspense.

7/31/92)

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
OGC
OCAA
OIG

ATTACHMENT 8

Draft Regulatory Analysis

**DRAFT REGULATORY ANALYSIS
10 CFR PARTS 20, 35**

**COMPREHENSIVE REVISION OF
10 CFR PART 35
"MEDICAL USE OF BYPRODUCT MATERIAL"
AND
PETITION FOR RULEMAKING
"REVISION OF DOSE LIMIT FOR MEMBERS OF THE
PUBLIC EXPOSED TO HOSPITALIZED PATIENTS"
(PRM 20-24)**

1. BACKGROUND

10 CFR Part 35

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,902 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 5,000 State licenses in Agreement States authorizing the medical use of byproduct material. An estimated more than eleven million patients annually are administered medical procedures involving byproduct materials.

The Nuclear Regulatory Commission (NRC) is revising its regulations governing the medical use of byproduct material in 10 CFR Part 35. During the last four years, the NRC has examined the issues surrounding its medical use program, and is now undertaking a comprehensive revision of 10 CFR Part 35. The NRC's reexamination of 10 CFR Part 35 began in 1993 with an internal senior management review report prepared by NRC. NRC then sponsored an external study, conducted between January 1994 and 1996, by the National Academy of Sciences, Institute of Medicine. 10 CFR Part 35 also was addressed in NRC's Strategic Assessment and Rebaselining Project (SA), culminating in the SA Direction-Setting Issue Paper Number 7 (DSI 7) released September 16, 1996. On March 20, 1997, the Commission issued a Staff Requirements Memorandum (SRM) ("COMSECY-96-057, Materials/Medical Oversight (DSI 7)") directing the staff to revise 10 CFR Part 35 to restructure it into a risk-informed, more performance-based regulation. The Commission, in SECY-97-131, directed the staff to conclude the 10 CFR Part 35 rulemaking by May 1999.

10 CFR Part 20

In addition, the NRC is revising its regulations in 10 CFR Part 20, Standards for Protection Against Radiation, in response to a Petition for Rulemaking (PRM 20-24) dated April 7, 1996,

from the University of Cincinnati. PRM 20-24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) per year (rather than the current limit of 1 mSv (0.1 rem) currently established by 10 CFR 20.1301).

The 1991 revision of 10 CFR Part 20 (56 FR 23398; May 21, 1991) established a public dose limit of 1 mSv (0.1 rem) per year (10 CFR 20.1301(a)). Section 10 CFR 20.1301(c) permits licensees to request NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) per year. However, fewer than ten medical licensees have applied for such an NRC authorization for visitors since the 1991 revision. Under 10 CFR 35.75(a), a licensee who is an authorized user of byproduct materials for medical use may authorize the release from its control of any patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from the released patient is not likely to exceed 5 mSv (0.5 rem).

The petitioner in PRM 20-24 requests that the NRC amend 10 CFR 20.1301 to authorize "specified visitors" of hospitalized radiation therapy patients, as individual member of the public, to receive up to 5 mSv (0.5 rem) per year. The petitioner argues that the higher dose limit is appropriate for visitors determined by the physician to be necessary for the emotional or physical support of the patient (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient).

1.1 Statement of the Problem

10 CFR Part 35

NRC has identified the following problems that require revisions to 10 CFR Part 35:

First, revisions are needed to address the unnecessarily overly prescriptive nature of specific sections of 10 CFR Part 35 that result in costs to licensees without commensurate health and safety benefits. Although licensees currently have the option of adopting alternative measures, this requires a license amendment. License amendments are costly both to the licensee and to NRC.

Second, revisions are needed to place the basis for regulation of certain well-established technologies into 10 CFR Part 35. Specifically, the regulations in 10 CFR Part 35 currently do not address high dose-rate remote brachytherapy, low dose-rate remote brachytherapy, pulsed dose-rate remote brachytherapy, and gamma stereotactic radiosurgery. The regulatory basis for these technologies currently is established by license conditions rather than regulations.

Third, revisions are needed to provide for the incorporation of new technologies in a timely manner. Currently, new technologies must be licensed through case-by-case reviews in which

the applicant or licensee must submit a request for an exemption for technologies not specifically addressed in 10 CFR Part 35.

Fourth, the regulations in § 35.2 regarding thresholds for misadministrations are not entirely dose based. These regulations do not address new technologies or patient intervention nor do they provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, the regulations currently do not require the identification and reporting of precursor events. This reduces the likelihood that NRC is informed of conditions or incidents falling outside the definition of a medical event that could ultimately cause serious injury to a patient or human research subject, worker or member of the public. The Commission directed the staff to address how best to capture not only relevant safety-significant events but also precursor events.

Sixth, the requirements in Subpart J, concerning training and experience, include requirements for clinical experience in all modalities. Because diagnostic procedures present a lower overall risk, as compared to therapeutic procedures, most of the supervised clinical experience currently required may not be necessary for most diagnostic uses.

Seventh, the regulations now permit medical use licensees to hold byproduct material with a half-life less than 65 days for decay-in-storage for a minimum of ten half-lives before disposal in ordinary trash. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

10 CFR Part 20

Revisions to 10 CFR Part 20 are required because the 100 mrem public dose limit in 10 CFR 20.1301(c) is overly restrictive with respect to visitors to patients undergoing therapy involving byproduct material. This is a problem because there are occasions when additional access to the radiation therapy patient by family or friends, as determined by the authorized user physician, is necessary to provide both physical and emotional support while the patient is under licensee control.

1.2 Earlier NRC Actions

10 CFR Part 35

The NRC published an announcement of its program for revision of 10 CFR Part 35 and a request for public input on the rule development in a Federal Register notice on August 6, 1997 (62 FR 42219). The NRC staff adopted a modality approach to the 10 CFR Part 35 rule. The proposed rule addresses the following modalities: (1) unsealed byproduct material - low dose; (2) unsealed byproduct material - high dose; (3) manual brachytherapy; (4) sealed sources for

diagnosis; (5) therapeutic medical devices; and (6) other medical uses of byproduct material or radiation from byproduct material.

Development of the text of the proposed rule as well as draft guidance documents was done by a governmental Working Group and a Steering Group. Representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc. took part in both the Working Group and the Steering Group.

To ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking issues and to discuss the rulemaking issues with one another and NRC convened or participated in a number of public workshops and meetings to discuss the fundamental approaches and issues to be addressed in the rulemaking. NRC participated in a workshop held during the Organization of Agreement States' 1997 All Agreement States meeting on October 18, 1997 in Los Angeles, California. (See 62 FR 52513; October 8, 1997). The All Agreement States meeting was attended not only by representatives of the 30 Agreement States but also by the public. NRC convened two facilitated public workshops, in Philadelphia, Pennsylvania on October 28, 29, and 30 and in Chicago, Illinois on November 12, 13, and 14, 1997. (See 62 FR 53249; October 14, 1997). These workshops were attended by nuclear medicine physicians; radiation oncologists; and other specialists (e.g., cardiologists and radiologists); medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients' rights advocates; Agreement States; Federal agencies; and members of the public. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an NRC advisory committee discussed the issues regarding the revision of 10 CFR Part 35 in its meetings on September 25 and 26, 1997 and March 1 and 2, 1998. Finally, NRC staff attended meetings with numerous groups representing physicians, pharmacists, medical physicists, technologists, and other stakeholders, including the following:

Interactions with Medical Professional Societies

Date	Location	Society
6/4/97	San Antonio, TX	Society of Nuclear Medicine American College of Nuclear Physicians
6/11/97	Lake Tahoe, CA/NV	American College of Medical Physicists
9/7/97	Atlanta, GA	American College of Radiology
9/16/97	Rockville, MD	American College of Radiation Oncology
9/26/97	San Francisco, CA	American Association of Clinical Endocrinologists
9/97	Professional Journal Notice	Oncology Nursing Services
10/16/97	Chicago, IL	American Hospital Association

Interactions with Medical Professional Societies (continued)

Date	Location	Society
10/18/97	Los Angeles, CA	Organization of Agreement States American Hospital Association
10/20/97	Orlando, FL	American Society of Therapeutic Radiology and Oncology
10/22/97	Bethesda, MD	American College of Cardiology American Society of Nuclear Cardiology
12/2/97	Chicago, IL	Radiation Society of North America
12/18/97	Rockville, MD	Society of Nuclear Medicine
2/1/98	Las Vegas, NV	Society of Nuclear Medicine

The two facilitated workshops sponsored by the NRC, as well as NRC's participation in other meetings, were intended to foster a clearer understanding of the positions and concerns of the affected interests, and were not intended to develop a consensus agreement of the participants on the rulemaking issues. This proposed rulemaking, however, is the evolutionary result of the numerous meetings described above, as well as the reasoned consideration of the Working Group and Steering Group.

10 CFR Part 20

The analysis of PRM 20-24 began on June 21, 1996, when the NRC published a notice of receipt and a request for comment on the petition (PRM 20-24) (61 FR 31874). All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of 1 mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC consolidated action on PRM 20-24 with the 10 CFR Part 35 rulemaking in January, 1998.

2. OBJECTIVES OF THE PROPOSED RULEMAKING

10 CFR Part 35

In its "Staff Requirements Memorandum (SRM)-COMSECY-96-057, Materials/Medical Oversight (SDI 7)," dated March 20, 1997, the Commission directed the staff to revise 10 CFR Part 35; associated guidance documents; and, if necessary, the Commission's 1979 Medical Policy Statement. The Commission's SRM specifically directed the restructuring of 10 CFR Part 35 into a risk-informed, more performance-based regulation. During development of the rule and associated guidance as well as during review of the Medical Policy Statement, the NRC staff was directed to consider the following issues:

- (1) Focusing 10 CFR Part 35 on those procedures that pose the highest risk;
- (2) Regulatory oversight alternatives for diagnostic procedures that are consistent with the lower overall risk of these procedures;
- (3) The best way to capture not only relevant safety-significant events, but also precursor events;
- (4) The need to change from the term "misadministration" to "medical event" or other comparable terminology;
- (5) Redesigning 10 CFR Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;
- (6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety (e.g., confirming patient identity requiring written prescriptions, and verifying dose; and
- (7) The viability of using or referencing available industry guidance and standards, within 10 CFR Part 35 and related guidance, to the extent that they meet NRC's needs.

In carrying out these objectives, the NRC has also sought the following:

- Restructuring 10 CFR Part 35 to incorporate a modality-based approach;
- Reducing or eliminating duplication or overlaps between 10 CFR Part 35 and other 10 CFR Parts of 10 CFR, particularly 10 CFR Part 20; and
- Reducing recordkeeping and/or reporting requirements whenever possible.

10 CFR Part 20

The objective of the proposed rulemaking to address PRM 20-24 is to permit authorized nuclear pharmacist physicians the discretion to permit specified visitors to receive doses in excess of the 1 mSv (0.1 rem) public dose limit in the course of providing physical and emotional support to hospitalized individuals administered radioactive materials or radiation therefrom.

3. ALTERNATIVES

The following alternatives were considered in this analysis:

Alternative One: **10 CFR Part 35:** Continue 10 CFR Part 35 without revision.

10 CFR Part 20: Deny PRM 20-24 and retain the 1 mSv (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the 5 mSv (0.5 rem) annual dose limit for visitors of radiation patients.

Alternative Two: **10 CFR Part 35:** Promulgate comprehensive proposed revisions to 10 CFR Part 35 that relax certain prescriptive requirements currently contained in 10 CFR Part 35 with respect to Radiation Safety Committees, quality management, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20. Substitute new requirements, including testing requirements, with respect to training and experience. Incorporate new requirements for therapeutic uses of radionuclides, including requirements for brachytherapy, teletherapy, remote afterloaders, and gamma stereotactic surgery.

10 CFR Part 20: Promulgate a new dose limit of 5 mSv (0.5 rem), as requested under PRM 20-24, including a requirement to provide basic radiation safety instruction for specified visitors of radiation therapy patients, but no requirement for visitor badging or recordkeeping.

Other Alternatives: **10 CFR Part 35:** NRC considered other alternatives for five "cross-cutting" issues: (1) the quality management program; (2) training and experience for authorized users, authorized nuclear pharmacists, and Radiation Safety Officers; (3) the Radiation Safety Committee; (4) patient notification of reportable events; and (5) the threshold for reportable events. However, these other alternatives were dismissed for various reasons and the staff is proposing Alternative Two as the preferred option.

4. UNDERLYING DATA AND ASSUMPTIONS

The following data and assumptions were used to evaluate the values and impacts of the alternatives for revisions to 10 CFR Part 35 and response to PRM 20-24.

4.1 Number and Type of Licensees

Table 1 provides data from NRC's License Tracking System on the number of NRC 10 CFR Part 35 licensees, by category, as of January 1998. The number of Agreement States licensees is estimated at 2.5 times the number of NRC licensees, based on discussions with cognizant staff of the NRC Office of State Programs. Estimates throughout are based on the assumption that Agreement States will adopt the proposed regulatory changes.

Table 1
Number and Type of Licenses

	Program Code ¹	NRC ²	Agreement States ³
Numbers and Types of Medical Licensees			
<i>Medical Institution-Broad</i>	2110	82	205
<i>Medical Institution-QMP Req.</i>	2120	984	2,460
<i>Medical Institution-QMP Not Req.</i>	2121	150	375
<i>Medical Private Practice-QMP Req.</i>	2200	165	418
<i>Medical Private Practice-QMP Not Req.</i>	2201	263	658
<i>Eye Applicators Strontium-90</i>	2210	23	58
<i>Mobile Nuclear Medicine Service</i>	2220	40	100
<i>High Dose-Rate Remote Afterloader</i>	2230	103	258
<i>Low Dose-Rate Remote Afterloader</i>		29 ⁴	71 ⁴
<i>Pulse Dose-Rate Remote Afterloader</i>		0	3 ⁵
<i>Mobile HDR Remote Afterloader</i>	2231	0	3 ⁶
<i>Mobile Therapy</i>	2240	0	0
<i>Teletherapy</i>	2300	63	158
		1,902	4,760

¹ NRC Material License Program Codes, June 1997.

² Data from NRC License Tracking System, January 20, 1998.

³ Estimated, based on 1 to 2.5 ratio of NRC licensees to Agreement States licensees.

⁴ Not based on NRC License Tracking System; estimated based on information supplied by ACMUI, March 2, 1998.

⁵ Estimated, based on information supplied by ACMUI, March 2, 1998.

⁶ Estimated, based on information supplied by NRC Office of State Programs.

4.2 General Administrative Activities

Table 2 provides estimates of the numbers of activities or persons subject to the general administrative requirements of 10 CFR Part 35, such as Radiation Safety Officers, meetings of Radiation Safety Committees, and license amendments under 10 CFR Part 35. It also provides estimates of the number of individuals per year becoming authorized users, authorized nuclear pharmacists, Radiation Safety Officers, or medical physicists for the first time.

Table 2
General Administrative Activities

	NRC	Agreement States
Number of Radiation Safety Officers ¹	1,872	4,680
Number of Medical Institutions with Quality Management Plans ²	1,317	2,304
Number of License Amendments Completed Annually ³	1,737	3,474
Number of Radiation Safety Committee Meetings ⁴	4,984	12,460
	NRC and Agreement States	
Number of individuals per year ⁵ seeking certification for:		
<i>Uptake, Dilution, and Excretion Studies</i>		1,110
<i>Imaging and Localization Studies</i>		1,110
<i>Therapeutic Unsealed Sources</i>		1,290
<i>Brachytherapy</i>		150
<i>Sealed Sources for Diagnosis</i>		1,260
<i>Therapeutic Medical Devices</i>		150
<i>Nuclear Pharmacists</i>		5
<i>Medical Physicist</i>		185

Footnotes to Table 2

- ¹ Estimated, based on regulatory requirement that all licensees must appoint RSO, but that for 85 percent of the teletherapy licensees (program code 2300) and 80 percent of the high dose-rate remote afterloader licensees (program code 2230) the RSO on the license will be the same as the RSO on the medical institution license because the activities take place entirely within the medical institution.
- ² Total of program codes 2110, 2120, 2200, 2210, 2230, and 2300 for NRC licensees. Agreement States estimate adjusted to reflect the proportion of Agreement States (9 of 30, according to data provided by the NRC Office of State Programs) that have not adopted a quality management rule.
- ³ Data from NRC License Tracking System, October 21, 1997; Total cases completed by Region, 10/01/96 thru 9/30/97, amendments for program codes 2110 thru 2300.
- ⁴ Estimated as number of medical institution licensees that are required to have a Radiation Safety Committee (estimated as the total for program codes 2110, 2120, and 2121, plus 20 percent of 2230 and 15 percent of 2300 to account for licensees not covered under medical institution licenses but working in such settings) times four (quarterly) meetings per year.
- ⁵ Compiled from estimates obtained from American Board of Radiology, American Board of Nuclear Medicine, American Board of Medical Physicists, Health Physics Society, Board of Pharmaceutical Specialities and from personal communications with Dr. Barry Siegel, Mr. Mark Rotman, and NRC staff.

4.3 Current Uses of Byproduct Materials

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. Diagnostic nuclear medicine in most cases involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium-99m hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine-131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine-131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate-32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically the sealed sources are either inserted in a cavity (e.g., cesium-137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine-125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

5.0 REVISIONS TO RULE TEXT AND CONSEQUENCES

SUBPART A--GENERAL INFORMATION

5.1 Purpose and scope (§ 35.1).

Section 35.1 currently provides that 10 CFR Part 35 prescribes requirements for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of public health and safety.

The proposed rule would substitute the words "radiation safety of workers, the general public, and patients, and human research subjects" for "protection of the public health and safety."

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Provide improved clarity and precision as well as consistency with the proposed revisions to the medical policy statement.

5.2 Definitions (§ 35.2).

Section 35.2 sets out the applicable definitions for 10 CFR Part 35.

The proposed rule would delete the definitions of "ALARA," "Dental use," "Ministerial change," "Misadministration," "Podiatric use," "Recordable event," and "Teletherapy physicist." The proposed rule would revise the definition of "Authorized user," "Authorized nuclear pharmacist" and "Brachytherapy source." The proposed rule would add definitions for "Authorized medical physicist," "High dose-rate remote afterloader," "Low dose-rate remote afterloader," "Medical event," "Mobile service," "Precursor event," "Prescribed dose," "Pulsed dose-rate remote afterloader," "Radiation Safety Officer," "Sealed Source and Device Registry," "Stereotactic radiosurgery," "Structured educational program," "Temporary jobsite," "Treatment site," "Unit dosage," and "Written directive."

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Provide improved clarity and precision.

5.3 Information collection requirements: OMB approval (§ 35.8).

Section 35.8(a) specifies the OMB-approved information collection requirements contained in 10 CFR Part 35, and specifies that OMB has approved the information collection requirements in this 10 CFR Part under control number 3150-0010.

The proposed rule would change section numbers in § 35.8(b) to conform with the proposed rule.

The proposed rule would delete § 35.8(d) referring to OMB control number 3150-0171, which covered the information collection requirements contained in §§ 35.32 and 35.33, because those two sections would be covered by the proposed rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change for restructuring of 10 CFR Part 35.

5.4 Implementation (§ 35.10).

The proposed rule would add a new section, § 35.10, that would define regulatory implementation schedules.

Section 35.10(a) would require licensees to implement the provisions in 10 CFR Part 35 on or before 6 months from publication of the final rule, except for the requirements contained in § 35.10(b).

Section 35.10(b) would require licensees to implement training requirements contained in 10 CFR Part 35 on or before 2 years from publication of the final rule.

Section 35.10(c) would allow licensees to satisfy the training requirements of Part 35 for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user, by complying with either the appropriate training requirements in Subpart J or the appropriate training requirements in Subpart B or Subparts D-H.

Section 35.10(d) would mandate that any existing license condition that is more restrictive than a requirement in this part would remain in effect until there is a license amendment or license renewal.

Section 35.10(e) would provide that any existing license condition that is more restrictive than a requirement in 10 CFR Part 35 would remain in effect until there is a license amendment or license renewal.

Section 35.10(f) would allow licensees currently exempted from a provision in the current 10 CFR Part 35 to continue to be exempt under the proposed regulations.

Section 35.10(g) would require that license conditions citing provisions in 10 CFR Part 35 that would be deleted in the proposed rule would remain in force until there is a license amendment or license renewal that modifies or removes this condition.

Cost Impacts:

Phasing in of regulatory implementation will provide savings from regulatory efficiency.

Health and Safety Impacts:

None anticipated.

Benefits:

Provide improved clarity and precision.

5.5 License required (§ 35.11).

Section 35.11(b) currently specifies that an individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in 10 CFR Part 35 under the supervision of an authorized nuclear pharmacist, as specified in the requirements on supervision in § 35.25.

The proposed rule would change the reference from § 35.25 to § 35.27 to conform with the numbering of the proposed rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change for restructuring of 10 CFR Part 35.

5.6 Application for license, amendment, or renewal (§ 35.12).

Section 35.12 specifies the procedures for license application, amendment, or renewal.

Section 35.12(a) currently specifies that if the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

Section 35.12(b) and (c) currently specify that an application for medical use of byproduct material as described in the pertinent sections of 10 CFR Part 35 must be made by filing Form NRC-313.

The proposed rule would provide in § 35.12(a) that the application must be signed by the management of the facility and eliminate the reference to application by "any person."

In § 35.12(b), the proposed rule would add a reference to § 35.600 to include application requirements for medical use of remote afterloaders.

Proposed § 35.12(c) would be added, specifying that except for medical use of remote afterloaders, a separate license application must be filed for each medical use of byproduct material as described in § 35.600.

The proposed rule would add a new § 35.12(d) that would establish requirements for license applications for other medical uses of byproduct material or radiation therefrom covered by Subpart K of the proposed rule and not covered elsewhere in 10 CFR Part 35. Specifically, § 35.12(d) would require that in addition to the information currently required in Form NRC-313, "Application for a Materials License," the applicant must also supply the following:

- Any information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR Part 35;

- Any specific information necessary for: (1) radiation safety precautions and instructions; (2) training and experience of proposed users; (3) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (4) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.
- Any other information requested by the Commission in its review of the application.

Cost Impacts:

NRC intends for this provision to allow applicants and licensees to submit license applications for medical uses not specifically addressed in Subparts D-H of the proposed rule. Thus, license applications for new or emerging technologies could be submitted under § 35.12 instead of requiring applicants or licensees to submit an exemption request under § 35.19. However, because of the nature of emerging technologies, all of the information needed for approval of such technologies cannot be specified in advance.

Cost savings may result from reduced time for applicants or licensees to prepare applications for new or emerging technologies not addressed in Subparts D-H.

Assumptions:

Licensees:

Total annual licensee applications:	2
Reduced application preparation time, hours:	4
Physician hourly rate: ¹	\$100
Total Annual Cost Savings for licensees:	\$800
Total Annual Cost Savings from amendment to § 35.12:	\$800

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees, the NRC, and Agreement States.

¹ The regulatory analysis assumes the following hourly rates, by labor category, fully loaded:

RSO/AU/Physician/Administrator/Management:	\$100
Scientific Staff:	\$50
Technical Staff:	\$30
Clerical Staff:	\$18

5.7 License amendments (§ 35.13).

Section 35.13 currently specifies the circumstances under which a licensee must apply for and receive a license amendment.

Section 35.13(b) currently requires a licensee to obtain a license amendment before it permits anyone to work as an authorized nuclear pharmacist or authorized nuclear pharmacist under the license, unless

- Under § 35.13(b)(1) the authorized nuclear pharmacist is certified by an organization specified in 10 CFR Part 35; or
- Under § 35.13(b)(2) the authorized nuclear pharmacist is certified by an organization specified in 10 CFR Part 35; or
- Under § 35.13(b)(3) the person is identified as an authorized nuclear pharmacist or authorized nuclear pharmacist on an NRC or Agreement States license; or
- Under § 35.13(b)(4) the person is identified as an authorized nuclear pharmacist or authorized nuclear pharmacist on a permit issued by an NRC or Agreement States specific licensee of broad scope.

Section 35.13(c) currently requires a licensee to obtain a license amendment before it changes Radiation Safety Officer or teletherapy physicist.

The proposed rule in § 35.13(b) would require a licensee to obtain a license amendment before it permits anyone to work as an authorized nuclear pharmacist, authorized user, or authorized medical physicist, unless the individual meets specified exemption conditions described in paragraphs (b)(1) through (b)(5). The proposed rule would specify in §§ 35.13(b)(1) and 35.13(b)(2) the sections in the proposed rule pertaining to required training and experience for authorized nuclear pharmacists and authorized users. The proposed rule would add a new § 35.13(b)(3) pertaining to the training and experience requirements for authorized medical physicists, and would renumber paragraphs (b)(3) and (b)(4) as (b)(4) and (b)(5), respectively, and would add references to authorized medical physicists.

The proposed rule in § 35.13(c) would eliminate the requirement for a licensee to obtain a license amendment before it changes teletherapy physicists. The proposed rule would also amend § 35.13(e), which requires a licensee to obtain a license amendment before adding to or changing the areas of use. Specifically, § 35.13(e) of the proposed rule would provide an exemption for licensees to submit a license amendment for changes of area of use for medical uses permitted under for §§ 35.100 and 35.200.

Cost Impacts:

NRC anticipates cost savings to licensees and NRC from a reduction in the number of license amendments that would be submitted to NRC to add teletherapy physicists (changed to medical physicists) to a license and areas of use where byproduct material is used in accordance with §§ 35.100 and 35.200.

Assumptions:Licensees:

License amendment applications ² (20% of 221 licensees need to apply for 1 amendment/year): ³	44
Physician/management amendment preparation time, hours:	1
Physician/management hourly rate:	\$100
Technical staff hours to prepare amendment:	4
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$10,000
<u>NRC/Agreement States:</u> ⁴	
NRC/Agreement States amendment fee:	\$460
Total amendments:	44
Total Annual Cost Savings for NRC and Agreement States:	\$20,000
Total Annual Cost Savings from amendment to § 35.13(c):	\$30,000

NRC also anticipates cost savings to licensees and NRC or Agreement States from a reduction in the number of license amendments that would be submitted for changes in areas of use.

² The NRC license tracking system does not generate data on license amendments by type of action requested. In addition, one amendment application may include a request for several actions. The estimated number of amendment applications per year therefore may overstate the number of requests received. Estimates are based on discussions with NRC Regional Staff and State personnel on the regulatory working group.

³ The labor turnover rate in the U.S. economy averages approximately 20 percent, as of March 1998. This rate may overstate slightly the turnover rate for medical physicists.

⁴ NRC fees are based on schedule published in 62 FR 29198; May 29, 1997, for FY 1997. When NRC has established a fee for a particular action (e.g., review of a license application) that fee is used as the value of the NRC review time for that action. When no fee is established, a labor rate of \$70/hour is used for NRC labor costs. This rate represents a partially loaded blended rate of technical, clerical, and managerial staff. A labor rate of \$70/hour also is used for Agreement States labor costs. Agreement States charge a wide range of fees and have varying labor rates for administration of their radiation control programs. Comparison of Agreement States Radiation Control Programs, Texas Department of Health, Bureau of Radiation Control, January 1996, summarizes information from 29 States and New York City. The \$70 per hour labor rate was selected as a conservative value, after review of the 1996 report.

Assumptions:**Licensees:**

Total annual amendments for changes in areas of use:	28 ⁵
Physician amendment preparation time, hours:	1
Physician hourly rate:	\$100
Technical staff amendment preparation time, hours:	4
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$6,000

NRC/Agreement States:

Total annual amendments for changes in areas of use:	28 ⁵
NRC/Agreement States amendment fee:	\$460
Total Annual Cost Savings for NRC and Agreement States:	\$13,000
Total Annual Cost Savings for amendment to § 35.13(e):	\$19,000
Total Annual Cost Savings from changes to § 35.13:	\$49,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees, NRC, and Agreement States.

5.8 Notifications (§ 35.14).

Section 35.14(a) currently requires licensees to provide the Commission with a copy of the board certification for each individual who is allowed to work as an authorized user or an authorized nuclear pharmacist. Section 35.14(b)(1) requires the licensee to notify the Commission by letter when an authorized user, authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change.

The proposed rule would amend § 35.14(a) and (b)(1) to add authorized medical physicist to the list of persons about whom the licensee must notify the Commission while simultaneously deleting teletherapy physicist from the list. The proposed rule would add § 35.14(b)(3) to clarify the requirement concerning notice when the licensee's name changes; and would add § 35.14(b)(4) to require notification when the licensee has added to or changed the areas of use for medical uses permitted under §§ 35.100 and 35.200.

⁵ Assuming approximately 10-15% of 221 annual amendments involve changes in areas of use.

Cost Impacts:

NRC anticipates a small cost increase as a result of an increase in the number of notices that licensees would be required to submit. Of those licensees employing a medical physicist (estimated at about 221 licensees) about 20 percent are estimated to notify NRC or Agreement States agencies at least one additional time per year.

Assumptions:Licensees:

NRC/Agreement States licensee notifications pertaining to medical physicists:	44
Annual licensee notification, hours:	0.5
Technical staff hourly rate:	\$30
Total Annual Cost Increase for licensees:	\$660

NRC/Agreement States:

NRC/Agreement States licensee notifications:	44
NRC/Agreement States review time:	0.25
NRC/Agreement States hourly rate:	\$70
Total Annual Cost Increase for NRC and Agreement States:	\$770
Total Annual Increase from notification amendment in § 35.14:	\$1,500

NRC also anticipates a small cost increase as a result of requiring licensees to report changes in the area of use. However, NRC estimates only a small number of total annual applications will be due to changes in license area of use (12.5% of 221 annual license notifications).

Assumptions:Licensees:

Total annual notification of changes in licensee's areas of use:	28
Notification preparation time, hours:	0.5
Technical staff hourly rate:	\$30
Total Annual Cost Increase for licensees:	\$420

NRC/Agreement States:

Total annual notification of changes in licensee's areas of use:	28
NRC/Agreement States review time, hours:	0.25
NRC/Agreement States hourly rate:	\$70
Total Annual Cost Increase for NRC and Agreement States:	\$490

Total Annual Cost Increase from notification of changes in areas of use in § 35.14:	\$1000
Total Annual Cost Increase from changes to § 35.14:	\$2,500

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change with substitution of term "medical physicist" for "teletherapy physicist." Also, increased flexibility and reduced regulatory burden would be anticipated.

5.9 Exemptions regarding Type A specific licenses of broad scope (§ 35.15).

Section 35.15(d) currently exempts a licensee possessing a Type A specific license of broad scope for medical use from the provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

The proposed rule would amend § 35.15(d) to add authorized medical physicist to the list of exemptions from § 35.14(b)(1). This change would be made to reflect requirements contained in the proposed § 35.13.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.10 License issuance (§ 35.18).

Section 35.18 currently specifies the requirements for license issuance for use of byproduct material.

The proposed rule would add a new § 35.18(b) providing that the Commission would issue a license for mobile services if: (1) the applicant met the requirements specified in § 35.18(a), and (2) individuals or human research subjects administered byproduct material or radiation therefrom by the applicant may be released following treatment in accordance with § 35.75.

Cost Impacts:

No cost impacts are anticipated for licensees. The proposed rule would promulgate, as a regulatory requirement, a criterion that formerly was implemented through licensing.

Health and Safety Impacts:

None anticipated.

Benefits:

If the amendment leads to an increase in the availability of mobile services, patients could experience benefits as a result of lessened travel to reach medical care.

5.11 Specific exemptions (§ 35.19).

Section 35.19 currently provides that the Commission may grant exemptions from the 10 CFR Part 35 requirements and states that the Commission will review requests for exemptions from the training and experience requirements, with the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

The proposed rule would eliminate the reference to assistance from the ACMUI. NRC anticipates, however, that the Commission would continue to review such exemptions requests with the assistance of ACMUI.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

The current text regarding the ACMUI is a Commission policy position and is not a regulatory requirement. Therefore, this text would be removed for improved clarity.

SUBPART B--GENERAL ADMINISTRATIVE REQUIREMENTS

5.12 ALARA program (§ 35.20).

Section 35.20 currently requires that licensees develop and implement a written radiation protection program that includes provisions for keeping doses as low as reasonably achievable (ALARA) and specifies program content and participants.

The proposed rule would eliminate § 35.20 in its entirety.

Cost Impacts:

None anticipated. NRC considers the requirements of 10 CFR Part 20, particularly 10 CFR 20.2011, commensurate with the scope and extent of 10 CFR Part 35 ALARA requirements. Specifically, 10 CFR Part 20 requires licensees to develop, document, and implement a radiation protection program. This is comparable to 10 CFR Part 35 where licensees are required to develop an ALARA program for activities conducted under 10 CFR Part 35.

In the proposed rule, § 35.20 ALARA requirements would be unnecessary, given a performance-based approach, because ALARA is already required under 10 CFR 20.2011. However, no costs would be avoided in the proposed rule because licensees would still be required by 10 CFR Part 20 to keep doses as low as reasonably achievable.

Health and Safety Impacts:

None anticipated because 10 CFR Part 20 would continue to require an ALARA program.

Benefits:

Eliminates the prescriptive requirements in § 35.20 and provides licensees with greater flexibility regarding ALARA programs.

5.13 Radiation Safety Officer (§ 35.21).

Section 35.21 currently requires that each licensee appoint a Radiation Safety Officer (RSO).

Section 35.21(a) requires each licensee to appoint an RSO who will implement the radiation safety program. The licensee, through the RSO, ensures compliance with the radiation safety program.

Section 35.21(b) specifies the duties and responsibilities of the RSO.

The proposed rule would eliminate § 35.21 in its entirety and replace it in 10 CFR Part 35 with § 35.24, which addresses the authority and responsibilities for the radiation protection program, including specific requirements regarding the RSOs.

Cost Impacts:

Cost impacts are evaluated under § 35.24.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.21 because § 35.24 specifically addresses requirements regarding the RSO.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.14 Radiation Safety Committee (§ 35.22).

Section 35.22 currently requires that each medical institution licensee establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. Section 35.22(a) specifies the required membership of the RSC, meeting frequency, quorum, content of minutes, (kept for the duration of the license), review topics, and review frequency.

The proposed rule would eliminate § 35.22 in its entirety, and would replace it with a new § 35.24, which would address the authority and responsibilities for the radiation protection program, including a requirement (§ 35.24(b)) for coordination of the licensees radiation safety program.

Cost Impacts:

The elimination of § 35.22 would result in significant cost savings for licensees because of the deletion of the requirement to hold quarterly Radiation Safety Committee meetings.

Assumptions:

Licensees:

Total annual meetings (4 per license):	17,024
Percent licensees no longer holding quarterly/RSC meetings:	70
Annual avoided RSC meetings:	11,917
Preparation time and total meeting length, hours:	4
Combined staff hourly rate (medical, scientific, technical and managerial):	\$70
Total Annual Cost Savings from elimination of §35.22:	\$3,337,000

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.22 because § 35.24 incorporates requirements for coordination of the radiation safety program.

Benefits:

Significant cost savings to licensees as well as greater flexibility to licensees in coordinating radiation safety activities.

5.15 Statements of authority and responsibility (§ 35.23).

Section 35.23(a) currently requires that each licensee provide Radiation Safety Officers and Radiation Safety Committees sufficient authority to fulfill their duties and responsibilities. Section 35.23(b) requires the licensee to establish those authorities, duties, and responsibilities in writing and to retain the current edition as a record until the Commission terminates the license.

The proposed rule would eliminate § 35.23 in its entirety, and would replace it with a new section, § 35.24, which specifies requirements for the radiation protection program, including written authorities, duties, and responsibilities of the RSO (§ 35.24(d)).

Cost Impacts:

Cost impacts are evaluated under § 35.24.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.23, because § 35.24 incorporates requirements for written statements of authorities, duties, and responsibilities.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.16 Authority and responsibilities for the radiation protection program (§ 35.24).

The proposed rule would contain a new section, § 35.24, specifying authority and responsibility for the radiation protection program.

Section 35.24(a) would provide that in addition to the radiation protection program requirements of 10 CFR 20.2011, a licensee's management must approve: (1) requests for license application, renewal, or amendment prior to submittal; (2) any individual, prior to allowing that individual to work as an RSO, authorized user, authorized nuclear pharmacist, or authorized medical physicist;

and (3) radiation protection program changes that do not require a license amendment and are permitted under § 35.26.

Section 35.24(b) would establish a new requirement for licensees with multiple modalities or multiple users. Such licensees must develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

Section 35.24(c) would require licensee's of management to appoint an RSO who is responsible for implementing the radiation protection program. The licensee, through the RSO, would ensure that the licensee's radiation safety activities are being performed in accordance with the licensee-approved procedures and regulatory requirements. (Addressed by §§ 35.21 and 35.23 of the current rule.)

Section 35.24(d) would require licensees to establish in writing the authority, duty, and responsibilities of the RSO. (Addressed by § 35.23 of the current rule.)

Section 35.24(e) would require licensees to provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to fulfill their duties to identify radiation safety problems; initiate, recommend, or provide corrective actions; stop unsafe operations; and verify implementation of corrective actions. (Addressed by § 35.23 of the current rule.)

Section 35.24(f) would require recordkeeping under paragraphs (a) and (d) in accordance with new § 35.2024.

Cost Impacts:

No cost impacts are anticipated from § 35.24(a), because licensees would continue to be allowed to make changes to their radiation protection program, as previously allowed by § 35.31.

Cost savings are anticipated from § 35.24(b) because the proposed rule would allow licensees greater flexibility in the implementation of radiation protection programs and eliminate the prescriptive requirements for Radiation Safety Committees contained in § 35.22 of the current rule. "Multiple users," for purposes of § 35.24(b), would encompass medical institutions and private practice facilities with more than one physician. NRC anticipates that under § 35.24(b) most private practice facilities using byproduct materials would be required to develop, document, and implement administrative procedures for coordination of the licensee's radiation protection program. Therefore, a greater number of licensees may need to implement coordination procedures. However, those procedures could be as simple as using electronic mail or teleconferencing. Also, licensees could utilize existing in-house committees (e.g., Safety Committees or Risk Assessment Committees) for coordination of radiation safety matters. Therefore, the cost of coordination activities is expected to decline substantially.

Based on these assumptions, NRC estimates that about 30 percent of medical institutions would use electronic mail, teleconferencing, or existing in-house committees as a means of coordination to satisfy § 35.24(b), substituting these procedures for the currently required Radiation Safety Committee meetings. The costs associated with § 35.24(b) are estimated as follows:

Assumptions:

Licensees:

Total licensee annual meetings:	1,277
Persons responsible for coordination:	3
Time required per meeting or meeting equivalents (e.g., exchanges of electronic mail):	2 hours
Combined staff hourly rate (medical, scientific, technical):	\$70
Total Annual Cost Increase from amendment to § 35.24:	\$536,000

No cost impacts are anticipated from the new §§ 35.24(c), (d), and (e), because they continue to specify duties and responsibilities of Radiation Safety Officers equivalent to those formerly specified under § 35.21.

Health and Safety Impacts:

No health or safety impacts are anticipated because licensees would continue to develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

No health and safety impacts are anticipated from the new §§ 35.24(c), (d), and (e) because they would continue to specify duties and responsibilities of Radiation Safety Officers equivalent to those formerly specified under § 35.21.

Benefits:

Provides greater flexibility to licensees.

5.17 Radiation protection program changes (§ 35.26).

Section 35.31(a) currently allow licensees to make minor changes to their radiation safety procedures that do not impact safety, and lists examples of such changes. Section 35.31(b) requires records of such changes to be kept until the license is renewed or terminated, and specifies that changes must be signed by the Radiation Safety Officer, the affected authorized user(s), and the licensee's management. In addition, in medical institutions the chairman of the Radiation Safety Committee also must sign.

The proposed rule would renumber § 35.31 as § 35.26 and would make the following changes:

Section 35.26(a) would continue to allow licensees to revise their radiation protection program without Commission approval, provided the changes: (1) do not require an amendment under § 35.13; (2) do not reduce radiation protection; (3) have been reviewed and approved by the RSO and licensee management; and (4) affected individuals are instructed on the revised program before the changes are implemented. Also, § 35.26(a) would eliminate the examples of ministerial changes previously listed in § 35.31(a).

Section 35.26(b) requires records of each change in accordance with § 35.2026.

Cost Impacts:

On balance, cost savings would be anticipated from the proposed rule.

Assumptions:

Licensees:

Total licensees:	6,662
Net reduction in time, hours:	0.08
Technical staff hourly rate:	\$30
Total Annual Cost Savings from § 35.26:	\$16,000

Health and Safety Impacts:

No health and safety impacts are anticipated from the changes to § 35.26.

Benefits:

Cost savings to licensees.

5.18 Supervision (§ 35.27).

Section 35.25(a) currently requires that each licensee permitting an individual to use byproduct material under the supervision of an authorized user must instruct the supervised individual in radiation safety and periodically review the supervised individual's use of byproduct material and records kept to reflect that use.

Section 35.25(b) currently requires that each licensee permitting preparation of byproduct material for medical use under the supervision of an authorized user, or authorized nuclear pharmacist or a physician who is an authorized user, must instruct the supervised individual in preparation of the material for medical use and in radiation safety and periodically review the supervised individual's use of byproduct material.

The proposed rule would renumber § 35.25 as § 35.27 and would make the following changes:

Section 35.27(a) would amend the requirement that the licensee instruct supervised individuals. It would require the instruction on the licensee's written radiation protection procedures requiring a written directive, 10 CFR Part 35 regulations, and license conditions with respect to the use of byproduct material and would add a requirement that the supervised individual follow the instructions of the supervising authorized user and written radiation protection procedures. The proposed rule would eliminate the requirement to periodically review the supervised individual's use of byproduct material and records.

Section 35.27(b) would continue to require the licensee to instruct supervised individuals in the preparation of byproduct material for medical use. The proposed rule would eliminate the requirement to periodically review the individual's work as it pertains to preparing byproduct material for medical use and records kept to reflect that work.

Section 35.27(c) would be added to require all licensees to establish a policy for all supervised individuals to request clarification, as needed, from the authorized user or authorized nuclear pharmacist about the instructions and requirements provided to the supervised individual in accordance with paragraphs (a) and (b) of this section.

Cost Impacts:

Increased costs are anticipated by requiring licensees to instruct the supervised individual on § 35.27(a)(1) procedures.

Assumptions:

Licensees:

Total NRC/Agreement States licensees:	6,662
Authorized user instruction time, hours:	1
Authorized user hourly rate:	\$100
Total Annual Cost Increase for § 35.27(a)(1):	\$666,000

Increased costs are anticipated by requiring licensees to instruct the supervised individual on § 35.27(b)(1) byproduct material preparation.

Assumptions:

Licensees:

Total NRC/Agreement State licensees:	6,662
Authorized user instruction time, hours:	1
Authorized user hourly rate:	\$100
Total Annual Cost Increase for § 35.27(b)(1):	\$666,000

Decreased costs are anticipated by § 35.27(b) no longer requiring licensees to conduct periodic reviews of supervised individuals' work and records.

Assumptions:

Licensees:

Total NRC/Agreement States licensees:	6,662
Authorized user periodic review time (quarterly reviews), hours:	4
Authorized user hourly rate:	\$100
Total Annual Cost Savings for § 35.27(b):	\$2,665,000

Increased costs are anticipated by requiring licensees to establish a new policy in § 35.27(c). At a minimum, one-half hour of an authorized user's time would be necessary to establish the required policy.

Assumptions:

Licensees:

Total NRC/Agreement States licensees:	6,662
Authorized user policy preparation time, hours:	0.5
Authorized user hourly rate:	\$100
Total Annual Cost Increase for § 35.27(c):	\$333,000
Total Annual Cost Savings for § 35.27(c):	\$1,000,000

Health and Safety Impacts:

Increased radiation safety.

Benefits:

Increased flexibility for licensees.

5.19 Administrative requirements that apply to the provision of mobile nuclear medicine service (§ 35.29).

Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine service licensees.

The proposed rule would eliminate § 35.29 in its entirety, and would replace it with requirements in proposed §§ 35.18(b) and 35.80.

Cost Impacts:

Cost impacts are addressed under §§ 35.18(b) and 35.80 of the proposed rule.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.29 because administrative requirements for mobile nuclear medicine services continue to be addressed under the proposed §§ 35.18(b) and 35.80.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.20 Quality Management Program (§ 35.32).

Section 35.32 currently requires that each licensee establish a written quality management program (QMP).

Section 35.32(a) requires that the quality management program must include procedures for preparing written directives for teletherapy, gamma stereotactic radiosurgery, brachytherapy, administrations of I-125 or I-131 in quantities greater than 30 microcuries, and therapeutic administrations of a radiopharmaceutical other than I-125 or I-131; verifying the patient's identity by more than one method; and ensuring that each administration is in accordance with the written directive.

Section 35.32(b) requires that the licensee must develop procedures for and conduct a review of the quality management program at least annually;

Section 35.32(c) requires evaluation and response to every recordable event;

Section 35.32(d) provides for retention of specified records.

The proposed rule would eliminate § 35.32 in its entirety. The proposed regulations in §§ 35.40 and 35.41 would establish requirements for written directives and procedures to be followed for administrations requiring a written directive. This change would result in significant cost saving to medical use licensees as compared to the current § 35.32.

Cost Impacts:

Cost savings are realized from the elimination of §§ 35.32(b) and (c).

Section 35.32(b) of the current rule requires licensees to develop procedures and to annually review and modify the Quality Management Program as necessary. These changes were required to be sent to NRC and Agreement State agencies where they were reviewed and accepted, or reviewed and returned for further changes. Elimination of § 35.32(b) is expected to result in cost savings for licensees and for NRC and Agreement States.

Assumptions:

Licensees:

Total affected licensees:	4,309
Time to develop procedures, hours	2
Hours for annual licensee QMP review/recordkeeping:	12
Authorized user hourly rate:	\$100
Total Annual Cost Savings for licensees:	\$6,033,000

NRC/Agreement States:

NRC/Agreement States review of each licensee's QMP review:	8
NRC/Agreement States staff hourly rate:	\$70
Total Annual Cost Savings to NRC and Agreement States:	\$2,413,000

Each applicable licensee was required by § 35.32(c) to evaluate and respond to each recordable event, including retaining records of the event for three years. The analysis assumes that each of the four types of recordable events occurs 20 times annually (from among all applicable licensees). For these 80 annual events, technical staff were able to address the provisions of § 35.32(c).

Assumptions:

Licensees:

Annual number of reportable events:	80
Licensee response time, hours:	2
Technical staff hourly rate:	\$30
Total Annual Cost Savings to licensees:	\$4,800
Total Annual Cost Savings from elimination of § 35.32 for licensees and NRC and Agreement States:	\$8,451,000

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.32 because § 35.40 retains requirements for written directives and § 35.41 retains requirements for procedures requiring a written directive.

Benefits:

Cost savings to licensees.

5.21 Notifications, reports, and records of misadministrations (§ 35.33).

Section 35.33 currently requires that each licensee notify NRC by phone, within one day, when a misadministration occurs; submit a written report to NRC; notify the referring physician and also notify the individual receiving the misadministration, unless the referring physician personally informs the licensee that he will inform the individual or that, based on medical judgment, telling

the individual would be harmful. Section 35.33 requires records of misadministrations to be retained for five years.

The proposed rule would eliminate § 35.33 in its entirety. Requirements for reporting "medical events" would be established by the proposed rule under § 35.3045.

Cost Impacts:

Costs impacts are evaluated under § 35.3045.

Health and Safety Impacts:

No health and safety impacts are anticipated from elimination of § 35.32 because § 35.40 retains requirements for written preparation of directives and § 35.3045 maintains reporting requirements.

Benefits:

Conforming change to restructuring of 10 CFR Part 35 to be more performance based.

5.22 Written directives (§ 35.40).

The proposed rule would add a new § 35.40(a) providing that a written directive must be prepared, dated, and signed by the authorized user prior to administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from byproduct material. Section 35.40(b) would specify the information that the written directive must contain. Section 35.40(c) would specify that the licensee must retain the written directive in accordance with new § 35.2040.

Cost Impacts:

No costs are either avoided or increased for licensees, Agreement States, or NRC because § 35.40 essentially retains the requirements in the current § 35.32(a) regarding written directives.

Health and Safety Impacts:

None anticipated.

Benefits:

Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program, while maintaining an adequate level of health and safety.

5.23 Procedures for administrations requiring a written directive (§ 35.41).

The proposed rule would add a new § 35.41. Section 35.41(a) would provide that for any administration requiring a written directive, the licensee must develop, maintain, and implement written procedures to provide high confidence that prior to each administration the patient's identity is verified and that each administration is in accordance with the written directive. Section 35.41(b) would specify procedures' contents include: (1) verifying the identity of the patient or human research subject; (2) verifying that the specific details of the administration are in accordance with the written directive and treatment plan; (3) checking both manual and computer-generated dose calculations; and (4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by § 35.600.

Cost Impacts:

No costs are either avoided or increased for licensees, Agreement States, or NRC because § 35.41 essentially retains the requirements in the current § 35.32(a) for written directives.

Health and Safety:

None anticipated.

Benefits:

Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program (i.e., flexibility in program management), while maintaining an adequate level of health and safety.

5.24 Training for Radiation Safety Officer (§ 35.50).

The current rule in § 35.900 specifies the training requirements for a Radiation Safety Officer.

Section 35.900(a) lists nine specialist boards through which an individual may become certified to be an RSO.

Alternatively, § 35.900(b) specifies training and experience requirements that may be met in lieu of certification by one of the nine listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires one year of full time supervised clinical experience.

Alternatively, § 35.900(c) allows an individual to fulfill the responsibilities of a Radiation Safety Officer if the individual is an authorized nuclear pharmacist identified on the licensee's license.

The proposed rule would renumber § 35.900 as § 35.50 and would make the following changes:

Section 35.50(a) would eliminate the specific list of nine approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.50(b)(1) would continue to require 200 hours of didactic training and one year of full time supervised practical training, and would add a description of specific subjects that must be covered in the practical training.

Section 35.50(b)(2) would add a requirement that the individual must obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the training has been completed.

Section 35.50(b)(3) would add a new requirement that following completion of the didactic and practical training, the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

Section 35.50(c) would be amended to provide that in addition to an authorized user, an authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license may be an RSO, and would also add a requirement that the individual have experience in similar types of use of byproduct materials for which they would have RSO responsibility.

Cost Impacts:

The cost impacts associated with this section would involve additional costs to NRC for approval of certifying specialty boards, and to licensees and individuals seeking to be an RSO.

NRC would incur costs for certifying specialty boards for purposes of § 35.50(a). NRC estimates that approval by NRC of specialty boards for certification would require 240 hours per board and that NRC will be required to review 5 boards for approval.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	5
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for § 35.50(a):	\$84,000

Licensees and preceptors would incur costs associated with securing a preceptor's certification for purposes of § 35.50(b)(2).

Assumptions:

Licensees:

Number of candidates:	19
Cost of preceptor certification:	¼ hour at \$20 hour for candidate ⁶ plus ¼ hour at \$100/hour for preceptor
Total Cost Increase for § 35.50(b)(2):	\$570

NRC will incur costs for certifying for purposes of § 35.50(b)(3). NRC estimates that approval by NRC of an organization(s) to prepare and administer the examination will require 240 hours per organization and that NRC will be required to review 5 organizations for approval.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	5
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase to certify boards for § 35.50(b)(3):	\$84,000

NRC estimates that approximately 190 physicians will seek to become Radiation Safety Officers under § 35.50 annually. Of these, 90 percent, or 171, will seek certification by a certifying board under § 35.50(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 19 physicians, will seek to become authorized users under § 35.50(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to licensees associated with taking an examination for purposes of § 35.50(b)(3) are estimated below.

Assumptions:

Licensees:

Registration cost:	\$600 per examination
Time to take an exam:	3 hours at \$20/hour
Number of examinations taken per year:	19
Total Cost Increase for § 35.50(b)(3) examinations:	\$13,000
Total Cost Increase for § 35.50:	\$182,000

Health and Safety Impacts:

None anticipated.

⁶ Candidate's time measured at \$20 per hour based on a resident physician's estimated annual salary of \$30,000 to \$40,000.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.25 Training for authorized medical physicist (§ 35.51).

The current rule in § 35.961 specifies the training requirements for a teletherapy physicist.

Section 35.961(a) and (b) each list one specialist board through which an individual may become certified.

Alternatively, § 35.961(c) specifies training and experience requirements that may be met in lieu of certification by one of the listed speciality boards. It currently requires holding a master's degree in one of four areas. In addition, one year of full time training in therapeutic radiological physics followed by one year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes performing specified tasks is required.

The proposed rule would renumber § 35.961 as § 35.51, would change "teletherapy physicist" to "authorized medical physicist," and would make the following additional changes:

Section 35.51(a) would eliminate the list of two approved speciality boards and would provide instead that the individual must be certified by a specialty board approved by the Commission.

Section 35.51(b)(1) would add medical physics to the list of degrees. Section 35.51(b)(1) continues to require one year of full time training in therapeutic radiological physics followed by one year of full time work experience but adds to the list of specified tasks that must be performed under supervision of a medical physicist.

Section 35.51(b)(2) would add a requirement that the candidate medical physicist must obtain written certification, signed by a preceptor authorized medical physicist, that the training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist.

Section 35.51(b)(3) would add a requirement that following completion of the requirements in (b)(1) and (b)(2), the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

Cost Impacts:

The cost impacts associated with this section involve additional costs to NRC to approve certifying specialty boards, and to the individuals seeking to become an authorized medical physicist for the cost of an examination.

NRC estimates that approval by NRC of specialty boards for certification for purposes of § 35.51(a) will require 240 hours per board and that NRC will be required to review 5 boards for approval. The costs to NRC for certifying specialty boards are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	5
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for § 35.51(a):	\$84,000

The costs to licensees and preceptors associated with securing a preceptor's certification for purposes of § 35.51(b)(2) are estimated below.

Assumptions:

Licensees:

Number of candidates:	19
Cost of preceptor certification:	¼ hour at \$20/hour for candidate plus ¼ hour at \$100/hour for preceptor
Total Cost Increase for § 35.51(b)(2):	\$570

NRC estimates that approval by NRC of an organization(s) to prepare and administer the examination for purposes of § 35.51(b)(3) will require 240 hours per organization and that NRC will be required to review 5 organizations for approval.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	5
NRC review time:	240 hours/board at \$70/hour
Total Cost Increase to certify boards for § 35.51(b)(3):	\$84,000

NRC estimates that approximately 190 physicists will seek to become authorized medical physicists under § 35.51 annually. Of these, 90 percent, or 171, will seek certification by a certifying board under § 35.51(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 19 physicists, will seek to become authorized medical physicists under § 35.51(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to licensees associated with taking an examination for purposes of § 35.51(b)(3) are estimated below.

Assumptions:

Licensees:

Registration cost:	\$700 per examination
Time to take an exam:	3 hours at \$20/hour
Number of examinations taken per year:	19
Total Cost Increase for § 35.51(b)(3):	\$14,000
Total Cost Increase for § 35.51:	\$183,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.26 Training for an authorized nuclear pharmacist (§ 35.55).

The current rule in § 35.980 specifies the training requirements for an authorized nuclear pharmacist.

Section 35.980(a) lists one specialist board through which an individual may become certified to perform these procedures.

Alternatively, § 35.980(b)(1) specifies training and experience requirements that may be met in lieu of certification by the listed speciality board. It currently requires 700 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised experience in specified tasks.

Section 35.980(b)(2) requires that the candidate pharmacist must obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the training has been completed.

The proposed rule would renumber § 35.980 as § 35.55 and make the following changes:

Section 35.55(a) would eliminate the listing of a specifically approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.55(b)(1) would continue to require 700 hours of classroom and laboratory training in specified subjects and supervised practical experience in performing specified tasks.

Section 35.55(b)(2) would continue to require that the candidate pharmacist must obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the training has been completed.

Section 35.55(b)(3) would add a new requirement that following completion of the didactic training and supervised practical experience detailed in § 35.55(b)(1), the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

Cost Impacts:

The cost impacts associated with this section involve additional costs to NRC for approve certifying specialty boards, and to the individuals seeking to be an authorized nuclear pharmacist for the cost of an examination. NRC will incur costs for certifying specialty boards for purposes of § 35.55(a). NRC estimates that approval by NRC of specialty boards for certification will require 240 hours per board and that NRC will be required to review 2 boards for approval.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	2
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for § 35.55(a):	\$34,000

NRC will incur costs for certifying organization(s) for purposes of § 35.55(b)(3). NRC estimates that approval by NRC of an organization(s) to prepare and administer the examination will require 240 hours per organization and that NRC will be required to review 2 organizations for approval.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	2
NRC review time:	240 hours/board at \$70/hour
Total cost to certify examining organizations for § 35.55(b)(3):	\$34,000

NRC estimates that approximately 50 pharmacists will seek to become authorized nuclear pharmacists under § 35.55 annually. Of these, 90 percent, or 45, will seek certification by a certifying board under § 35.55(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 5 pharmacists, will seek

to become authorized nuclear pharmacists under § 35.55(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to licensees associated with taking an examination for purposes of § 35.55(b)(3) are estimated below.

Assumptions:

<u>Licensees:</u>	
Registration cost:	\$600 per examination
Time to take an exam:	3 hours at \$20/hour
Number of examinations taken per year:	5
Total Cost Increase for § 35.55(b)(3) examinations:	\$3,000
Total Cost Increase for § 35.55:	\$71,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.27 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (§ 35.57).

Three sections of the current rule, §§ 35.901, 35.970, and 35.981, specify the training requirements for experienced Radiation Safety Officers, experienced authorized users, and experienced nuclear pharmacists.

The current rule in § 35.901 provides that an individual identified as a Radiation Safety Officer on Commission or Agreement States license before October 1, 1986, need not comply with § 35.900.

The current rule in § 35.970 provides that physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on Commission or Agreement States licenses before April 1, 1987, performing only those tasks they were originally licensed for, need not comply with the training requirements and Subpart J.

The current rule in § 35.981 requires licensees to apply for and receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before the individual can begin work as an authorized nuclear pharmacist. It allows pharmacists who completed a structured educational program, as specified in § 35.980(b)(1) before December 2, 1994, to qualify as an

“experienced nuclear pharmacist” and need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) or recentness of training (§ 35.972).

The proposed rule would renumber and merge §§ 35.901, 35.970, and 35.981 as § 35.57 and would make the following changes:

Section 35.57(a) would provide that a Radiation Safety Officer, teletherapy physicist, or medical physicist identified on an NRC or Agreement State license before a specified date is not required to comply with training requirements of § 35.50 and 35.51. It changes training and experience citations to account for the renumbered Radiation Safety Officer section (§ 35.900 instead of § 35.50) and to add teletherapy and medical physicists (§ 35.51).

Section 35.57(b) would eliminate the April 1, 1987, threshold date associated with physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material for a date to be later specified. It would also change the training and experience citation from Subpart J to include Subparts C through H.

Section 35.57(c) would eliminate the December 2, 1994, threshold date associated with “experienced nuclear pharmacists” for a date to be later specified. It would change the regulatory citations defining a structured educational program from § 35.980(b)(1) to § 35.55(b)(1); the preceptor statement requirement from § 35.980(b)(2) to § 35.55(b)(2); and the recentness of training from § 35.972 to § 35.59.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.28 Recentness of training (§ 35.59).

The current rule in § 35.972 specifies that the training and experience required under 10 CFR Part 35 must have been obtained within the seven years preceding the application date or been met by continuing education and experience.

The proposed rule would renumber § 35.972 as § 35.59 and would substitute references to the appropriate sections of Subparts B and D through H of the proposed rule for the citations to the training and experience requirements in the current rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

SUBPART C--GENERAL TECHNICAL REQUIREMENTS

5.29 Possession, use, calibration, and check of instruments to measure activity of photon-emitting radionuclides (§ 35.60).

Section 35.50 of the current rule requires licensees to possess a dose calibrator and to check each dose calibrator for accuracy, constancy, linearity, and geometric dependence. It specifies when such tests must occur, and how they are to be performed.

The proposed rule would renumber § 35.50 as § 35.60. Section 35.60(a) would require licensees to possess and use, for other than unit dosages, instrumentation to measure the activity of photon-emitting radionuclides. Section 35.60(b) would replace existing testing specifications with requirements that if the licensee uses instrumentation to measure the activity of dosages, including unit dosages it must develop, maintain, and implement written procedures for use of the instrumentation. Section 35.60(b) also would require that tests be performed on each instrument, before initial use and following repair, for accuracy, linearity, and geometry dependence. In addition, accuracy tests would be performed annually, and each instrument would be checked at the beginning of each day of use for constancy and proper operation. Section 35.60(c) would specify accuracy test sources. Section 35.60(d) would require that licensees mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 0.37 MBq (10 μ Ci) and shall repair or replace the instrumentation if the accuracy or constancy error exceeds 10 percent. Section 35.60 would require a record of each check and test be retained in accordance with § 35.2060.

Cost Impacts:

Cost savings are anticipated with the proposed changes to § 35.60(b) that reduce linearity testing from being performed quarterly to annually.

Assumptions:

Licensees:

Total licensees:	5,900
Reduced annual linearity testing, hours:	3
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$31,000

NRC anticipates a cost increase for licensees due to this developing procedures required by § 35.60(b).

Assumptions:

Licensees:

Total licensees:	5,900
Preparation of written procedures, hours:	1
Technical staff hourly rate:	\$30

Total Annual Cost Increases for licensees:	\$177,000
Total Cost Savings from changes to § 35.60:	\$354,000

Health and Safety Impacts:

No health and safety impacts are anticipated from this amendment, if the activities of unit dosages prepared by a licensed manufacturer or commercial nuclear pharmacy are correctly measured prior to delivery to the licensee, who subsequently can calculate activity by a decay correction, as provided under § 35.63 of the proposed rule.

Benefits:

Cost savings to licensees who use only unit doses and cost savings to all licensees from reduction in requirements for linearity testing.

5.30 Calibration and check of survey instruments (§ 35.61).

Section 35.51 currently requires licensees to calibrate each survey instrument before first use, annually, and following repair. The current rule also requires the licensee to check each survey instrument for proper operation with a dedicated check source each day of use.

The proposed rule would renumber § 35.51 as § 35.61 and would make the following changes:

The proposed rule would add a reference to § 35.61(a) requiring licensees to calibrate survey instruments used to show compliance with 10 CFR Part 35 and with 10 CFR Part 20 before first use, annually, and following repair.

The proposed § 35.61(a) would specify licensee's calibration methods and would require the calibration date to be conspicuously noted on the instrument.

Section 35.61(b) would define a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent. The proposed § 35.61(b) would require a correction chart or graph be conspicuously attached to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent.

Section 35.61(c) would require licensees to remove from use those survey instruments where the indicated exposure rate differs from the calculated exposure rate by more than 20 percent.

The proposed rule would eliminate the requirement that the survey instrument be checked for proper operation with a dedicated check source each day of use. Section 35.61(d) would amend the rule to place recordkeeping requirements in § 35.2061.

Cost Impacts:

Cost savings are anticipated for NRC licensees from the elimination of daily checks with a dedicated check source.

Assumptions:Licensees:

Total licensees:	6,662
Annual days survey instruments checked:	260
Time to test survey instruments daily, hours:	0.003
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$156,000

Health and Safety Impacts:

Licensees will have greater flexibility for determining that instruments are working properly, accurately, and consistently over time, but may continue to use check sources of use. Under 10 CFR 20.1501(b) licensees would continue to be required to ensure that instruments and equipment are calibrated periodically.

5.31 Possession, use, calibration, and check of instruments to measure dosages of alpha- and beta-emitting radionuclides (§ 35.62).

Section 35.52 currently requires that each licensee possess instruments to measure the radioactivity of alpha- and beta-emitting radionuclides that are not unit dosages.

The proposed rule would renumber § 35.52 as § 35.62. Section 35.52(a) in the current rule would be eliminated and § 35.52(b) would be renumbered as § 35.62(a). Section 35.62(a) of the proposed rule would require for other than unit dosages, licensees to possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides by using direct measurement or by combination of measurements and calculations prior to administration to each patient or human research subject.

Section 35.62(b) would require licensees to develop, maintain and implement written procedures for the use of instrumentation.

Section 35.62(c) would specify that licensees use sources either traceable to NIST or from a supplier who has compared the source to a source that was calibrated by NIST when performing accuracy tests.

Section 35.62(d) would require licensees to retain a record of each check and test required by this section in accordance with § 35.2060.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change for restructuring of 10 CFR Part 35.

5.32 Measurement of dosages of unsealed byproduct material for medical use (§ 35.63)

Section 35.53 currently requires that licensees measure the activity of dosages of unsealed byproduct material for medical use. It requires activity of dosages of a photon-emitting radionuclide to be measured, and activity of dosages of alpha- and beta- emitting radionuclides to be measured by direct measurement or a combination of measurements and calculations. Results are required to be kept for three years and § 35.53 includes requirements for the contents of these records.

The proposed rule would renumber § 35.53 as § 35.63. Section 35.63(a) would require licensees to determine and record the activity prior to medical use. Section 35.63(b) would provide that units dosages of alpha-, beta-, or photon-emitting radionuclides may be measured by direct measurement or by a decay correction, based on the measurement made by the manufacturer or preparer. Section 35.63(c) would require that dosages of alpha- or beta-emitting radionuclides prepared by the licensee must be measured by direct measurement or by a combination of measurements and calculations. Section 35.63(d) would specify that doses that differ from the prescribed dose by 20 percent or more may not be used. Section 35.63(e) would provide that records must be retained in accordance with new § 35.2063.

NRC anticipates that licensees using only unit dosages will gain added flexibility under § 35.63 to rely on decay correction rather than direct measurement to measure dosages. If those licensees who use only unit doses have no other need for a dose calibrator, they will not be required to obtain or replace dose calibrators for measurement of dosages.

Cost Impacts:

The time necessary to perform a decay correction to determine the dosage of a unit dose that is not measured directly is not significant different from the time necessary to remeasure a unit dose in a dose calibrator. Cost savings would result only for licensees who use only unit dosages from not having to possess, use, and maintain a dose calibrators. However, most licensees are expected to retain possession of existing dose calibrators for use if needed.

Health and Safety Impacts:

No health and safety impacts are anticipated from the changes to § 35.63 because unit dosages will be measured by the manufacturer or commercial nuclear pharmacy.

Benefits:

Cost savings to licensees who use only unit dosages and would not possess a dose calibrator.

5.33 Authorization for calibration and reference sources (§ 35.65).

Section 35.57 currently allows each authorized licensee to receive, possess, and use byproduct material for check, calibration, and reference use, including byproduct material with a half-life not longer than 100 days.

The proposed rule would renumber § 35.57 as § 35.65 and would allow any person authorized by § 35.11 for medical use of byproduct material to receive, possess, and use byproduct material for check, calibration, and reference use as specified in §§ 35.65(a), (b), and (c).

Section 35.65(a) would increase the maximum sealed source dose from 0.555 MBq (15 mCi) to 1.11 MBq (30 mCi).

Sections 35.65(b) would increase the maximum allowable half-life of byproduct material to 120 days for individual amounts that would not exceed 0.555 MBq (15mCi) in § 35.65(b).

Section 35.65(c) would increase the maximum allowable half-life of byproduct material to 120 days in individual amounts not to exceed 7.4 MBq (200 μ i) each and not to exceed 10E-3 times the quantities in Appendix B of 10 CFR Part 30, whichever is more limiting.

Section 35.65(d) would provide that technicium-99m may be received, possessed, and used in amounts "as needed," rather than in amounts not to exceed 50 millicuries, as provided in the current rule.

Cost Impacts:

Cost savings are anticipated with the proposed changes to § 35.65, formerly § 35.57. Licensees will not need to obtain license amendments to obtain higher activity check sources. NRC estimates that up to 151 amendments per year will be avoided.

Assumptions:

Licensees:

Total NRC/Agreement States amendments avoided (estimated):	151
Technical staff preparation time, hours:	1
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$5,000
<u>NRC/Agreement States:</u>	
NRC/Agreement States amendments avoided:	151
NRC amendment fee:	\$460
Total Annual Cost Savings for NRC and Agreement States:	\$69,000
Total Annual Cost Savings from § 35.65:	\$74,000

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.34 Requirements for possession of sealed sources and brachytherapy sources (§ 35.67).

Section 35.59 currently requires each licensee in possession of sealed or brachytherapy sources to follow the radiation safety and handling instructions supplied by the manufacturer as well as leak test requirements specified in § 35.59.

The proposed rule would renumber § 35.59 as § 35.67. Section 35.67(a) would require licensees to follow the radiation safety and handling instructions supplied by manufacturers when in possess of any sealed or brachytherapy source. This section would also require licensees to maintain the instructions in a legible form convenient to users for the duration of source use.

Section 35.67(b) would specify licensee testing intervals for sealed sources. Section 35.67(c) would require that to satisfy leak test requirements licensees must measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 μ Ci) of radioactive material on the sample.

Section 35.67(d) would require licensees to retain leakage test records in accordance with § 35.2067.

Section 35.67(e) would specify licensee actions, including withdrawal of the source from use and storage, disposal, or repair in accordance with 10 CFR Parts 20 and 30 and filing of a report in accordance with § 35.3067 when leakage tests indicate the presence of 185 Bq (0.005 μ Ci) or more of radioactive contamination.

Section 35.67(f) would allow licensees to not perform leakage tests on certain specified sources.

Section 35.67(g) would require licensees in possession of sealed or brachytherapy sources, except for gamma stereotactic radiosurgery sources, to conduct a semi-annual physical inventory of all such sources in their possession. This section would require the inventory records from each licensee to be retained in accordance with § 35.2067.

The proposed rule also would eliminate in their entirety paragraphs §§ 35.59(h) and (i) in the current rule, which require quarterly measurement of ambient dose rates in areas where sealed sources or brachytherapy sources are stored, and retention of records of such surveys. Surveys would continue to be required to be performed to demonstrate compliance with 10 CFR Part 20.

Cost Impacts:

Cost savings, from reduction in frequency of required source inventory from quarterly to semiannually.

Assumptions:

Licensees:

Total affected licensees:	1,885
Reduction in frequency of required source inventory, hours:	1
Technical staff hourly rate:	\$30
Total Annual Cost Savings for § 35.67:	\$57,000

Health and Safety Impacts:

None anticipated. The source inventory requirements of § 35.67(g) of the proposed rule, the requirements of 10 CFR 20.1501(a)(2)(iii), as well as the occupational dose and ALARA requirements of 10 CFR Part 20, adequately address ambient dose rate measurements in areas where sealed sources are stored.

Benefits:

Increased flexibility for licensees.

5.35 Labeling and shielding of vials and syringes (§ 35.69).

Section 35.60 currently requires that licensees keep syringes containing byproduct material conspicuously labeled and in a radiation shield that is also conspicuously labeled. Use of a syringe radiation shield is required when preparing and administering the radiopharmaceutical.

Section 35.61 currently requires that licensees preparing or handling vials containing byproduct material keep them conspicuously labeled and in a vial radiation shield that is also conspicuously labeled.

The proposed rule would delete §§ 35.60 and 35.61 and would replace them with a new § 35.69. Section 35.69(a) would not retain specific requirements for the use of syringe radiation shields or shielding of vials. The proposed rule would substitute a new requirement that licensees develop, maintain and implement procedures for labeling vials, syringes, syringe shields, and vial shields that contain a radiopharmaceutical to ensure that the contents are conspicuously identified as containing radioactive materials. Section 35.69(b) would require licensees to instruct individuals, commensurate with the individual's assigned duties, in the procedures required by paragraph § 35.69(a) of this section.

Cost Impacts:

Incremental costs are anticipated for licensees to develop the required procedures and to instruct individuals in those procedures. Labeling under the proposed rule is expected to require approximately the same time as under the current rule.

Assumptions:

Licensees:

Total licensees:	5,974
Time to prepare procedure, hours:	1
Technical staff training time:	0.5
Trainer per licensee:	1
Trainees per licensee:	8
Technical staff hourly rate:	\$30
Total Annual Cost Increase for § 35.69:	\$986,000

Health and Safety Impacts:

None anticipated. Increased dose to the hands and/or eyes of technologists could result, in the absence of syringe radiation shields. However, NRC believes 10 CFR Part 35 licensees would continue to provide, and technologists would continue to use, radiation syringe shields for administering intravenous diagnostic dosages of byproduct material, based on the ALARA requirements of 10 CFR Part 20.

Benefits:

Increased flexibility for licensees.

5.36 Surveys for contamination and ambient radiation exposure rate (§ 35.70).

Section 35.70(a) and (b) currently require that licensees survey daily and weekly with a radiation detection survey instrument all areas where radiopharmaceuticals are routinely prepared or administered. Section 35.70(e) requires licenses to survey for removable contamination weekly all areas where radiopharmaceuticals, or their waste, are stored.

Section 35.70(a) of the proposed rule would require surveys with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered.

Section 35.70(b) would require licensees to retain a record of each survey in accordance with § 35.2070.

The proposed rule also would eliminate in their entirety paragraphs § 35.70(b)-(g) in the current rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

No health or safety impact is anticipated from this amendment. NRC assumes most 10 CFR Part 35 licensees would continue to carry out weekly surveys as part of their radiation protection program.

Benefits:

Increased flexibility for licensees.

5.37 Release of individuals containing radiopharmaceuticals or implants (§ 35.75).

Section 35.75 currently requires the following:

- (a) The licensees may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
- (b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses

to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were not interruption of breast-feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast-feeding and
 - (2) Information on the consequences of failure to follow the guidance.
- (c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:
- (1) Using the retained activity rather than the activity administered,
 - (2) Using an occupancy factor less than 0.25 at 1 meter,
 - (3) Using the biological or effective half-life, or
 - (4) Considering the shielding by tissue.
- (d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

The proposed rule would retain § 35.75 and would provide that records of the release of individuals containing radiopharmaceuticals or implants are to be maintained in accordance with § 35.2075(a) and (b). Section 35.75 also would make the following changes in the proposed rule: (1) eliminated "permanent" from the section title and in the text; (2) added "parent or guardian" to § 35.75(b); and (3) added "potential" and "if any" to § 35.75(b)(2).

Cost Impacts:

No incremental costs or cost savings are anticipated with § 35.75 for licensees, Agreement States, or NRC.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.38 Provision of mobile service (§ 35.80).

Section 35.80 currently provides technical requirements for mobile nuclear medicine service.

The proposed rule would make the following changes to § 35.80:

Sections 35.80(a), (b) and (c) of the current rule would be eliminated.

Section 35.80(a) of the proposed rule would include a requirement moved from the former § 35.29(b) that licensees providing mobile nuclear medicine services must obtain a letter from each client's management permitting and agreeing to the services, including a discussion of each entity's responsibilities, and keep such letters for three years after the service is rendered.

Section 35.80(b) would prohibit mobile nuclear medicine service from having by product material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material. This section would require that radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

Section 35.80(d) in the current rule would be renumbered as § 35.80(c) in the proposed rule, and would reference the sections of the proposed rule that provide for checking of instruments before use.

Section 35.80(c) would add a new requirement to check instruments as described in §§ 35.60 and 35.62 with a dedicated source prior to use at each address of use.

Section 35.80(d) would require licensees to check survey instruments for proper operation with a dedicated check source before use at each address of use.

Section 35.80(e) would eliminate the requirement that each vehicle carry a radiation detection survey meter. The section would continue to require that all areas of use at the client address be surveyed, to ensure compliance with the requirements in 10 CFR Part 20.

Section 35.80(f) would provide that the letter required in paragraph § 35.80(a) would be retained and a record of each survey be retained in accordance with the requirements of new § 35.2080.

Cost Impacts:

Licensees may be required to incur costs to obtain a dedicated check source, although in many cases such sources will be supplied with the survey instruments. Licensees also may already possess check sources, because the current rule requires instruments to be checked for proper operation. Therefore, minimal cost impacts (i.e., <\$1,000) are expected.

Health and Safety Impacts:

Elimination of the requirements currently in §§ 35.80(1)(a) through (c) is not expected to result in impacts to health or safety, because licensees will be required to comply with 10 CFR 20.1801 and 20.1802.

Benefits:

Increased safety.

5.39 Storage of volatiles and gases (§ 35.90).

Section 35.90 currently requires that licensees store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container and store multi-dose containers in a fume hood after drawing the first dosage from it.

The proposed rule would eliminate § 35.90 in its entirety.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated. Section 10 CFR 20.1701 currently requires licensees to use, to the extent practical, process or other engineering controls, such as containment or ventilation, to control the concentration of radioactive material in air, and 10 CFR 20.1702 requires use of other controls, if necessary, to control concentrations to values below those that define an airborne radioactivity area. Elimination of § 35.90 would provide licensees with flexibility to determine the most effective method of storage. NRC anticipates that in general licensees would continue to store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container and to store multi-dose containers in a fume hood.

Benefits:

Increased flexibility for licensees.

5.40 Decay-in-storage (§ 35.92).

Section 35.92 currently allows licensees to hold byproduct material with a physical half-life of less than 65 days and dispose of it in ordinary trash, provided it follows specified handling procedures.

The proposed rule in § 35.92(a) would increase the maximum allowable half-life for byproduct material that may be held for decay in storage from 65 days to 120 days and would eliminate a requirement that byproduct material must be held for decay in storage a minimum of ten half-lives. Section 35.92(a) also would eliminate the requirement to separate and monitor each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

Section 35.92(b) would require licensees to retain a record of each disposal permitted under paragraph § 35.92(a) in accordance with § 35.2092.

Cost Impacts:

Costs are expected to be avoided by the amendment to § 35.92(a) as a result of a reduced number of requests for license amendments to allow an exemption for 120 day half-life for holding material for a minimum of 10 half-lives. Numerous licensees have already obtained such amendments, although the precise number is not available. Therefore, relatively few are expected to be avoided annually in the future.

Assumptions:**Licensees:**

Total annual amendments avoided:	17
Technical staff preparation time, hours:	1
Technical staff hourly rate:	\$30
Total Annual Cost Savings for licensees:	\$500

NRC/Agreement States:

NRC/Agreement States amendment review time, hours:	0.5
NRC/Agreement States staff hourly rate:	\$70
Total Annual Cost Savings for NRC or Agreement States:	\$600
Total Annual Cost Savings for § 35.92:	\$1,000

Health and Safety Impacts:

None anticipated because licensees would continue to monitor waste to ensure it has decayed to background radiation levels before disposal.

Benefits:

Increased flexibility for licensees and reduced number of license amendments.

SUBPART D--UNSEALED BYPRODUCT MATERIAL - LOW DOSE

5.41 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (§ 35.100).

The current rule in § 35.100 permits a licensee to use for uptake, dilution, or excretion studies any unsealed byproduct material that is obtained from a manufacturer licensed by NRC or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized nuclear pharmacist and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

The proposed rule would amend § 35.100 to specify that a licensee may use any unsealed byproduct material, except in quantities that require a written directive pursuant to § 35.40 for uptake, dilution, and excretion studies.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

Increases health and safety. The proposed revision would increase radiation safety by requiring physicians to meet the qualification requirements in the proposed § 35.390 if the physician desires to perform uptake, dilution, or excretion studies requiring a written directive.

Benefits:

Increased radiation safety. The proposed amendment would require physicians, authorized only under § 35.290, desiring to perform uptake, dilution, and excretion studies requiring a written direction (higher risk procedure), to obtain training and experience (i.e., § 35.390) commensurate with the risk of the procedure.

5.42 Possession of survey instrument (§ 35.120).

The current rule in § 35.120 requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The proposed rule would eliminate § 35.120 in its entirety.

Cost Impacts:

None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.43 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200).

The current rule in § 35.200 permits a licensee to use for imaging and localization studies any unsealed byproduct material that is obtained from a manufacturer licensed by NRC or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized nuclear pharmacist and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

The proposed rule would amend § 35.200 by limiting the use of unsealed byproduct material for imaging and localization studies to medical uses that do not require a written directive pursuant to § 35.40.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

Increased health and safety. The proposed rule would increase radiation safety by requiring physicians, authorized under § 35.292 who desire to perform imaging and localization studies requiring a written directive (higher risk procedures) to meet training and experience requirements in § 35.390.

Benefits:

Increased health and safety.

5.44 Permissible molybdenum-99 concentration (§ 35.204).

Section 35.204(a) of the current rule prohibits licensees from administering to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. Section 35.204(b) requires licensees using molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical to measure the molybdenum-99 concentration of each eluate or extract.

The proposed rule in § 35.204(b) would require that instead of each eluate, a licensee must measure the molybdenum-99 concentration of the first eluate from a generator to demonstrate compliance with § 35.204(a). Licensees are required to retain records of each measurement in accordance with the requirements specified in § 35.2204.

Cost Impacts:

Cost savings are anticipated from elimination of the requirement that licensees must measure the molybdenum-99 concentration of each eluate or extract.

NRC assumes that 674 NRC licensees and 1,685 Agreement States licensees use molybdenum-99/technetium-99m generators. Under the proposed rule, sale or transfer of a generator will require the new owner or user to measure the concentration of the first eluate. Assuming that generators are replaced weekly, this amendment is expected to reduce the frequency of measurements from approximately one per day to about one per week.

Assumptions:

Licensees:

Number of licensees:	2,359
Number of avoided eluate tests per licensee:	200
Time required to measure concentration of eluate, hours:	0.08
Technical staff hourly rate:	\$30
Total Annual Cost Savings for amendment to § 35.204:	\$1,132,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees.

5.45 Control of aerosols and gases (§ 35.205).

The current rule in § 35.205(a) requires licensees to administer radioactive aerosols or gases in a room with a system that will keep airborne concentrations below the limits prescribed by 10 CFR 20.1201 and 20.1301. Section 35.205(c) requires that before receiving, using, or storing a gas, a licensee must calculate the amount of time needed after a spill to reduce the concentration to the limits specified in 10 CFR 20.1201, and § 35.205(d) requires the licensee to make a record of the calculations required by Paragraph (c) and retain that record for the duration of the use of the area.

The proposed rule would eliminate § 35.205 in its entirety.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated. Licensees would continue to meet the requirements for occupational dose limits for adults and dose limits for individual members of the public, as specified in 10 CFR 20.1201 and 20.1301 respectively.

Benefits:

Regulatory flexibility for licensees.

5.46 Possession of survey instruments (§ 35.220).

The current rule in § 35.200 requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The proposed rule would eliminate § 35.200 in its entirety.

Cost Impacts:

None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.47 Training for uptake, dilution, and excretion studies (§ 35.290).

The current rule in § 35.910 specifies the training requirements for an authorized user of a radiopharmaceutical for uptake, dilution, and excretion studies.

Section 35.910(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.910(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 40 hours of classroom and laboratory training in specified subjects. In addition, it requires 20 hours of supervised clinical experience.

Alternatively, § 35.910(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The proposed rule, § 35.290, would provide the following:

Section 35.290(a) would eliminate the specific list of five approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.290(b)(1) would retain the required 40 hours of didactic training except for changing "radiopharmaceutical chemistry" to "chemistry of byproduct material for medical use" in the proposed § 35.290(b)(1)(i)(D). The proposed changes in § 35.290 would essentially eliminate most of the supervised "clinical" experience, including: (1) deletion of § 35.910(b)(2)(i) "Examining patients or human research subjects...; (2) deletion of part of § 35.910(b)(2)(ii) (i.e., radiopharmaceuticals)" but retain calculation and measuring dosages in the proposed § 35.290(b)(ii)(c); (3) deletion of part of § 35.910(b)(2)(iii) (i.e., "... and using syringe shields") but retain "Administering dosages to patients or human research subjects" in the proposed § 35.290(b)(ii)(F); (4) deletion of § 35.910(b)(iv), "Collaborating with ..."; and (5) deletion of § 35.910(b)(v), "Patient or human research subject followup." The proposed rule would require 20 hours of "supervised practical experience," to include the items which were not deleted from "supervised clinical experience" (i.e., calculating and measuring dosages and administering dosages to patients or human research subjects). In addition, "supervised practical experience" also would include the following: (1) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (2) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; (3) using administrative controls to prevent a medical event involving the use of byproduct material; and (4) using procedures to contain spilled byproduct material safely and using proper decontamination procedures. The NRC is proposing this change to focus the training and experience requirements in § 35.290 on radiation safety.

Section 35.290(b)(2) would add a requirement that the licensee must obtain written certification, signed by a preceptor authorized user, that the requirements in § 35.290(b)(1) have been satisfactorily completed and that the individual has

achieved a level of competency sufficient to independently function as an authorized user of a diagnostic radiopharmaceutical for the uses listed in § 35.100.

Section 35.290(b)(3) would add a requirement that following completion of the didactic and practical training, the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

The proposed rule would eliminate the alternative of completing a six-month program approved by the Accreditation Council for Graduate Medical Education.

Cost Impacts:

NRC anticipates incremental costs associated with this section involving additional costs to NRC for certifying specialty boards and providers of examinations, and to the authorized user for the cost of obtaining preceptor certifications and of taking an examination.

Because both § 35.910(a) and § 35.920(a) contain identical lists of certifying organizations, NRC assumes that one review of each organization will satisfy the requirements of § 35.290(a) and § 35.292(a). Assuming that one additional organization would seek approval, NRC has divided the burden associated with approval of certifying organizations equally between § 35.290(a) and § 35.292(a). The same assumption is followed for § 35.290(b)(3) and § 35.292(b)(3), which requires NRC to review and approve organizations which will administer examinations to candidates.

The costs to NRC for certifying specialty boards for purposes of § 35.290(a) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for § 35.290(a):	\$50,000

The costs to NRC for certifying examining organizations for purposes of § 35.290(b)(3) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for certifying examining organizations for § 35.290(b)(3):	\$50,000

NRC estimates that approximately 110 physicians will seek to become authorized users under § 35.290 annually. Of these, 90 percent, or 99 physicians, will seek certification by a certifying board under § 35.290(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under § 35.290(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to licensees associated with securing a preceptor's certification for purposes of § 35.290(b)(2) are estimated on the basis of 10 percent of candidates seeking authorization through § 35.290(b).

Assumptions:

Licensees:

Number of candidates:	11
Cost of preceptor certification (½ hour of authorized user's time and ½ hour of candidate's time):	\$60
Total Cost Increase for § 35.290(b)(2):	\$1,000

The costs to licensees associated with taking an examination for purposes of § 35.290(b)(3) are estimated on the basis of 10 percent of candidates seeking authorization through § 35.290(b)(3) rather than through the board certification covered by § 35.290(a).

Assumptions:

Licensees:

Registration cost:	\$600 per examination
Time to take an exam:	2 hours at \$20/hour
Number of examinations taken per year:	11
Total Cost Increase for taking examinations for § 35.290(b)(3):	\$7,000
Total Cost Increase for § 35.290:	\$108,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.48 Training for imaging and localization studies (§ 35.292).

The current rule in § 35.920 specifies the training requirements for an authorized user of radiopharmaceuticals and generators for imaging and localization studies.

Section 35.920(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.920(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. The regulations currently require 200 hours of classroom and laboratory work training (§ 35.920(b)(i)); 500 hours of supervised work experience (§ 35.920(b)(2)); and 500 hours of supervised clinical experience (§ 35.920(b)(3)).

Alternatively, § 35.920(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The proposed rule in § 35.292 would provide the following:

Section 35.292(a) would eliminate the specific list of five approved speciality boards, and would provide instead that the certification of the speciality board must be approved by the Commission.

Section 35.292(b)(1) would reduce the required hours of training and experience from 1,200 hours to 120 hours. The proposed rule, in § 35.292(b)(1)(i) reduces the number of classroom and laboratory training (proposed as didactic training) from 200 hours to 80 hours; in § 35.292(b)(1)(ii) reduces the number of "supervised work experience" of "supervised practical experience") from 500 hours to 40 hours and essentially eliminates 500 hours of "supervised clinical experience." The NRC is proposing this change to focus the training and experience requirements in § 35.292 on radiation safety.

Section 35.292(b)(2) would add a requirement that the licensee must obtain written certification, signed by a preceptor authorized user, that the training has been completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of diagnostic radiopharmaceuticals and generators for imaging and localization studies.

Section 35.292(b)(3) would add a requirement that following completion of the didactic and practical training, the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

The proposed rule would eliminate the alternative of completing a six-month training program approved by the Accreditation Council for Graduate Medical Education.

Cost Impacts:

Cost savings are associated with the proposed rule due to the reduction in required training hours. NRC assumes that the reduction in required hours would not be reflected in the educational process of the certifying boards. NRC expects that 90 percent of physicians seeking approval for medical use for imaging and localization studies would obtain certification through a certification board, as specified by § 35.292(a). Ten percent of the candidates are expected to seek to qualify under § 35.292(b). Additional costs to NRC and to authorized users are associated with the certification of specialty boards and the costs of taking an exam.

Because both § 35.910(a) and § 35.920(a) contain identical lists of certifying organizations, NRC assumes that one review of each organization would satisfy the requirements of § 35.290(a) and § 35.292(a). Assuming that one additional organization will seek approval, NRC has divided the burden associated with approval of certifying organizations equally between § 35.290(a) and § 35.292(a). The same assumption is followed for § 35.290(b)(3) and § 35.292(b)(3), which requires NRC to review and approve organizations which would administer examinations to candidates.

The costs to NRC for certifying specialty boards for purposes of § 35.292(a) are estimated below.

Assumptions:NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours/board at \$70 per hour
Total Cost Increase for § 35.292(a):	\$50,000

NRC estimates that approximately 110 physicians will seek to become authorized users under § 35.292 annually. Of these, 90 percent, or 99, will seek certification by a certifying board under § 35.292(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under § 35.292(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to licensees associated with securing a preceptor's certification for purposes of § 35.292(b)(2) are estimated on the basis of 10 percent of candidates seeking authorization through § 35.292(b):

Assumptions:Licensees:

Number of candidates:	11
Cost of preceptor certification (½ hour of authorized user's time and ½ hour of candidate's time):	\$60
Total Cost Increase for § 35.292(b)(2):	\$1,000

The cost to licensees associated with taking an examination for purposes of § 35.292(b)(3) are estimated on the basis of 10 percent of candidates seeking authorization through § 35.292(b)(3) rather than through the board certification covered by § 35.292(a).

Assumptions:

Licensees:

Registration cost:	\$600 per examination
Time to take an exam:	3 hours at \$20/hour
Number of examinations taken per year:	11
Total Cost Increase for examinations for § 35.290(b)(3):	\$7,000

Cost savings due to the reduction in training hours required in §§ 35.292(b)(1)(i) and (ii) are estimated below.

Assumptions:

Licensees:

Number of candidates seeking certification through § 35.290(b):	11
Training hours required under current rule:	1,200 at \$20/hour
Training hours required under proposed rule:	120 at \$20/hour
Total Cost Savings from changes to §§ 35.292(b)(1)(i) and (ii):	\$240,000
Total Cost Savings of § 35.292:	\$298,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.49 Physician training in a three month program.

Section 35.971 of the current rule provides that a physician who began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education before July 1, 1984, and successfully completed the program was not required to comply with the requirements of §§ 35.910 or 35.920.

The proposed rule would delete § 35.971 in its entirety.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

None anticipated.

SUBPART E--UNSEALED BYPRODUCT MATERIAL - HIGH DOSE**5.50 Use of unsealed byproduct material for which a written directive is required (§ 35.300).**

The current rule in § 35.300 provides that a licensee may use unsealed byproduct material for therapeutic administration that is either obtained from a manufacturer licensed by NRC or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

The proposed rule would revise § 35.300 to indicate that it applies to any medical use of unsealed byproduct material requiring a written directive. The proposed rule also would change the reference to the regulatory requirements for authorized nuclear pharmacists (§ 35.292) and the reference to the regulatory requirements for supervision (§ 35.27).

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

Provides clarification that any medical use (e.g., diagnostic or therapeutic) would be included under this subpart if a written directive is required.

5.51 Safety Instruction (§ 35.310).

Section 35.310(a) of the current rule requires safety instruction for all personnel caring for the patient or human research subject receiving radiopharmaceutical therapy and hospitalized under § 35.75. Instruction is required in the following areas: (1) patient or human research subject control; (2) visitor control; (3) contamination control; (4) waste control; and (5) notification of the Radiation Safety Officer in case of patient death or medical emergency. Section 35.310(b) requires that the licensee retain records of individual receiving instruction for three years.

The proposed rule would add a provision specifying that the requirements of § 35.310 are in addition to the worker instruction requirements of 10 CFR 19.12. Section 35.310(a) also would provide that radiation safety instruction must be given initially and at least annually to personnel caring for patients or human research subjects that have received radiopharmaceutical therapy and cannot be released in accordance with § 35.75. Section 35.310(a) also would specify that such training must be commensurate with the duties of the personnel and what such training

would include. Section 35.310(b) of the proposed rule would require records of persons receiving instruction to be retained in accordance with § 35.2310.

Cost Impacts:

No cost impacts anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased radiation safety.

5.52 Safety Precautions (§ 35.315).

Section 35.315(a) currently specifies safety precautions that licensees must take for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75.

Section 35.315(a)(1) requires a private room with a private sanitary facility.

Section 35.315(a)(2) requires posting a "Radioactive Materials" sign on the patient's door and indicating on the door or in the patient's chart how long visitors may stay in the room.

Section 35.315(a)(3) authorizes visits by individuals under age 18 on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer.

Section 35.315(a)(4) requires the licensee to measure dose rates in contiguous areas after administration of the dosage and retain for three years a record of each survey demonstrating compliance with 10 CFR Part 20.

Section 35.315(a)(5) requires the licensee to monitor items removed from the patient's room to determine that their radioactivity is not greater than background radioactivity.

Section 35.315(a)(6) is reserved.

Section 35.315(a)(7) requires the licensee to survey the patient's room for removable contamination prior to assigning another patient the same room.

Section 35.315(a)(8) requires the licensee to measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 and retain a record of each measurement.

Section 35.315(b) requires a licensee to notify the Radiation Safety Officer if the patient has a medical emergency or dies.

The proposed rule would make the following changes to § 35.315:

Section 35.315(a) would specify licensee actions for each patient or human research subject that cannot be released in accordance with § 35.75.

Section 35.315(a)(2) would require the patient's or the human research subject's room be posted with a "Radioactive Materials" sign rather than on the door, as in the current rule.

Sections 35.315(a)(3) and 35.315(a)(4) in the current rule would be eliminated in their entirety.

Section 35.315(a)(5) in the current rule would be renumbered as § 35.315(a)(3) in the proposed rule.

Sections 35.315(a)(6), (a)(7) and (a)(8) in the current rule would be eliminated in their entirety.

Section 35.315(b) would clarify that licensees shall notify the authorized user and the Radiation Safety Officer, or his designee, as soon as possible if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

Cost Impacts:

None anticipated. Licensees will continue to be required to comply with 10 CFR Part 20.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.53 Possession of survey instruments (§ 35.320).

The current rule in § 35.320 requires each licensee to have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The proposed rule would eliminate § 35.320 in its entirety.

Cost Impacts:

None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.54 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive (§ 35.390).

The current rule in § 35.930 specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I-131 for treatment of thyroid carcinoma in 3 individuals.

The proposed rule would renumber § 35.930 as § 35.390 and would make the following changes:

Section 35.390(a) would eliminate the specific list of four approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.390(b)(1) would continue to require 80 hours of didactic training (formerly classroom and laboratory training). Section 35.390(b)(1)(ii) would require adding an additional 40 hours of "supervised practical experience."

Section 35.390(b)(2) would replace the current §§ 35.930(b)(2). Section 35.390(b)(2) would require that the individual has had experience, obtained under the direct supervision of an authorized user, involving at least five cases for each procedure with radiation safety hazards similar to that use for which the individual is requesting authorized user status.

Section 35.390(b)(3) would add a requirement that the licensee must obtain written certification, signed by a preceptor authorized user, that the training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct materials for the uses listed in § 35.300.

Section 35.390(b)(4) would add a requirement that following completion of the structured education program required in § 35.390(b)(1) and the experience requirement in § 35.390(b)(2), the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

Cost Impacts:

NRC anticipates incremental costs associated with this section involving additional costs to NRC for certifying specialty boards and providers of examinations, and to the physician seeking authorized user status for uses described in § 35.300, for the cost of obtaining an additional 40 hours of supervised practical experience, preceptor certifications, and of taking an examination.

The costs to NRC for certifying specialty boards for purposes of § 35.390(a) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	2
NRC review time:	240 hours/board at \$70/hour
Total Cost Increase for § 35.390(a)(1):	\$34,000

The costs to NRC for certifying examiners for purposes of § 35.390(b)(4) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	2
NRC review time:	240 hours/board at \$70/hour

Total Cost Increase for certifying examining groups for § 35.390(b)(3):	\$34,000
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NRC estimates that approximately 1,290 physicians will seek to become authorized users under § 35.390 annually. Of these, 90 percent, or 1,161, will seek certification by a certifying board under § 35.390(a). Additional cost impacts would be created for them under the proposed rule as a result of an increase of 40 hours of training required.

Cost Impacts:

Cost increases are anticipated from proposed requirements in § 35.390(b)(1)(ii) that would require physicians seeking certification to take an additional 40 hours of training to become an authorized user.

Assumptions:

Licensees:

Total licensees:	1,161
Number of additional hours of training required:	40
Authorized user candidate hourly rate:	\$20
Total Annual Cost Increase from additional training requirements for § 35.390(a):	\$929,000

NRC estimates that the remainder, or approximately 129 physicians, will seek to become authorized users under § 35.390(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to candidates associated with taking an examination for purposes of § 35.390(b)(4) are estimated on the basis of 10 percent of candidates seeking to become authorized through § 35.390(b) rather than through board certification under § 35.390(a).

The costs to licensees associated with securing a preceptor's certification for purposes of § 35.390(b)(2) are estimated below.

Assumptions:

Licensees:

Number of candidates:	129
Cost of preceptor certification (½ hour of preceptor's time at \$100/hour plus ½ hour of candidate's time at \$20/hour):	\$60
Total Cost Increase for § 35.390(b)(2):	\$8,000

Assumptions:

Licensees:

Registration cost:	\$600 per examination
Time to take an exam:	3 hours at \$20/hour

Number of examinations taken per year:	129
Total Cost Increase to candidates for § 35.390(b)(3):	\$85,000
Total Cost Increase for § 35.390:	\$1,113,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

SUBPART F--MANUAL BRACHYTHERAPY**5.55 Use of sources for brachytherapy (§ 35.400)**

Section 35.400 currently requires a licensee to use specified sources for brachytherapy in accordance with the manufacturer's radiation safety and handling instructions. Section 35.400 approves the use of seven sealed sources for brachytherapy and specifies how they may be used (e.g., topically, interstitially).

The proposed rule would amend § 35.400 to eliminate the listing of permissible sealed sources and therapeutic use specifications and would replace them with the provision that a licensee may use any brachytherapy source in any therapeutic manner as approved in the Sealed Source and Device Registry (SSDR).

Cost Impacts:

Cost savings are associated with this section in the proposed rule. Use of a brachytherapy source or employment of a brachytherapy therapeutic treatment method not listed in § 35.400 currently requires a license amendment. The proposed rule would eliminate the need for a licensee to obtain a license amendment to use a source or therapeutic method not listed in § 35.400.

The NRC anticipates cost savings with the changes to § 35.400 in the proposed rule. No longer requiring licensees to submit license amendments if they want to use a source or therapeutic method not listed in § 35.400 would reduce both licensee costs and NRC and Agreement States costs.

Assumptions:**Licensees:**

Total licensees seeking amendments (10 NRC and 25 Agreement States licensees):	35
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	\$30
Total Annual Cost Savings to licensees:	\$2,000

NRC/Agreement States:

Total license amendment submittals (10 NRC and 25 Agreement States licensees):	35
NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	\$70
Total Annual Cost Savings to NRC and Agreement States:	\$2,000
Total Annual Cost Savings from changes to § 35.400:	\$4,000

Health and Safety Impacts:

Physicians would have a wider range of therapeutic options and the methods in which the sealed sources can be used will increase. Use of new or revised techniques would no longer require a rule amendment or license, if the manufacturer updates the SSDR.

Benefits:

Improved licensee flexibility due to the elimination of license amendments.

5.56 Radiation surveys (§ 35.404).

Section 35.404(a) currently specifies that immediately after implanting a brachytherapy source the licensee must make a radiation survey of the patient or human research subject and area of use to confirm that no source has been misplaced. The licensee must record each survey.

Section 35.404(b) currently specifies that immediately after removing the last temporary brachytherapy source the licensee must make a radiation survey of the patient or human research subject to confirm that all sources have been removed. The licensee must record each survey. A patient treated with temporary implants cannot be released from medical care confinement until all temporary sources have been removed.

The proposed rule in § 35.404(a) would require a radiation survey of the patient or research subject and the area of use immediately after implanting sources in a patient or the human research subject. The proposed rule in § 35.404(b) would eliminate the requirement that patients with temporary implants cannot be released until all implants have been removed. In the proposed rule, all requirements regarding the release of patients with temporary implants would be contained in § 35.75. Section 35.404(c) would require licensees to retain a record of patient or human research subject surveys in accordance with § 35.2404.

Cost Impacts:

Currently, a license amendment is required to allow for the release of patients with temporary implants from hospital confinement. The NRC anticipates cost savings for both licensees and NRC and Agreement States with the changes to § 35.404 in the proposed rule. These cost savings would result from no longer requiring the submission of license amendments to allow the release of patients with temporary implants.

Assumptions:Licensees:

Total licensees seeking amendments (10 NRC and 25 Agreement States licensees):	35
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	\$30
Total Annual Cost Savings to licensees:	\$2,000

NRC and Agreement States:

Total license amendment submittals (10 NRC and 25 Agreement States licensees):	35
NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	\$70
Total Annual Cost Savings to NRC and Agreement States:	\$2,000
Total Annual Cost Savings from changes to § 35.404:	\$4,000

Health and Safety Impacts:

None anticipated.

Benefits:

Reduced regulatory burden due to the elimination of license amendments.

5.57 Brachytherapy source inventory (§ 35.406).

Section 35.406(b) currently requires a licensee to return brachytherapy sources to the storage area promptly after removal and to count the number of sealed sources to ensure all sources taken from the storage area have been returned. Sections 35.406(b)(1) to 35.406(b)(3) describe the specific records that must be kept concerning the use of the source. Section 35.406(c) requires a radiation survey of the patient and area of use immediately following a source implantation and § 35.406(d) mandates that these inventory and survey records must be kept for three years.

The proposed rule in § 35.406(b) would eliminate the requirement for a count of sources returned to the storage area. The proposed rule would eliminate detailed specifications for the source inventory and survey requirements found in § 35.406(b) and §§ 35.406(b)(1) to 35.406(d) of the current rule. The proposed rule would remove the requirement for a radiation survey immediately following a source implant from § 35.406(c) and moves it to § 35.404(a).

Section 35.406(a) of the proposed rule would require licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.406(b) of the proposed rule would require licensees to promptly return brachytherapy sources to a secure storage area, once removed from a patient or a human research subject.

Section 35.406(c) would require that licensees make a record of brachytherapy source accountability in accordance with § 35.2406.

Cost Impacts:

None anticipated. Licensees would continue to be required to maintain accountability for each brachytherapy source.

Health and Safety Impacts:

None anticipated. Licensees would continue to be required to maintain records so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

Benefits:

Improved flexibility for licensees.

5.58 Safety instruction (§ 35.410).

Section 35.410 currently requires that radiation safety instruction be given to all personnel caring for patients or human research subjects undergoing implant therapy and confined pursuant to § 35.75. Sections 35.410(a)(1) to 35.410(a)(5) specify the subjects that must be covered in the instruction. Section 35.410(b) requires that records of individuals receiving instruction must be retained for three years.

The proposed rule would amend § 35.410(a) to specify that radiation safety instruction must be provided to all personnel caring for patients undergoing implant therapy and to require that the instruction be given "initially and at least annually." The instruction must be "commensurate with the duties of the personnel." Section 35.410(a)(1)-(5) would specify the topics for instruction. Section 35.410(b) would be amended to eliminate instructions for record retention and would instead require that licensees retain a record of radiation safety instruction in accordance with the new § 35.2310.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased radiation safety.

5.59 Safety precautions (§ 35.415)

Currently, § 35.415(a)(1) requires that implant patients confined to medical care may not be quartered with other hospital patients not receiving radiation therapy. Section 35.415(a)(2) stipulates that a sign warning the public of the presence of radioactive material must be posted on an implant patient's door along with patient visiting instructions. Section 35.415(a)(3) requires that requests by minors to visit implant patients must be reviewed on a case-by-case basis by the authorized user in consultation with the RSO. Radiation surveys immediately following the implantation of a brachytherapy source to demonstrate compliance with 10 CFR Part 20 are required by § 35.415(a)(4) and instructions regarding the notification of the RSO and authorized nuclear pharmacist immediately upon patient death or patient medical emergency are required by § 35.415(b).

The proposed rule would eliminate §§ 35.415(a)(1), 35.415(a)(3), and 35.415(a)(4). Section 35.415(b) of the proposed rule would require licensees to have available, near each treatment room, emergency response equipment. This section of the proposed rule also would specify what equipment would be necessary for licensees to be in compliance. In the proposed rule, § 35.415(c) would provide that the authorized user and RSO, or his designee, be notified by the licensee, as soon as possible, if the patient or human research subject has a medical emergency and immediately if the patient dies.

Cost Impacts:

None anticipated.

Health and Safety:

Safety would be enhanced by assuring that both the authorized nuclear pharmacist and the RSO must be notified.

Benefits:

Enhanced safety and increased flexibility for licensees.

5.60 Possession of survey instrument (§ 35.420)

The current rule in § 35.420 requires each licensee to have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The proposed rule would eliminate § 35.420 in its entirety.

Cost Impacts:

None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated because licensees would continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.61 Full calibration measurements of brachytherapy sources (§ 35.432)

Section 35.432(a) would require licensees to perform full calibration measurements on all brachytherapy sources before their first medical use. Sections 35.432(b) to 35.432(e) would specify the brachytherapy source calibration measurements that are required by the proposed rule. Section 35.432(f) would require that records of these calibration measurements be retained by licensees in accordance with § 35.2432.

The proposed rule would not allow the licensee to rely on the output measurement provided by the manufacturer or distributor. NRC assumes that the majority of licensees using long-lived radionuclides would need to calibrate these sources. Each such licensee is estimated to spend approximately \$1,000 annually to calibrate these sources.

Because of the limited information available on the number of short-lived sealed therapy sources (e.g., iodine-125, iridium-192) and variability in the type of dosimetry equipment available at licensees' facilities to perform the calibration, no cost is estimated for calibration of short-lived sealed therapy sources.

Cost Impacts:

Cost increases are anticipated from proposed requirements in § 35.432 that would require licensees using long-lived radionuclides to calibrate their sources.

Assumptions:Licensees:

Total licensees:	3,812
Annual source calibration cost:	\$1,000
Total Annual Cost Increase for licensees from § 35.432:	\$3,812,000

Health and Safety Impacts:

Enhanced safety. A required calibration measurement of brachytherapy sealed sources is expected to help ensure that the sealed source dose that is administered matches the prescribed dose.

Benefits:

Enhanced safety.

5.62 Training for use of brachytherapy sources (§ 35.490).

The current rule in § 35.940 specifies the training requirements for an authorized user of brachytherapy sources.

Section 35.940(a) lists four specialist boards through which an individual may become certified to become an authorized user of brachytherapy sources.

Section 35.940(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. Finally, the current rule also requires 3 years of supervised clinical experience to include: (1) examining individuals and reviewing their case histories to determine their suitability for manual brachytherapy treatment, and any limitations or contradictions; (2) selecting the proper manual brachytherapy sources and dose and method of administration; (3) calculating the dose; and (4) post-administration follow up and review of case histories in collaboration with the authorized user.

The proposed rule would make the following changes:

Section 35.490(a) would eliminate the specific list of four approved speciality boards, and would provide instead that the licensee shall require the authorized user to be a physician certified by a specialty board whose certification must be approved by the Commission.

Section 35.490(b)(1) would continue to require 200 hours of didactic training and 500 hours of supervised practical experience, and would add a description of specific subjects that must be covered in the practical training.

The proposed rule would add radiation experience requirements as § 35.490(b)(2) in the proposed rule.

Section 35.490(b)(3) would add a requirement that the licensee must obtain written certification, signed by a preceptor authorized user, that the requirements in §§ (b)(1) and (b)(2) have been completed.

Section 35.490(b)(4) would add a requirement that following completion of the didactic and practical training contained in §35.490(b)(1), the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission.

Cost Impacts:

The cost impacts of the proposed rule would apply to both NRC and licensees.

The costs to NRC for certifying specialty boards for purposes of § 35.490(a) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours per board at \$70 per hour
Total Cost Increase for § 35.490(a):	\$50,000

The costs to NRC for certifying examination boards for purposes of § 35.490(b)(4) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours per board at \$70 per hour
Total Cost Increase for certifying examiners for § 35.490(b)(4):	\$50,000

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.490 annually. Of these, 90 percent, or 135, will seek certification by a certifying board under § 35.490(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 15 physicians, will seek to become authorized users under § 35.490(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.490(b)(3) are estimated below.

Assumptions:

Licensees:

Number of candidates:	15
Cost per preceptor statement (½ hour of preceptor's time plus ½ hour of candidate's time):	\$60
Total Cost Increase for § 35.490(b)(3):	\$1,000

The costs to applicants associated with taking an examination for purposes of § 35.49(b)(4) are estimated below.

Assumptions:

Licensees:

Number of candidates:	15
Examination fee:	\$425
Time for examination:	3 hours at \$20 per hour
Total Cost Increase for examinations under § 35.490(b)(4):	\$7,000
Total Cost Increase for § 35.490:	\$108,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

SUBPART G--SEALED SOURCES FOR DIAGNOSIS**5.63 Use of sealed sources for diagnosis (§ 35.500).**

Section 35.500 currently requires a licensee to use specified sources for diagnosis in accordance with the manufacturer's radiation safety and handling instructions. Section 35.500 approves the use of four sealed sources for diagnostic procedures and specifies how they may be used.

The proposed rule in § 35.500 would eliminate the listing of permissible sealed sources and use specifications and would replace them with a provision that a licensee may use any sealed source in any manner for diagnostic procedures as approved in the Sealed Source and Device Registry.

Cost Impacts:

The NRC anticipates cost savings with the proposed changes to § 35.500. No longer requiring licensees to submit license amendments each time they want to use a diagnostic source or procedure not listed in § 35.500 would reduce both licensee costs and NRC and Agreement States costs.

Assumptions:Licensee:

Total licensees seeking amendments (5 NRC and 13 Agreement States licensees):	18
Licensee amendment preparation time, hours:	2
Technical staff hourly rate:	\$30
Total Annual Cost Savings to licensees:	\$1,000

NRC/Agreement States:

Total license amendment submittals (5 NRC and 13 Agreement States licensees):	18
NRC/Agreement States amendment review time, hours:	1
NRC/Agreement States staff hourly rate:	\$70
Total Annual Cost Savings for NRC and Agreement States:	\$1,000
Total Annual Cost Savings from changes to § 35.500:	\$2,000

Health and Safety Impacts:

None anticipated.

Benefits:

Increased licensee flexibility and elimination of license amendments.

5.64 Availability of survey instrument (§ 35.520)

The current rule in § 35.520 requires each licensee to have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The proposed rule would eliminate § 35.520 in its entirety.

Cost Impacts:

None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated, because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits:

Increased flexibility for licensees.

5.65 Training for use of sealed sources for diagnosis (§ 35.590)

The current rule in § 35.950 specifies the training requirements for an authorized user of sealed sources for diagnosis.

Section 35.950(a) lists four specialist boards through which an individual may become certified to use sealed sources for diagnosis.

Section 35.950(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 8 hours of classroom and laboratory training in basic radioisotope handling techniques.

The proposed rule would make the following changes:

Section 35.590(a) would eliminate the specific list of four approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.590(b) would specify 8 hours of classroom and laboratory training in radioisotope handling techniques specifically applicable to the use of the device that would include: (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use and measurement of

radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested.

Cost Impacts:

The cost impacts associated with this section would involve additional costs to NRC for approval of certifying specialty boards.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	4
NRC review time:	240 hours per board at \$70 per hour
Total Cost Increase for § 35.590(a):	\$67,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

SUBPART H--THERAPEUTIC MEDICAL DEVICES

5.66 Use of a sealed source in a device for therapeutic medical uses (§ 35.600)

Section 35.600 currently regulates the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

The proposed rule would amend the title and text of § 35.600 to eliminate the reference to teletherapy and the references to a sealed source of cobalt-60 or cesium-137, and would specify instead that a licensee shall use sealed sources in devices for therapy as approved in the Sealed Source and Device Registry for medical use.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility for licensees.

5.67 Radiation surveys of patients and human research subjects treated with remote afterloaders. (§ 35.604)

The proposed rule would add a new § 35.604 pertaining to radiation surveys for remote afterloaders. Section 35.604(a) would require that prior to releasing a patient or human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the device with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. Section 35.604(b) would require licensees to retain a record of the survey in accordance with § 35.2404. This record would be required to confirm that the source has been removed from the patient and returned to the shielded portion of the device.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved regulatory efficiency and consistency.

5.68 Installation, maintenance, and repair (§ 35.605)

Section 35.605 currently establishes maintenance and repair requirements for teletherapy units. Section 35.605(a) provides that only persons authorized by the Commission or an Agreement State can perform teletherapy unit maintenance and repair. Section 35.605(b) specifies that only persons specifically licensed may maintain, adjust, or repair the source drawer, shutter, or other mechanism of a teletherapy unit.

The proposed rule would eliminate the reference to teletherapy units. Section 35.605(a) would provide that only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

Section 35.605(b) of the proposed rule would provide that except for low dose-rate remote afterloader devices, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device.

A new § 35.605(c) would be added to provide that a person specifically licensed by NRC or an Agreement State or an authorized medical physicist may install, replace, relocate, or remove a sealed source or a source contained in low dose-rate remote afterloader.

A new § 35.605(d) would provide that records of installation, maintenance, and repair must be retained in accordance with new § 35.2605.

Cost Impacts:

None anticipated. The proposed § 35.605(a) would make no change with respect to teletherapy. It would add requirements for high dose-rate and pulsed dose-rate remote afterloaders and gamma stereotactic radiosurgery. However, such requirements are consistent with current license conditions.

The proposed § 35.605(c) would create a new exemption for low dose-rate remote afterloaders from the requirement that maintenance and repair personnel must be specifically licensed, by providing that authorized medical physicists may install, replace, relocate, or remove sources contained in low dose-rate remote afterloaders. This is anticipated to provide a small savings for licensees using a new source for every treatment.

Health and Safety Impacts:

No health or safety impacts are anticipated. Maintenance and repair will continue to be performed only by qualified personnel.

Benefits:

Improved flexibility and a small cost savings for licensees.

5.69 License amendments (§ 35.606)

Currently § 35.606 requires a licensee to apply for and receive a license amendment before making any change in the treatment room shielding; making any change in the location of the teletherapy unit within the treatment room; using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room; relocating the teletherapy unit; or allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

The proposed rule would eliminate § 35.606 in its entirety.

Cost Impacts:

No significant cost impacts are anticipated.

Health and Safety Impacts:

None anticipated. Occupational exposure and control of exposure and control of access continue to be covered by the requirements of 10 CFR Part 20.

Benefits:

Improved flexibility for licensees.

5.70 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.610)

Section 35.610 currently establishes safety instruction requirements for teletherapy units. Sections 35.610(a)(1) and 35.610(a)(2) require that instructions regarding the proper operation of a teletherapy unit must be posted at the unit console. The instructions must include procedures to follow if the teletherapy unit malfunctions and the individuals that need to be contacted in case of unit failure. In addition, § 35.610(b) requires that operators of teletherapy units receive initial training on topics identified in § 35.610(a) and § 35.610(c) requires that records of individuals receiving training must be kept for three years.

The proposed rule would amend the title and text of § 35.610 to require that licensees develop, maintain, and implement specified safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units. Section 35.610(a) would require licensees to develop, maintain, and implement specified safety procedures and § 35.610(b) would require a copy of those procedures to be located at the unit console. Section 35.610(c) would require that licensees post written instructions for individuals who operate the devices at the device console. These instructions would inform the operator of the location of the procedures required by § 35.610(a) and the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the device or console unit or console operates abnormally. Section 35.610(d) would require licensees to provide initial training, refresher training, and practice drills in the procedures identified in § 35.610(a) for all individuals who operate devices regulated by this section. Section 35.610(e) would require that licensees retain a record of individuals receiving instruction required by § 35.610(b), in accordance with § 35.2310.

Cost Impacts:

No incremental costs would be associated with § 35.610. These requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulator efficiency and consistency, as a result of codifying requirements previously used as license conditions.

5.71 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.615)

Section 35.615 currently specifies detailed access controls and equipment requirements, including radiation monitoring equipment, for teletherapy rooms. In particular, § 35.615(a) requires access control to teletherapy rooms and § 35.615(b) requires an electrical interlock system on the door that will not allow operation of the unit if a door is open. Section 35.615(c) requires a indicator light above the door that monitors beam use. A radiation monitor and instructions regarding checks for proper operation are required by § 35.615(d). Finally, § 35.615(e) requires that each teletherapy unit treatment room contain a viewing chamber where a irradiation procedure can be overseen

The proposed rule would amend the title of the section to specify that the section pertains to remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units and their treatment facilities. It would eliminate requirements for equipping each entrance with a beam

condition indicator light, permanent radiation monitoring, and associated record keeping requirements. The proposed rule also would add requirements for viewing and intercom systems for all modalities except low-dose rate remote afterloaders.

Sections 35.615(f)(1) through 35.615(f)(4) in the proposed rule would establish requirements pertaining to remote afterloaders and gamma stereotactic radiosurgery units. Section 35.615(f)(1) would require an authorized user or an authorized medical physicist to be physically present during the initiation of a low-dose rate remote afterloader procedure. For the duration of the low dose-rate procedure, an authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician who has been trained in emergency response for the device, would be required to be immediately available during continuation of all patient treatments involving the device.

Section 35.615(f)(2) would require an authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving a high dose-rate remote afterloader. For the duration of the high dose-rate procedure, an authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician who has been trained in emergency response for the device, would be required to be physically present during continuation of all patient treatments involving the device.

Section 35.615(f)(3) would require an authorized user and an authorized medical physicist to be physically present during the initiation of all procedures involving a pulsed-dose rate remote afterloader. An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician who has been trained in emergency response for the device, would be required to be immediately available during continuation of all patient treatments involving the device.

Section 35.615(f)(4) would require for gamma stereotactic radiosurgery units that an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving the unit.

Section 35.615(f)(5) would require specified emergency response equipment to be available near each treatment room.

Cost Impacts:

The elimination of prescriptive requirements in §§ 35.615(a)-(e) for the treatment room is not anticipated to result in cost impacts because 10 CFR 20.1601 continues to require control measures for high radiation areas.

Costs savings would be associated with § 35.615(f)(2). Under the proposed rule, an authorized nuclear pharmacist would be allowed to leave a high-dose rate remote afterloader procedure following procedure initialization if a radiology oncology physician with remote afterloader

emergency response training is available to observe the procedure. Currently, the authorized nuclear pharmacist is required to remain for the duration of the procedure.

Other requirements are consistent with current license conditions.

Assumptions:

Licensees:

Number of annual HDR treatment fractions (35,000 procedures with 4 fractions per procedure):	140,000
Time to complete fraction after initiation, hours:	0.0667
Net reduction in hourly rate: ⁷	\$20
Total Annual Cost Savings from § 35.615:	\$187,000

Health and Safety Impacts:

None anticipated.

Benefits:

Improved flexibility and cost savings for licensees.

5.72 Possession of survey instrument (§ 35.620)

The current rule in § 35.620 requires a licensee authorized to use byproduct material in a teletherapy unit to have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour. The proposed rule eliminates this section in its entirety.

Cost Impacts:

None anticipated, because licenses are expected to continue to possess survey instruments.

Health and Safety Impacts:

None anticipated, because licensees are expected to continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

⁷ Difference between authorized user at \$100/hour and technical staff at \$80/hour.

Benefits:

Increased flexibility for licensees.

5.73 Dosimetry equipment (§ 35.630).

Section 35.630(a)(1) of the current rule specifies that dosimetry equipment must be calibrated after any servicing and every two years at a minimum by the NIST or any calibration laboratory accredited by the AAPM. Alternatively, § 35.630(a)(2) allows dosimetry equipment to be calibrated every four years and subsequently intercompared at an intercomparison meeting to dosimetry equipment calibrated within the past two years by NIST or any other calibration laboratory accredited by AAPM. In addition, the current rule requires that dosimetry equipment be available for spot-check measurements. This equipment can be the same equipment required by § 35.630(a). Finally, § 35.630(c) requires a record of each calibration and equipment comparison.

The proposed rule would require that licensees have a calibrated dosimetry system available for use. Section 35.630(a) of the proposed rule would require either (1) that dosimetry systems be calibrated within the previous two years using a source whose activity is traceable to the National Institute of Standards and Technology (NIST) and in accordance with published protocols approved by a nationally recognized body or by a calibration laboratory approved by the American Association of Physicists in Medicine (AAPM) or (2) that the system must have been calibrated within the previous four years, and that within a specified period thereafter it must have been intercompared with another system that was calibrated by the National Institute of Standards and Technology (NIST) or by a calibration laboratory approved by the American Association of Physicists in Medicine (AAPM). The proposed rule would eliminate the requirement in the current rule that equipment comparison must take place during an intercomparison meeting.

A record of each calibration, intercomparison, and comparison is required to be retained in accordance with § 35.2630.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased flexibility for licensees.

5.74 Full calibration measurements on teletherapy units (§ 35.632)

Section 35.632 currently requires licensees to perform full calibration measurements on each teletherapy unit, and provides specific requirements for such calibration measurements. Section 35.632(d) specifies that the calibration shall be performed according to certain protocols cited in the regulation.

The proposed rule would amend only § 35.632(d) to eliminate the citations to specific protocols and would instead provide that the licensee shall make full calibration measurements in accordance with "published protocols approved by nationally recognized bodies."

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

The amendment would provide greater flexibility to licensees to adopt calibration protocols, and would avoid the problem that protocols cited in 10 CFR Part 35 may over time become outdated. NRC would experience regulatory efficiencies as a result of not being required to periodically amend § 35.632.

5.75 Full calibration measurements on remote afterloaders (§ 35.633)

The proposed rule would add a new section, § 35.633, providing detailed specifications for calibration measurements on remote afterloaders.

Sections 35.633(a)(1) and (2) of the proposed rule would require full calibration measurements on a remote afterloader before the first medical use of the device and before medical use following certain specified conditions.

Sections 35.633(a)(3) and (a)(4) of the proposed rule would require an additional calibration at intervals not exceeding 120 days for high dose-rate and pulsed dose-rate remote afterloaders and annually for low dose-rate remote afterloaders.

Section 35.633(b) would specify the determinations that must be included in full calibration measurements.

Section 35.633(c) would require, in addition to full calibrations, certain other specified calibrations on high dose-rate and pulsed dose-rate remote afterloaders components, and on low dose-rate remote afterloaders.

Section 35.633(d) would require the dosimetry system described in § 35.630(a) to be used.

Section 35.633(e) would specify that full calibration measurements be in accordance with published protocols approved by nationally recognized bodies.

Section 35.633(f) would specify requirements for mathematical correction of outputs for physical decay.

Section 35.633(g) would require that full calibration measurements mandated by § 35.633(a) and physical decay corrections required by (g) must be performed by an authorized medical physicist.

Section 35.633(h) would stipulate that a record of each calibration must be kept in accordance with § 35.2633.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.76 Full calibration measurements on gamma stereotactic radiosurgery units (§ 35.635)

The proposed rule adds a new section, § 35.635, that would provide detailed specifications for calibration measurements on gamma stereotactic radiosurgery units.

Sections 35.635(a)(1) and (2) would require full calibration measurements on a gamma stereotactic radiosurgery unit before the first medical use of the device and whenever spot checks measurements indicate re-calibration is warranted. In addition, calibrations would need to occur after the replacement of a sealed source in a device, after a device repair, and after a device reinstallation.

Section 35.635(a)(3) in the proposed rule would require an additional calibration measurement at intervals not to exceed one year.

Section 35.635(b) would detail the measurements that need to take place in the annual calibration.

Section 35.635(c) would require that the calibration measurements described in § 35.655(a) be done with the dosimetry equipment regulated by § 35.630. The remaining measurements required in paragraph (b)(1) may be made using a dosimetry system that indicates relative dose rates.

Section 35.635(d) would require full calibration measurements to be in accordance with published protocols approved by nationally recognized bodies.

Section 35.635(e) would specify requirements for mathematical correction of outputs.

Section 35.633(f) would require that calibration measurements mandated by § 35.633(a) need to be performed by an authorized medical physicist.

Section 35.635(g) would require that records of calibrations must be retained in accordance with § 35.2635.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

Elimination of former § 35.636:

Section 35.636 of the current requires that licensees check all teletherapy operation systems listed in § 35.634(d) immediately following an installation of a source. A safety check is also required immediately following a teletherapy unit charge pursuant to § 35.606. Section 35.636(b) stipulates that if a teletherapy unit malfunction is detected, the device console must be locked in the off position. Section 35.636(c) requires the retention of records of facility checks following an installation of a source for three years.

The proposed rule would eliminate § 35.636 in its entirety.

Cost Impacts:

None anticipated. Requirements from this section would be incorporated into §§ 35.642, 35.643, 35.644, and 35.645 of the proposed rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Improved regulatory efficiency by reducing redundancy of requirements.

5.77 Radiation surveys for teletherapy facilities (§ 35.641)

The current rule in § 35.641 specifies detailed requirements for radiation surveys for teletherapy facilities.

The proposed rule eliminates § 35.641 in its entirety.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Increased flexibility for licensees.

5.78 Periodic spot checks for teletherapy units (§ 35.642)

Section 35.634 of the current rule requires periodic spot checks of teletherapy units to determine proper unit operation.

The proposed amendment would replace the term "teletherapy physicist" with "authorized medical physicist." The amended § 35.642(c) would eliminate the requirement that the licensee must keep a record of the reports detailing the results of teletherapy unit periodic spot-checks for three years. The proposed rule would add a new § 35.642(f) requiring records of each spot-check required by § 35.642(a) and § 35.642(d) to be kept in accordance with § 35.2642. Section

35.642(d) would add a new requirement for safety spot-checks after each source installation. Section 35.642(d)(4) also would be amended to require the installation of intercom systems in teletherapy unit treatment rooms. Section 35.642(e) would provide that if the required checks indicate the malfunction of any system, the control console must be locked in the off position and the licensee may not use the unit except as necessary to check, repair, or replace it.

Cost Impacts:

No incremental costs are associated with § 35.642. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.79 Periodic spot-checks for high dose rate and pulsed dose-rate remote afterloaders (§ 35.643)

The proposed rule adds a new section, § 35.643, that would provide detailed specifications for periodic spot checks for high dose-rate and pulsed dose-rate remote afterloaders.

Section 35.643(a)(1) would require a periodic spot-check for high dose-rate and pulsed dose-rate remote afterloaders before each week of use.

Section 35.643(a)(2) would require a periodic spot-check for high dose-rate and pulsed dose-rate remote afterloaders before each day of use.

Section 35.643(a)(3) would require a periodic spot-check for high-dose rate remote afterloaders and pulsed rate remote afterloaders after each source installation.

Section 35.643(b)(1) would require an authorized medical physicist to establish procedures for high dose rate and pulsed dose-rate remote afterloaders spot-check. In addition the medical physicist is required to review the results of each spot-check required by § 35.643(a)(1) within 15 days of its completion.

Section 35.643(c) and (d) would describe the measurements and the systems that must be accounted for in a spot-check.

Section 35.643(e) would require a simulated cycle of treatment as part of spot-checks under paragraph (d).

Section 35.643(f) would require prompt repair of any system identified under paragraph (c) as not operating.

Section 35.643(g) would require the licensee to lock the console in the off position and not use the unit if checks under paragraph (d) indicate any system malfunction.

Section 35.643(h) would require spot checks mandated by §§ 35.643(a)(2) and (a)(3) to be recorded and retained in accordance with § 35.2643.

Cost Impacts:

None anticipated. The proposed requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

Elimination of former § 35.643:

Section 65.643 would be eliminated in the proposed rule. Currently, § 35.643 of the current rule stipulates that if, under § 35.646, a radiation survey indicates that an individual in an unrestricted area could be exposed to radiation levels greater than those permitted by 10 CFR Part 20.1301, either the unit has to be equipped with stops or additional shielding has to be added.

Section 35.643(a)(3) requires that a report describing the survey and corrective action has to be forwarded to NRC according to § 35.645.

Section 35.643(b) allows radiation levels to exceed those mandated by 10 CFR Part 20.1301 if a license amendment is applied for and issued.

The proposed rule would eliminate § 35.643 in its entirety.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated, because 10 CFR Part 20, particularly Subparts C and D, establishing occupational and public dose limits will continue to apply.

Benefits:

Improved flexibility for licensees.

5.80 Periodic spot-checks for low dose-rate remote afterloaders (§ 35.644)

The proposed rule would add a new section, § 35.644, providing detailed specifications for periodic spot checks for low dose-rate remote afterloaders.

Section 35.644(a) would require a periodic spot check prior to patient treatment and after each source-installation.

Section 35.644(b) would require a simulated cycle of treatment as part of spot-checks.

Section 35.644(c)(1-2) would require an authorized medical physicist to establish low dose-rate remote afterloaders spot-check procedures. In addition, the medical physicist would be required to review the results of each spot-check required by § 35.644(a) within 15 days of its completion.

Section 35.644(d) would require the licensee to lock the console in the off position and not use the unit if checks under paragraph (d) indicate any system malfunction.

Section 35.644(e) would require spot checks mandated by § 35.644(a) to be recorded and retained in accordance with § 35.2643.

Cost Impacts:

None anticipated. The proposed requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency.

5.81 Periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.645)

Section 35.645 of the current rule is eliminated in its entirety as unnecessary. The proposed rule would include a new § 35.645 that would require periodic spot checks for gamma stereotactic radiosurgery units.

Section 35.645(a)(1) would require a periodic spot-check for gamma stereotactic radiosurgery units before each month of use.

Section 35.645(a)(2) would require a periodic spot-check for gamma stereotactic radiosurgery units before each day of use.

Section 35.645(a)(3) would require a periodic spot-check for gamma stereotactic radiosurgery units after each source installation.

Section 35.645(b)(1) and (b)(2) would require an authorized medical physicist to establish gamma stereotactic radiosurgery unit spot-check procedures. In addition, the medical physicist would require to review the results of each spot-check required by § 35.645(a)(1) within 15 days of its completion.

Section 35.645(c-d) would describe the measurements and the systems that have to be accounted for in a spot-check.

Section 35.645(e) would require the licensee to arrange for prompt repair of any system identified under paragraph (c) that is not working properly.

Section 35.645(f) would require a licensee to lock the control console in the off position and not use the unit of checks required in paragraph (d) indicate a malfunction.

Section 35.645(g) would require spot checks mandated by § 35.643(a)(1) to be recorded and retained in accordance with § 35.2645.

Cost Impacts:

Small cost savings (<\$1,000) from elimination of requirement to submit survey results to Regional Office for review.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

Elimination of the former § 35.645:

Section 35.645 of the current rule requires that records required by §§ 35.363, 35.641, 35.643, and full calibration measurements required in § 35.632 to be mailed to the appropriate NRC Regional Office.

The proposed rule would eliminate § 35.645 in its entirety.

Cost Impacts

The elimination of the forwarding requirement would result in savings to licensees, estimated below:

Assumptions:

Licensees:

Number of mailings by NRC licensees avoided annually:	45
Estimated cost per mailing	\$20
Total Annual Cost Savings to NRC licensees:	\$900

Agreement States:

Number of mailings by Agreement States licensees avoided annually:	113
Estimated cost per mailing:	\$20
Total Annual Cost Savings to Agreement State licensees:	\$2,300
Total Annual Cost Savings from elimination of the former § 35.645:	\$3,000

Health and Safety Impacts

None anticipated.

Benefits:

Cost savings to licensees.

5.82 Additional requirements for mobile remote afterloaders (§ 35.647)

Requirements in the current § 35.647, "five-year inspection," were moved to the proposed § 35.655.

The proposed rule would add a new section establishing technical requirements for mobile remote afterloaders. Section 35.647(a) in the proposed rule would require that all survey instruments be checked and that all sources be accounted for before leaving the base facility. Section 35.647(b) would require spot checks of mobile remote afterloader equipment to ensure proper operation before each use and according to § 35.643. Section 35.647(b) would describe the afterloader components that must be checked in a spot-check. Section 35.647(c) would require licensees to ensure overall proper operation by conducting a simulated cycle of treatment prior to use at each address of use. Section 35.647(e) would require that spot-check records be kept in accordance with § 35.2647.

Cost Impacts:

Minimal cost impacts (<\$1,000) are anticipated because of a small number (3) of licensees.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.83 Radiation surveys (§ 35.652)

Currently, § 35.641 requires a radiation survey before teletherapy use, after each installation of a source in a teletherapy unit, and after making other changes to a teletherapy unit. Section 35.641(a) describes the scope of the survey and what operational conditions need to be verified. Section 35.641(b) requires that the teletherapy unit control be locked if the survey indicates that radiation levels exceed the limit set in 10 CFR Part 20.1301.

The proposed rule would amend § 35.641 and would renumber it as § 35.652. Section 35.652(a) of the proposed rule would require that in addition to the survey requirement in 10 CFR 20.1501, a licensee shall make such surveys as defined in the Sealed Source and Device Registry in order to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed levels stated in the Registry. Section 35.652(b) of the proposed rule would require that licensees make the surveys required in (a) at installation of a new source and following specified repairs. Section 35.652(c) would require licensees to retain records of radiation surveys in accordance with § 35.2652.

Cost Impacts:

None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.84 Five year inspection for teletherapy and gamma stereotactic radiosurgery units (§ 35.655)

Section 35.647 of the current rule stipulates that teletherapy units must be inspected and serviced during sealed source replacement or every five years, whichever comes first. Section 35.647(b) of the current rule requires that this inspection and servicing needs to be performed by a individual licensed by the Commission or Agreement States.

The proposed rule would amend § 35.647 and would renumber it as § 35.655. The proposed rule would add a requirement for inspection and servicing of gamma stereotactic radiosurgery units during source replacement or every five years, whichever comes first. Proposed § 35.655(b) would require that the servicing must be performed only by persons specifically licensed by NRC or an Agreement State.

The proposed § 35.655(c) would require that licensees keep a record of inspection and servicing in accordance with new § 35.2655.

Cost Impacts:

None anticipated. Requirements are consistent with current licensee activities. Although inspection cycle is currently 7 years, inspections are being conducted more frequently as standard of practice.

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.85 Therapy-related computer systems (§ 35.657)

The proposed rule would add a new § 35.657 requiring licensees to ensure that computerized operating systems and treatment planning systems are operating properly, and to perform acceptance testing in accordance with published protocols approved by nationally recognized bodies.

Cost Impacts:

None anticipated. Licensees using computerized operating and planning systems currently verify their proper operation by conducting detailed acceptance testing.

Health and Safety Impacts:

Acceptance testing and verification of correct operation would ensure safe operation of these systems.

Benefits:

Would codify existing practice.

5.86 Training for use of therapeutic medical devices (§ 35.690)

The current rule in § 35.960 specifies the training requirements for the authorized user of a sealed source in a teletherapy unit.

Section 35.960(a) lists four specialist boards through which an individual may become certified to use sealed sources in a teletherapy unit.

Section 35.960(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. The current rule also requires 3 years of supervised clinical experience.

The proposed rule would make the following changes:

Section 35.690 would require that, except as provided in § 35.57, the licensee shall require the authorized user of a sealed source for a use listed in § 35.600 to be a physician who meets the requirements in § 35.690.

Section 35.690(a) would eliminate the specific list of four approved speciality boards, and would provide instead that the certification of the specialty board must be approved by the Commission.

Section 35.690(b)(1)(i) would continue to require 200 hours of didactic training. Section 35.690(b)(1)(ii) would continue to require 500 hours of supervised experience. However, the proposed rule would require "supervised practical experience" rather than the "supervised work experience" required by the current rule.

Section 35.690(b)(2) would add a requirement that the licensee must obtain written certification, signed by a preceptor authorized user, that the training has been completed.

Section 35.690(b)(3) would add a requirement that following completion of the requirements in paragraphs (b)(1) and (b)(2), the individual must demonstrate knowledge of radiation safety commensurate with the use requested by passing an examination given by an organization approved by the Commission.

Cost Impacts:

The cost impacts of the proposed rule apply to both NRC and licensees.

The costs to NRC for certifying specialty boards for purposes of § 35.690(a) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards:	3
NRC review time:	240 hours per board at \$70 per hour
Total Cost Increase for § 35.690(a):	\$50,000

The costs to NRC for certifying specialty boards for purposes of § 35.690(b)(3) are estimated below.

Assumptions:

NRC/Agreement States:

Number of boards reviewed:	3
NRC review time:	240 hours per examiner at \$70 per hour
Total Cost Increase for certifying examiners for § 35.690(b)(4):	\$50,000

NRC estimates that approximately 150 physicians would seek to become authorized users under § 35.690 annually. Of these, 90 percent, or 135, would seek certification by a certifying board under § 35.690(a). No additional cost impacts would be created for them under the proposed rule. NRC estimates that the remainder, or approximately 15 physicians, would seek to become authorized users under § 35.690(b). New costs for securing a preceptor statement and taking an examination would be created by the proposed rule.

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.690(b)(2) are estimated below.

Assumptions:

Licensees:

Number of candidates:	15
Cost per preceptor statement (½ hour of preceptor's time and ½ hour of candidate's time):	\$60
Total Cost Increase for § 35.690(b)(3):	\$900

One hundred fifty applicants per year are expected to take a radiation safety exam to become authorized for the use of sealed sources in a therapeutic medical devices. The costs to applicants associated with taking an examination for purposes of § 35.690(b)(3) are estimated below.

Assumptions:

Licensees:

Number of candidates:	15
Examination fee:	\$700
Time for examination:	3 hours at \$20 per hour
Total Cost Increase for examinations under § 35.690(b)(4):	\$11,000
Total Cost Increase from changes to § 35.690 are estimated at:	\$112,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

SUBPART J

Under the proposed rule, licensees would have up to 2 years after the effective date of the final rule to comply with the proposed training requirements for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers. During this 2 year period, licensees would have the option of complying with either the existing training requirements in Subpart J, or as the proposed training requirements in Subparts B and D through H. At the end of the 2 years, subpart J would be deleted and licensees would have to comply with the proposed training and experience criteria. The training and experience requirements in the proposed Subpart J are assigned to Agreement State compatibility Category "D," as they are in the current rule. Subparts B and D through H of the proposed rule have been assigned to compatibility Category "C" for Agreement States. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission in June 30, 1997, the Agreement States are required to adopt NRC program elements (or promulgate regulations) required for compatibility within 3 years of the effective date of the NRC rulemaking. Therefore, the Commission recognizes that if an Agreement State does not revise its regulations until 2 years after the effective date of the NRC rule, it may choose not to include Subpart J training and experience requirements in the newly promulgated rules, since the Subpart J requirements are assigned a compatibility Category "D" (not required for compatibility). In this case, the Agreement States would only be expected to adopt the proposed training and experience requirements in Subpart B and D through H.

5.87 Radiation Safety Officer (§ 35.900).

Section 35.900 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.900 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.88 Training for uptake, dilution, and excretion studies (§ 35.910).

Section 35.910 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.910 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.89 Training for imaging and localization studies (§ 35.920).

Section 35.920 is contained in the current 10 CFR Part 35, Subpart J “Training and Experience Requirements.”

The proposed rule would retain § 35.920 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.90 Training for therapeutic use of unsealed byproduct materials (§ 35.930).

Section 35.930 is contained in the current 10 CFR Part 35, Subpart J “Training and Experience Requirements.”

The proposed rule would retain § 35.930 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to

comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.91 Training for treatment of hyperthyroidism (§ 35.932).

Section 35.932 of the current rule establishes requirements for authorized nuclear pharmacists of I-131 for the treatment of hyperthyroidism.

The proposed rule would eliminate § 35.932 in its entirety. The proposed rule would require individuals seeking to use I-131 for treatment of hyperthyroidism to satisfy the requirements of § 35.390.

Cost Impacts:

Incremental costs are anticipated by NRC due to increased training requirements.

Assumptions:

Licensees:

Total affected applicants:	30
Total additional training, hours:	40
Preceptor certification (½ hour of preceptor's time at \$100/hour plus ½ hour of candidate's time at \$20/hour):	\$60
Registration cost per exam:	\$600
Time to take exam, hours:	3
Medical physician/intern hourly rate:	\$20
Total Cost Increase to candidates for § 35.932:	\$46,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.92 Training for treatment of thyroid carcinoma (§ 35.934).

Section 35.934 of the current rule establishes requirements for authorized users of I-131 for the treatment of thyroid carcinoma.

The proposed rule would eliminate § 35.934 in its entirety. The proposed rule would require individuals seeking to use I-131 for treatment of thyroid carcinoma to satisfy the requirements of § 35.390 when § 35.934 is eliminated.

Cost Impacts:

Incremental costs are anticipated by NRC due to increased training requirements.

Assumptions:Licensees:

Total affected applicants:	30
Total additional training, hours:	40
Preceptor certification (½ hour of preceptor's time at \$100/hour plus ½ hour of candidate's time at \$20/hour):	\$60
Registration cost per exam:	\$600
Time to take exam, hours:	3
Medical physician/intern hourly rate:	\$20
Total Cost Increase to candidates for § 35.934:	\$46,000

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.93 Training for use of brachytherapy sources (§ 35.940).

Section 35.940 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.940 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.94 Training for ophthalmic use of strontium-90 (§ 35.941).

Section 35.941 of the current rule specifies the training requirements for ophthalmic use of strontium-90. The proposed rule would eliminate § 35.941 in its entirety.

Cost Impacts:

The proposed rule would require individuals seeking to become authorized for the ophthalmic use of strontium-90 to undergo training for the authorized use of brachytherapy. This rule amendment would represent a significant increase in training requirements for those seeking to become authorized for the use of strontium-90. These new training requirements would not apply to those physicians already authorized for the ophthalmic use of strontium-90 under the current rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Training and experience commensurate with risk and focused on radiation safety.

5.95 Training for use of sealed sources for diagnosis (§ 35.950).

Section 35.950 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.950 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.96 Training for teletherapy (§ 35.960).

Section 35.960 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.960 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the

proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.97 Training for teletherapy physicist (§ 35.961).

Section 35.961 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.961 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.98 Training for an authorized nuclear pharmacist (§ 35.980).

Section 35.980 is contained in the current 10 CFR Part 35, Subpart J "Training and Experience Requirements."

The proposed rule would retain § 35.980 for up to two years after the proposed rule is implemented. The two year implementation period would allow time for potential examining organizations and entities to prepare an application in accordance with Appendix A of the proposed rule; for NRC to review and approve the applications submitted in accordance with Appendix A and to review and approve certification of the speciality boards in §§ 35.50(a), 35.55(a), 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a). Similarly, the two year implementation period would allow licensees and affected individuals sufficient time to comply with the proposed training and experience requirements. During the two year period, licensees would have the option of complying with either the existing training and experience requirements or the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule. After the two year period, the requirements contained in 10 CFR Part 35, Subpart J in the proposed rule would be eliminated and the training and experience requirements contained in 10 CFR Part 35, Subparts B and D-H of the proposed rule would become effective for all licensees, affected individuals, NRC and Agreement States.

Cost Impacts:

None anticipated.

Health and Safety:

None anticipated.

Benefits:

None anticipated.

5.99 SUBPART K--OTHER MEDICAL USES OF BYPRODUCT MATERIAL OR RADIATION THEREFROM

The proposed rule in new § 35.1000 would provide that a licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in Subpart D through H of 10 CFR Part 35 provided: (1) the applicant or licensee submitted the required information pursuant to § 35.12(d); and (2) the applicant or licensee received written approval from the Commission and uses the material in accordance with the regulations and specific conditions deemed necessary by the Commission for the medical use of the material.

Cost Impacts:

Applicants for other medical uses would incur costs to prepare and submit information as specified under § 35.12(d). Costs are estimated under § 35.12(d).

Health and Safety Impacts:

None anticipated.

Benefits:

Regulatory efficiency, as a result of specification of requirements in advance.

SUBPART L**5.100 Records of authority and responsibilities for the radiation protection program (§ 35.2024).**

The proposed rule in § 35.2024(a) would add a new section to require licensees to retain a record of actions taken by the licensee's management pursuant to § 35.24(a) for five years and specifies the contents of those records. Section 35.2024(b) would require licensees to retain a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(d) of the proposed rule. Section 35.2024 would require the record to include the signature of the Radiation Safety Officer and licensee management.

Cost Impacts:

The proposed rule would reduce the record retention period for records of actions taken by licensee's management under § 35.24(a), which under the current rule lasts until the Commission terminates the license, to five years. Therefore, small cost reductions would occur with shorter record retention periods.

Assumptions:Licensees:

Licensees:	4,256
Reduction in storage requirements:	1 cubic foot (about ½ file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Savings from § 35.2024:	\$6,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.101 Records of radiation protection program safety changes (§ 35.2026).

Section 35.2026 of the proposed rule, a new section, would provide that a licensee must retain a record of each radiation protection program change, as required by § 35.26(a), for five years. The record must include a copy of the old and new procedure; the effective date of the change; and the signature of the Radiation Safety Officer and licensee management that reviewed and approved the change.

Section 35.31(b) currently requires that a licensee retain a record of each "radiation safety program" change until the license has been renewed or terminated. Under the current rule, the

record must include "the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative." Section 35.26 of the proposed rule would amend § 35.31(b) to eliminate the quoted requirements and would provide that a licensee shall retain a record of each change in accordance with § 35.2026. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the Radiation Safety Officer that reviewed and approved the change.

Cost Impacts:

Small cost reductions would be expected with shorter record retention periods, as follows:

Assumptions:

Licensees:

Total licensees:	6,662
Reduction in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Savings for § 35.2026:	\$10,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.102 Records of written directives (§ 35.2040).

Section 35.2040 of the proposed rule, a new section, would require licensees to retain a copy of the written directive, as required by § 35.40, for three years.

Cost Impacts:

Because the number of procedures requiring written directives is not expected to change under the requirements of § 35.40 of the proposed rule, the scope of the recordkeeping requirements under § 35.2040 of the proposed rule is not expected to change. The proposed rule would require a three year record retention period, which corresponds to the record retention period for written directives under the current rule. Therefore, no cost impacts are anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.103 Records of medical events and precursor events (§ 35.2045).

Section 35.2045 of the proposed rule, a new section, would require a licensee to retain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for three years and would specify the contents of the records.

The proposed rule, in § 35.2, would define "medical event" as an event that meets the criteria of § 3045(a). Section 35.3045(a) of the proposed rule, a new section, would revise the requirements in §§ 35.2 and 35.33 of the current rule. Section 35.3045(a) would replace the word "misadministration" with "medical event" and makes other changes defining the situations in which reports must be made. However, the changes to § 35.3045 of the proposed rule are not expected to substantially change the number or type of medical events that would be reported under § 35.2045 from the number and type of misadministrations reported under the current rule. Section 35.2045 of the proposed rule would change the record retention period from five years, under § 35.33(b) of the current rule, to three years. Therefore, the proposed § 35.2045 would be expected to create small cost savings for licensees maintaining records of medical events under this section of the proposed rule.

Section 35.3046 of the proposed rule, a new section, would create a new requirement to report precursor events, as defined in the new proposed definitions in § 35.2 and § 35.3046 of the proposed rule, and to maintain records of precursor events under § 35.2046. The new proposed requirement to report precursor events is expected to increase the costs of records maintained by licensees pursuant to § 35.2045.

Cost Impacts:

The proposed rule is anticipated to result in decreased recordkeeping costs due to the reduced retention period for reports of medical events. The proposed rule also is expected to result in increased recordkeeping costs due to the new requirement to retain records of precursor events. The net effect is anticipated to be their offsetting each other.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.104 Records of instrument calibrations (§ 35.2060).

The proposed rule in § 35.2060, a new section, would require a licensee to maintain a record of instrument calibrations performed in accordance with §§ 35.60 and 35.62 for three years and would specify the records, with respect to constancy, accuracy, linearity, and geometric dependence, that must be maintained.

The proposed rule would parallel § 35.50(e) of the current rule, with one change. The proposed rule would pertain to calibrations of instruments rather than calibrations of dose calibrators. Therefore, the scope of the proposed rule potentially would be increased, through the inclusion of records of calibrations of instruments in addition to dose calibrators.

Cost Impacts:

No significant cost increase.

Health and Safety Impacts:

None anticipated.

Benefits:

Ensures that instruments are functioning correctly and establishes trends in equipment performance.

5.105 Records of radiation survey instrument calibrations (§ 35.2061).

The proposed rule in § 35.2061, a new section, would require a licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for three years and would specify the contents of that record.

Cost Impacts:

The proposed rule would duplicate the recordkeeping requirements in § 35.51(d) of the current rule. The record retention period would remain three years. Therefore, no cost impacts would be anticipated from the proposed rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

**5.106 Records of dosages of unsealed byproduct material for medical use
(§ 35.2063).**

The proposed rule in § 35.2063, a new section, would require a licensee to maintain a record of dosage determinations required by § 35.63 for three years and would specify the records that must be maintained.

The recordkeeping requirements in the proposed rule would parallel the recordkeeping requirements in § 35.53 of the current rule. The record retention period would remain three years. The proposed rule would make two changes: (1) eliminating the requirement that the record contain the expiration dates of the radiopharmaceutical; and (2) changing “measurements” to “determination” in § 35.2063(b)(3) of the proposed rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

**5.107 Records of possession of sealed sources and brachytherapy sources
(§ 35.2067).**

The proposed rule in § 35.2067(a), a new section, would require records of leak tests of sealed sources and brachytherapy sources required by § 35.67(b) of the proposed rule to be retained for three years and would specify the contents of the records. The proposed rule in § 35.2067(b) would require records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) of the proposed rule to be retained for three years and would specify the content of the inventory records.

Cost Impacts:

The proposed rule would duplicate, with one change, the recordkeeping requirements in § 35.59(d) and 35.59(g) of the current rule. The proposed rule would reduce the record retention

time from five years to three years. Reduction of the record retention period by two years would be expected to result in small cost savings to licensees, as follows:

Assumptions:

Licensees:

Licensees:	4,713
Reduction in storage requirements:	1 cubic foot (about ½ file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Savings from § 35.2067:	\$7,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.108 Records of surveys for ambient radiation exposure rate (§ 35.2070).

The proposed rule in § 35.2070, a new section, would require licensees to retain a record of each survey required by § 35.70 for three years. The proposed rule would duplicate the recordkeeping requirements in § 35.70(h) of the current rule.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.109 Records of the release of individuals containing radiopharmaceuticals or implants (§ 35.2075).

The proposed rule in § 35.2075(a), a new section, would require licensees to retain records of patient release required by § 35.75 for three years. Section 35.2075(b) would specify the criteria for retaining the record describing the basis for release. Section 35.2075(c) would specify that the record of instructions to a breast feeding woman required by § 35.75(b) be retained.

Cost Impacts:

None anticipated. The recordkeeping requirements in the proposed rule would parallel the recordkeeping requirements in §§ 35.75(c) and (d) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the proposed rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.110 Records of administrative and technical requirements that apply to the provision of mobile services (§ 35.2080).

The proposed rule in § 35.2080, a new section, would require licensees to retain a copy of the letter(s) that would permit the use of byproduct material at a client's address of use, in accordance with § 35.80(l). Section 35.2080(a) also would require the letter to clearly delineate the authority and responsibility of each entity and must be retained for 3 years after the provision of last service. Section 35.2080(b) would require licensees to retain a record of each survey required by § 35.80(4) for three years and would specify the contents of the records.

Cost Impacts:

None anticipated. The recordkeeping requirements in the proposed rule would duplicate the recordkeeping requirements in § 35.80(f) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the proposed rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.111 Records of waste disposal (§ 35.2092).

The proposed rule in § 35.2092, a new section, would require a licensee to maintain records of the disposal of licensed materials made pursuant to § 35.92 for three years. The record must include: (1) the date of the disposal; (2) the radionuclides disposed; (3) the survey instrument

used; (4) the background dose rate; (5) the dose rate measured at the surface of each waste container; and (6) the name of the individual who performed disposal.

Cost Impacts:

The proposed rule would parallel, with one change, the recordkeeping requirements in § 35.92 of the current rule. The proposed rule would eliminate the requirement that the record include the date on which the byproduct material was placed in storage. Therefore, the proposed rule may create small cost savings (i.e., <\$1,000) for licensees, as a result of the slight reduction in the scope of records that must be maintained.

Health and Safety Impacts:

None anticipated.

Benefits:

Small cost savings for licensees (<\$1,000).

5.112 Records of molybdenum-99 concentration (§ 35.2204).

The proposed rule in § 35.2204, a new section, would require licensees to maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for three years and specifies the contents of the record.

Cost Impacts:

The proposed rule would parallel, with changes, the recordkeeping requirements in the current rule in § 35.204(c). The proposed rule would eliminate the requirement that the record must include the measured activity of the technetium expressed in millicuries and the measured activity of the molybdenum expressed in microcuries. Therefore, the proposed rule would create costs savings for licensees based on the scope of the records that must be maintained. In addition, the proposed changes in § 35.204 would reduce the number of records that must be maintained.

Cost savings to licensees are estimated at:

Assumptions:

Licensees:

Total licensees:	2,359
Reduction in storage requirements:	4 cubic feet (about 2 file drawers)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Savings from § 35.2204:	\$14,000

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.113 Records of instruction and training (§ 35.2310).

The proposed rule in § 35.2310, a new section, would require a licensee to maintain a record of instructions and training required by §§ 35.310, 35.410, and 35.610 for three years. The record must include: (1) a description of the institution; (2) the date of the instruction or training; (3) the names of the attendee(s) and instructor(s); and (4) the name(s) of the individual(s) who provided the instruction.

The proposed rule would parallel, with one change, the recordkeeping requirements in the current rule in §§ 35.310(b), 35.410(b), and 35.610(c). The proposed rule would eliminate the requirement that the record include a description of the instruction. Therefore, the proposed rule would create small cost savings (i.e., <\$1,000) for licensees using unsealed byproduct material for therapeutic administration, manual brachytherapy, and teletherapy. However, §§ 35.310, 35.410, and 35.610 would have been amended to require radiation safety instruction "initially and at least annually." Such annual training, and records of such training, previously has been required by license condition.

Cost Impacts:

Small cost savings are anticipated (<\$1,000).

Health and Safety Impacts:

None anticipated.

Benefits:

Small cost savings to licensees.

5.114 Records of radiation surveys of patients and human research subjects (§ 35.2404).

The proposed rule in § 35.2404, a new section, would require that a licensee maintain a record of the radiation surveys required by §§ 35.404 and 35.406 for three years and would specify that each record must contain the date, location, and results of the survey; an identifier for the patient

or human research subject, the survey instrument used; and the name of the individual who made the survey.

The proposed rule would slightly reduce the scope of the records that must be maintained, because licensees for manual brachytherapy would not be required to maintain a record of the dose rate from the patient or human research subject, as currently required by § 35.404(b).

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.115 Records of brachytherapy source inventory (§ 35.2406).

The proposed rule in § 35.2406, a new section, would require licensees to maintain a record of brachytherapy source accountability required by § 35.406 for three years and would specify the records that must be maintained.

The proposed rule would reorganize and reduce the recordkeeping requirements in § 35.406 of the current rule. The record retention period would not change.

Section 35.2406(b), which would parallel the requirements in the current rule in § 35.406(b), with changes, would specify requirements for records of temporary implants. However, it would eliminate the requirement to maintain a record of the name of the individual permitted to handle the sources; the requirement to record the name and room number of the patient or human research subject; and the number and activity of sources in storage after the return of sources after removal from a patient or human research subject.

Section 35.2406(c), a new section, would specify requirements for records of permanent implants. It would require the record to include the number and activity of sources removed from storage; the date they were removed from storage; the number and activity of sources returned to storage; the date they were returned to storage; and the number and activity of sources permanently implanted in the patient or human research subject.

The proposed rule would not be expected to increase the scope of the records that must be maintained, because records of inventory for brachytherapy sources used for permanent implants

would be covered, under the current rule. The proposed rule would be expected to result in small cost savings (i.e., <\$1,000) for licensees from the reduced scope of the inventory records that must be maintained.

Cost Impacts:

Small cost savings to licensees (<\$1,000).

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings to licensees.

5.116 Records of full calibrations on brachytherapy sources (§ 35.2432).

The proposed rule in § 35.2432, a new section, would require that a licensee maintain a record of the full calibrations on brachytherapy sources required by § 35.432 for three years after the last use of the source. The proposed rule would specify that the record must include the date of the calibration; the manufacturer's name, the model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

Cost Impacts:

The current rule contains no requirements pertaining to records of full calibrations on brachytherapy sources. Therefore, this section of the proposed rule would create small (i.e., <\$1,000), new cost impacts for licensees.

Health and Safety Impacts:

Increased safety.

Benefits:

Conforming change.

5.117 Records of installation, maintenance, and repair (§ 35.2605).

The proposed rule in § 35.2605, a new section, would require that a licensee retain a record of the installation, maintenance, and repair done on therapeutic medical devices as required by § 35.605 for 3 years and would specify that for each installation, maintenance and repair, the record must

include the date; description of the service; and name(s) of the individual(s) who performed the work.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Cost savings for licensees.

5.118 Records of dosimetry equipment (§ 35.2630).

The proposed rule in § 35.2630, a new section, would require that a licensee retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license and would specify in detail what information must be included in each of these records.

Cost Impacts:

The proposed rule would parallel the recordkeeping requirements in the current rule in § 35.630. However, the proposed rule would eliminate the requirement for evidence to be provided that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM. Therefore, this section of the proposed rule would create no new cost impacts for licensees.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.119 Records of teletherapy full calibrations (§ 35.2632).

The proposed rule in § 35.2632, a new section, would require that a licensee maintain a record of the teletherapy full calibrations required by § 35.632 for 3 years and would specify in detail what information must be included in each of these records.

Cost Impacts:

The proposed rule would parallel, with three exceptions, the recordkeeping requirements in the current rule in § 35.632(g). The proposed rule would change the record retention period from the duration of use of the teletherapy source to three years after the last use of the source. It would not require maintenance of a record of the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit. It would refer to the "authorized medical physicist" instead of the "teletherapy" physicist, to conform to the nomenclature of the proposed rule. Therefore, this section of the proposed rule would create small incremental costs (i.e., <\$1,000) for licensees as a result of the increase in the length of the record retention period.

Health and Safety Impacts:

None anticipated. Records already being retained.

Benefits:

Demonstrates that calibrations were done correctly and correct doses administered. Conforming change to restructuring of 10 CFR Part 35.

5.120 Records of remote afterloader full calibrations (§ 35.2633).

The proposed rule in § 35.2633, a new section, would require that a licensee maintain a record of remote afterloader full calibrations required by § 35.633 for three years. The proposed rule also would specify in detail what information must be contained in each of these records.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated. Records already being retained.

Benefits:

Conforming change.

5.121 Records of gamma stereotactic radiosurgery unit full calibrations (§ 35.2635).

The proposed rule would require that a licensee maintain a record of the gamma stereotactic radiosurgery full calibrations required by § 35.635 for three years. The proposed rule also would specify in detail what information must be contained in each of these records.

Cost Impacts:

The current rule contains no section addressing recordkeeping for gama stereotactic radiosurgery full calibrations.

Assumptions:Licensees:

Total licensees:	30
Increase in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Increase from § 35.2635:	<\$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.122 Records of periodic spot-checks for teletherapy units (§ 35.2642).

The proposed rule in § 35.2642, a new section, would require that a licensee retain a record of each periodic spot check for teletherapy units required by § 35.642 for 3 years. The proposed rule also would specify in detail what information must be contained in each of these records.

The proposed rule would parallel, with two minor changes, the recordkeeping requirements for periodic spot-checks for teletherapy units in the current rule in § 35.634(f).

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.123 Records of periodic spot-checks for remote afterloaders (§ 35.2643).

The proposed rule in § 35.2643, a new section, would require that a licensee retain a record of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for 3 years. The proposed rule also would specify in detail what information must be contained in each of these records.

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.124 Records of periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.2645).

The proposed rule in § 35.2645, a new section, would require that a licensee retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. The proposed rule also would specify in detail what information must be contained in each of these records.

Cost Impacts:

The current rule contains no section addressing records of periodic spot-checks for gamma stereotactic radiosurgery units. Therefore, this section of the proposed rule would create cost impacts for licensees, as follows:

Assumptions:

Licensees:

Total licensees:	30
Increase in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Increase from § 35.2645:	<\$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.125 Records of additional technical requirements for mobile remote afterloaders (§ 35.2647).

The proposed rule in § 35.2647, a new section, would require that a licensee retain a record of each check for mobile remote afterloaders required by § 35.647 for 3 years. The proposed rule also would specify in detail what information must be contained in each of these records.

Cost Impacts:

None anticipated. The current rule contains no section addressing records of additional technical requirements for mobile remote afterloaders. Three mobile remote afterloaders currently are licensed by Agreement States but recordkeeping requirements are already established by the individual Agreement State.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.126 Records of surveys (§ 35.2652).

The proposed rule in § 35.2652, a new section, would require that a licensee maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of the unit and would specify the records that must be maintained.

The proposed rule would parallel, with changes, the requirements for records of radiation surveys for teletherapy facilities in § 35.641 of the current rule. The proposed rule would require records to be maintained for the duration of use of the unit, rather than for the duration of the license. It would not require a record to be maintained for why the survey would be required; a plan of the areas surrounding the treatment room that would be surveyed; the measured dose rate at several points in each area, or the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area. This section of the proposed rule would reduce the cost impacts for licensees of teletherapy sources. The proposed rule also would create a new regulatory requirement for other therapy units. However, the net effect is anticipated to be small (i.e., <\$1,000).

Cost Impacts:

None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.127 Records of five-year inspection for teletherapy and gamma stereotactic surgery units (§ 35.2655).

The proposed rule in § 35.2655, a new section, would require that a licensee maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit and would specify the records that must be maintained.

The proposed rule would parallel, with changes, the requirements for 5-year inspections of teletherapy units in § 35.647 of the current rule. The costs of conducting the inspections would be estimated under that section of the proposed rule. The proposed rule would require records to be maintained for the duration of use of the unit, rather than for the duration of the license. It would not require a record to be maintained of the list of components replaced. Therefore, this section of the proposed rule would reduce the cost impacts for licensees of teletherapy sources.

Cost Impacts:

The current rule does not contain requirements for records of five-year inspections for gamma stereotactic radiosurgery units. A cost increase would be anticipated, as follows:

Assumptions:

Licensees:

Total licensees:	30
Increase in storage requirements:	2 cubic feet (about 1 file drawer)
Cost of storage:	\$1.50 per cubic foot
Total Annual Cost Increase from § 35.2655:	<\$1,000

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

SUBPART M**5.128 Reports of medical events (§ 35.3045).**

Paragraph 35.3045(b) would require licensees to notify NRC by telephone no later than the next calendar day after discovery of the medical event that involves an administration of byproduct material or radiation therefrom that meets or exceeds the criteria in §3045(a). Paragraph 35.3045(a) would require a licensee to report any administration of byproduct material or radiation therefrom that meets the definition in §35.3045(a)(1) and (2) and is not the direct result of intervention by the patient that could have been reasonably prevented by the physician. This reporting requirement is needed to ensure that NRC is aware of medical events and to promptly take any necessary actions based on the circumstances.

Paragraph 35.3045(c) would require licensees to submit a written report to NRC within 15 days of the discovery of the medical event. The report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it appears the precipitating event might be generic.

Paragraph 35.3045(d) would require the licensee to notify the referring physician and the individual affected by the medical event, or to that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Paragraph 35.3045(e) would require the licensee to furnish a written report of the medical event to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect the individual. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee. This report is needed to ensure that patients obtain a written report as a record of information furnished to them verbally.

Cost Impacts:

None anticipated. The changes to § 35.3045 of the proposed rule are not expected to substantially change the number or type of medical events to be reported under § 35.2045 from the number and type of misadministrations reported under the current rule.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change.

5.129 Reports of precursor events (§ 35.3046).

Paragraph 35.3046(a) would require that licensees notify the NRC Operations Center by telephone no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event. This report is needed to ensure that NRC is aware of defects that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

Paragraph 35.3046(b) would require the licensee to submit a written report within 15 days after discovery of the precursor event to the appropriate NRC Regional Office. The report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. This written report will ensure that NRC is aware of events that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

Cost Impacts:

The current rule contains no section addressing records of precursor events. Therefore, this section of the proposed rule would create cost impacts for all licensees, and for NRC and Agreement States to analyze and respond to reports of precursor events.

Assumptions:

Licensees:

Total anticipated annual precursor events	50
RSO/Authorized user precursor event report preparation time, hours	2
RSO/Authorized user hourly rate	\$100
Technical staff report preparation time, hours	2

Technical staff hourly rate	\$30
Clerical staff report preparation time, hours	1
Clerical staff hourly rate	\$18
Total Annual Cost Increase for licensees:	\$14,000
<u>NRC/Agreement States:</u>	
Total anticipated annual precursor events	50
NRC/Agreement States precursor event report review time, hours	4
NRC/Agreement States staff hourly rate	\$70
Total Annual Cost Increase for NRC and Agreement States:	\$14,000
Total Annual Cost Increase from § 35.3046:	\$28,000

5.130 Report of a dose to an embryo/fetus or a nursing child (§ 35.3047).

Paragraph 35.3047(a) would require the licensee to report any administration of byproduct material or radiation therefrom to a pregnant woman unless the administration was specifically approved, in advance, by the authorized user if the administration results in a dose that is greater than 5 mSv (500 mrem) effective dose equivalent to an embryo. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(b) would require the licensee to report any administration of byproduct material to a breast feeding woman, unless the administration was specifically approved, in advance, by the authorized user, if the administration results in a dose that is greater than 5 mSv (500 mrem) total dose equivalent to a nursing child. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(c) would require the licensee to notify by telephone the NRC Operation Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Paragraph 35.3047(d) would require the licensee to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). The written report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Cost Impacts:

Cost increases are anticipated from proposed requirements in § 35.3047(a) that would require licensees to report an administration of byproduct material or radiation to pregnant women unless the administration was specifically approved in advance by the authorized user if the administration results in a dose that is greater than 5 mSv (5 mrem) effective dose equivalent to an embryo and § 35.3047(b) requirements that would require licensees to report an administration of byproduct material or radiation to breastfeeding women unless the administration was specifically approved in advance by the authorized user if the administration results in a dose that is greater than 5 mSv (5 mrem) total dose equivalent to a nursing child. NRC anticipates that 50 such administrations would occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees:

Total annual licensee administrations:	50
Total report preparation time, hours:	10
Technical staff hourly rate:	\$30
Total Annual Cost Increase for licensees from § 35.3047(a) and (b):	\$15,000

Cost increases are anticipated from proposed requirements in § 35.3047(c) that would require licensees to notify by phone the NRC Operation Center within 5 days after discovery of a dose to an embryo/fetus or nursing child. NRC anticipates that 50 such administrations would occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees:

Total annual licensee administrations:	50
Total phone reporting time, hours:	0.5
Technical staff hourly rate:	\$30
Total Annual Cost Increase for licensees from § 35.3047(c):	\$1,000

Cost increases are anticipated from proposed requirements in § 35.3047(d) that would require licensees to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child. NRC anticipates that 50 such administrations would occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees:

Total annual licensee administrations:	50
Total report preparation time, hours:	8
Technical staff hourly rate:	\$30
Total Annual Cost Increase for licensees from § 35.3047(d):	\$12,000
Total Annual Cost Increase for licensees from § 35.3047:	\$28,000

Health and Safety Impacts:

None anticipated.

Benefits:

Provide NRC with information to determine the frequency of such events.

5.131 Reports of leaking sources (§ 35.3067).

This section would require that licensees report detection of a leaking source by submitting a written report within 5 days after a leakage test reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office. The report must include the model number and serial number, if assigned, of the leaking source; radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample, and the date of the test. This will enable NRC to promptly determine if the necessary follow-up actions are necessary following discovery of the leaking source.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

No health and safety impacts are anticipated.

Benefits:

Conforming change.

SUBPART N--ENFORCEMENT

The proposed rule would amend the former Subpart K to Subpart N and would make the following changes:

5.132 Violations (§ 35.4001).

Section 35.990 of the current rule specifies that the Commission may obtain an injunction or other court order to prevent specified violations.

The proposed rule would renumber § 35.990 as new § 35.4001, without other changes.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.133 Criminal penalties (§ 35.4002).

Section 35.991(a) of the current rule specifies that the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, or attempted violation of, or conspiracy to violate, any regulation issued under specified sections of the Act. Section 35.991(b) lists the regulatory sections that are not covered by criminal sanctions, because not issued under the specified sections of the Act.

The proposed rule would renumber § 35.991 as new § 35.4001 and would amend § 35.4001(b) to conform the section numbers to the numbering of the proposed rule.

The proposed amendment would not be expected to have any cost or health and safety impacts.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.134 Resolution of conflicting requirements during transition period (§ 35.4010).

Section 35.999 of the current rule specifies that if the rules in 10 CFR Part 35 conflict with the licensee's radiation safety program as identified in its license, and if the license was approved by the Commission before April 1, 1987, and has not been renewed since April 1, 1987, the requirements in the license will apply.

The proposed rule would renumber § 35.999 as new § 35.4010 and would amend the section to insert a new date.

The proposed amendment is not expected to have any cost or health and safety impacts.

Cost Impacts:

None anticipated.

Health and Safety Impacts:

None anticipated.

Benefits:

Conforming change to restructuring of 10 CFR Part 35.

5.135 Appendix A - Examining Organization or Entity.

The current rule does not contain an Appendix describing the requirements for an examining board or entity.

The proposed rule would add a new Appendix A specifying requirements for an examining board or entity to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.292(b)(3), 35.294(b)(3), 35.390(b)(3), 35.490(b)(3), or 35.690(b)(3).

Cost Impacts:

Review of applications for approval by the Commission of an examining board or entity are expected to involve cost impacts to NRC and to the organizations or entities.

Costs to NRC are estimated under §§ 35.50, 35.51, 35.55, 35.292, 35.294, 35.390, 35.490, and 35.690.

Costs to the entities or organizations are anticipated to require approximately 240 hours per organization or entity for the preparation of an application for approval at \$100 per hour. An estimated 39 organizations or entities may request approval.

Total Cost Increases of Appendix A to specialty boards to submit applications to NRC:	\$936,000.
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Health and Safety Impacts:

Ensures safety through review of potential examining boards of entities.

Benefits:

Ensures safety.

5.136 Dose limits for individual members of the public (10 CFR 20.1301).

10 CFR Part 20.1301(a) of the current rule provides that each licensee shall conduct operations so that certain dose limits are maintained for members of the public.

The proposed rule would amend 10 CFR Part 20.1301(a) to add a new paragraph 10 CFR Part 20.1301(a)(3), which would provide that notwithstanding the requirements in paragraph (a)(1), if the authorized user, as defined in 10 CFR Part 35, determines that it is appropriate in accordance with 10 CFR Part 35, the licensee may permit visitors to individuals confined in accordance with § 35.75 to receive a radiation dose greater than 1 mSv (0.1 rem) but not to exceed 5 mSv (0.5 rem).

The proposed rule would address a Petition for Rulemaking (PRM 20-24) dated April 7, 1996, from the University of Cincinnati. On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on the petition (PRM 20-24). All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of 1 mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC determined that the following alternatives should be evaluated:

- Alternative 1: retain the 1 mSv (0.1 rem) public dose limit

This alternative would evaluate the cost effectiveness of retaining the current dose limit of 1 mSv (0.1 rem) to an individual exposed to a hospitalized radiation patient. The petition would be denied on the basis that there are sufficient provisions within 10 CFR Part 20.1301(c) to allow case-by-case use of the 5 mSv (0.5 rem) annual dose limit for visitors of radiation patients.

- Alternative 2: 5 mSv (0.5 rem) public dose limit for specified visitors of radiation therapy patients

This alternative would incorporate the provisions requested by the petitioner and would evaluate the cost effectiveness of amending 10 CFR Part 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to radiation therapy patients and to direct the authorized user to provide basic radiation safety instruction to visitors to minimize their doses while visiting the patient and require licensees to badge those visitors whose total effective dose equivalent would exceed 1 mSv (0.1 rem).

- Alternative 3: 5 mSv (0.5 rem) public dose limit for visitors of radiation patients without licensee prescriptions

This alternative would evaluate the cost effectiveness of amending 10 CFR Part 20.1301 to permit, on a case-by-case basis, a radiation dose limit of 5 mSv (0.5 rem) in a year for any adult visitor to individuals administered radioactive material. No requirement for visitor badging or recordkeeping would be included in this alternative.

Cost Impacts:

Costs of safety instructions:

Alternatives 1 and 3 would have no requirement for providing ALARA instructions to either the hospitalized patient or the visitor to the radiation patient and therefore would have no related cost. However, the rule associated with Alternative 2 would impose additional costs for providing basic radiation safety instruction to the 4,650 patients and 9,300 visitors. A cost of \$22 per radiation patient or \$102.3 thousand per year would be the estimated total cost of providing instruction for Alternative 2. This estimate, obtained from NUREG-1492 (NRC 1997), assumes that the licensee would spend 10 minutes providing instruction to the patient and visitors. Using a \$70 hourly rate, total annual instruction costs for Alternative 2 are estimated at \$54,250.

Costs of recordkeeping:

Alternatives 1 and 3 have no recordkeeping requirements and therefore have no related costs. However, the rule associated with Alternative 2 would impose additional paperwork and recordkeeping requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide therapeutic administrations of radiopharmaceuticals to hospitalized patients. A record documenting the receipt of informed consent from the visitor to potentially

receive up to the 5 mSv (0.5 rem) dose limit, receipt of basic safety instruction, and external radiation dosimetry records must be maintained for 3 years. It is estimated that approximately 4,650 procedures per year would be subject to these requirements. A cost of \$17 per radiation patient or \$79.1 thousand per year is the estimated total cost for record keeping. This estimate, obtained from NUREG-1492 (NRC 1997), assumes that the licensee would spend 8 minutes per patient documenting the provisions of instruction and dosimetric monitoring. Using a \$70 hourly rate, annual recordkeeping costs are anticipated to be \$43,400.

Costs of Providing Dosimetry:

Alternatives 1 and 3 would have no dosimetry requirements, and therefore, would have no related costs. However, the rule associated with Alternative 2 would impose new dosimetry and paperwork requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide diagnostic and therapeutic administrations of radiopharmaceuticals to hospitalized patients. The cost of the dosimeter and dosimeter processing is estimated at \$2.50 each. Labor associated with TLD or film badge issuance to and return from the visitor, and badge receipt from and shipment to a NVLAP accredited processing contractor is estimated at \$14.00. A cost of \$16.50 per visitor is estimated. This results in an annual estimated cost of approximately \$153,400.

Qualitative Benefits:

Retention of patients in a hospital by design necessitates that the patient be "isolated" and that human contact, inclusive of family members, is either minimized or avoided. Such isolation may bring about numerous changes and impositions in the lives of the patient and family members. The deterioration in the quality of life brought on by illness is frequently referred to as an "intangible cost." For thyroid cancer or thyroid dysfunction requiring therapeutic doses of I-131, for example, a deterioration in the quality of life may be precipitated by the loss of bodily function, a lifetime dependence on medication, hormonal instability, uncertainty of normal life-expectancy, disruption of normal daily routines, and reduced financial security related to employment, lost earnings, and medical expenses.

While some of these elements of intangible costs are the result of the disease itself, others such as disruption of normal routines, social isolation, and enhanced financial strain are clearly elements of psychological costs that are directly related to patient retention. Allowing greater visitor access to the patient while they are under licensee control will provide an unquantifiable amount of physical and emotional benefit to the patient and the visitor alike. However, the conversion of this benefit into an equivalent dollar amount is complex, highly subjective, and

dependent upon the individual situation. Instead, this analysis uses a qualitative and reasonable approach to scope the range of possible responses.

Health and Safety.

Selection of the 5 mSv (0.5 rem) total effective dose equivalent per year criterion would be consistent with: (1) the Commission's provision in 10 CFR 20.1301(c) for authorizing a licensee to operate up to this limit; (2) the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection"; (3) the recommendations of the NCRP in NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation"; and (4) the International Atomic Energy Agency (IAEA) in Safety Series No. 115, "International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources." Each of these documents provide a basis for allowing visitors to radiation patients to receive annual doses up to 5 mSv (0.5 rem).

The ICRP recommends that dose limits should not be applied to medical exposures, if the medical exposure is intended to provide a direct benefit to the exposed individual and the dose is kept as low as is compatible with the medical purposes. In this instance, medical exposure would be defined to include "exposures incurred by individuals as part of their own medical diagnosis and treatment and to exposures (other than occupational) incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis and treatment."

Current NCRP guidance regarding radiation protection dose limits (NCRP Report No. 116) recommends that any activity which involves radiation exposure must be justified on the basis of the expected benefits to society exceeding the overall cost, the total societal detriment is maintained ALARA, economic and social factors are taken into account, and individual dose limits are applied to ensure that the procedures of ALARA and justification do not result in individuals exceeding levels of acceptable risk. Based upon this basic radiation protection philosophy, NCRP Commentary 11 (1995), "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," noted that members of a radionuclide therapy patient's family are likely to perceive that the visitors also will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Consequently, the NCRP Commentary No. 11 recommends that the dose limit for adult family members⁸ "exposed to a radionuclide therapy patient should not exceed 50 mSv annually. When family members are likely to receive exposures in excess of 5 mSv annually, they should receive appropriate training and individual monitoring."

⁸ NCRP Commentary No. 11 defines family member as "any person who spends a substantial amount of time in the company of the patient on a regular basis, providing support and comfort, and whom the patient considers a member of their "family," whether by birth, by marriage, or by virtue of a close, caring relationship."

The IAEA description of dose limits for individual members of the general public is similar to the recommendations of the ICRP and NCRP. IAEA-115 specifies that:

"II-9. The dose limits set out in this part shall not apply to comforters or patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of the patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv."

Preferred Alternative:

To determine the preferred alternative, the costs and benefits that result when Alternatives 2 and 3 are each compared with Alternative 1 (the status quo) were analyzed. Both Alternatives 2 and 3 allow greater visitor access to the radiation patient, hence a larger collective dose is associated with these alternatives. Any potential detriment associated with this additional collective dose is offset by the qualitative benefit the patient and visitor receive under Alternatives 2 and 3. No monetary value was placed upon the qualitative benefit to either the patient or the specified visitor under each alternative. However, a net cost would be associated with Alternative 2 to provide visitor badging, instruction and recordkeeping. No such requirements would be associated with Alternative 3. Consequently, Alternative 2 would have a net cost of \$334,800 relative to Alternatives 1 or 3. On a per patient basis, this amounts to approximately \$62. The net cost of Alternative 2, using a \$70 hourly rate and the existing \$153,400 annual cost of providing dosimetry, is anticipated to be \$251,050.

6. COSTS AND BENEFITS FOR ALTERNATIVES FOR REVISIONS TO 10 CFR PART 35

6.1 Summary of Estimated Annual Costs of Proposed Rule

Table 6-1 presents a summary of the estimated values and impacts of the revisions to 10 CFR Part 35. For each regulatory change described above, Table 6-1 lists the total costs avoided (-) or total added costs (+) estimated for that section.

Table 6-1. Summary of the Proposed Rule's Cost Effects

Subpart	Section	Licensee Costs (nominal \$)	NRC and Agreement States Costs (nominal \$)	Total Costs (nominal \$)
A	35.1	0	0	0
	35.2	0	0	0
	35.5	0	0	0
	35.6	0	0	0
	35.7	0	0	0
	35.8	0	0	0
	35.10	0	0	0
	35.11	0	0	0
	35.12	-1,000	0	-1,000
	35.13	-16,000	-33,000	-49,000
	35.14	1,000	1,500	2,500
	35.15	0	0	0
	35.18	0	0	0
	35.19	0	0	0
B	35.20	0	0	0
	35.21	0	0	0
	35.22	-3,337,000	0	-3,337,000
	35.23	0	0	0
	35.24	536,000	0	536,000
	35.26	-16,000	0	-16,000
	35.27	-1,000,000	0	-1,000,000
	35.29	0	0	0
	35.32	-6,038,000	-2,413,000	-8,451,000
	35.33	0	0	0
	35.40	0	0	0
	35.41	0	0	0
	35.49	0	0	0

Table 6-1. Summary of the Proposed Rule's Cost Effects (continued)

Subpart	Section	Licensee Costs (nominal \$)	NRC and Agreement States Costs (nominal \$)	Total Costs (nominal \$)
	35.50	14,000	168,000	182,000
	35.51	15,000	168,000	183,000
	35.55	3,000	68,000	71,000
	35.57	0	0	0
	35.59	0	0	0
C	35.60	-385,000	0	-385,000
	35.61	-156,000	0	-156,000
	35.62	0	0	0
	35.63	0	0	0
	35.65	-5,000	-69,000	-74,000
	35.67	-57,000	0	-57,000
	35.69	986,000	0	986,000
	35.70	0	0	0
	35.75	0	0	0
	35.80	0	0	0
	35.90	0	0	0
	35.92	-500	-600	-1,000
D	35.100	0	0	0
	35.120	0	0	0
	35.200	0	0	0
	35.204	-1,132,000	0	-1,132,000
	35.205	0	0	0
	35.220	0	0	0
	35.290	8,000	100,000	108,000
	35.292	248,000	50,000	298,000
	35.294	0	0	0
E	35.300	0	0	0
	35.310	0	0	0
	35.315	0	0	0
	35.320	0	0	0
	35.390	1,045,000	68,000	1,113,000
F	35.400	-2,000	-2,000	-4,000
	35.404	-2,000	-2,000	-4,000
	35.406	0	0	0
	35.410	0	0	0
	35.415	0	0	0
	35.420	0	0	0

Table 6-1. Summary of the Proposed Rule's Cost Effects (continued)

Subpart	Section	Licensee Costs (nominal \$)	NRC and Agreement States Costs (nominal \$)	Total Costs (nominal \$)
	35.432	3,812,000	0	3,812,000
	35.490	8,000	100,000	108,000
G	35.500	-1,000	-1,000	-2,000
	35.520	0	0	0
	35.590	0	67,000	67,000
H	35.600	0	0	0
	35.604	0	0	0
	35.605	0	0	0
	35.606	0	0	0
	35.610	0	0	0
	35.615	-187,000	0	-187,000
	35.620	0	0	0
	35.630	0	0	0
	35.632	0	0	0
	35.633	0	0	0
	35.635	0	0	0
	35.636	0	0	0
	35.641	0	0	0
	35.642	0	0	0
	35.643	0	0	0
	35.644	0	0	0
	35.645	-3,000	0	-3,000
	35.647	0	0	0
	35.652	0	0	0
	35.655	0	0	0
	35.657	0	0	0
	35.690	12,000	100,000	112,000
J	35.900	0	0	0
	35.910	0	0	0
	35.920	0	0	0
	35.930	0	0	0
	35.932	46,000	0	46,000
	35.934	46,000	0	46,000
	35.940	0	0	0
	35.941	0	0	0
	35.950	0	0	0
	35.960	0	0	0

Table 6-1. Summary of the Proposed Rule's Cost Effects (continued)

Subpart	Section	Licensee Costs (nominal \$)	NRC and Agreement States Costs (nominal \$)	Total Costs (nominal \$)
	35.961	0	0	0
	35.980	0	0	0
K		0	0	0
L	35.2024	-6,000	0	-6,000
	35.2026	-10,000	0	-10,000
	35.2040	0	0	0
	35.2045	0	0	0
	35.2060	0	0	0
	35.2061	0	0	0
	35.2063	0	0	0
	35.2067	-7,000	0	-7,000
	35.2070	0	0	0
	35.2075	0	0	0
	35.2080	0	0	0
	35.2092	0	0	0
	35.2204	-14,000	0	-14,000
	35.2310	0	0	0
	35.2404	0	0	0
	35.2406	0	0	0
	35.2432	0	0	0
	35.2605	0	0	0
	35.2630	0	0	0
	35.2632	0	0	0
	35.2633	0	0	0
	35.2635	0	0	0
	35.2642	0	0	0
	35.2643	0	0	0
	35.2645	0	0	0
	35.2647	0	0	0
	35.2652	0	0	0
	35.2655	0	0	0
M	35.3045	0	0	0
	35.3046	14,000	14,000	28,000
	35.3047	28,000	0	28,000
	35.3067	0	0	0

Table 6-1. Summary of the Proposed Rule's Cost Effects (continued)

Subpart	Section	Licensee Costs (nominal \$)	NRC and Agreement States Costs (nominal \$)	Total Costs (nominal \$)
N	35.4001	0	0	0
	35.4002	0	0	0
	35.4010	0	0	0
Appendix A		936,000	0	936,000
10 CFR 20.1301	Alternative 2	251,000	0	251,000
TOTAL COSTS (SAVINGS)		(\$4,366,500)	(\$1,616,100)	(\$5,982,500)

6.2 Estimated Lifetime Costs of Proposed Rule

NRC estimates the revisions to 10 CFR Part 35 would result in total annual cost savings of \$5,982,500.

Based on OMB guidance, lifetime costs are estimated using a 7 percent discount rate, which approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years.

Using both a 7 percent discount rate and a 20 year time-horizon (i.e., base year plus 20), NRC estimates the lifetime cost savings of 10 CFR Part 35 to be \$69,361,000 in 1998 dollars.

7. DECISION RATIONALE

7.1 Decision rationale for revisions to 10 CFR Part 35

1. Alternative 2 is less expensive than Alternative 1 (status quo).
2. Overall costs of Alternative 2 are lower than the status quo, the testing requirements for Radiation Safety Officers, medical physicists, nuclear pharmacists, individuals performing dilution and uptake studies, individuals performing imaging and localization studies, individuals using unsealed material for therapeutic use, individuals performing brachytherapy, and individuals using therapeutic medical devices are higher than under the status quo alternative. However, qualitative benefits are expected from separately testing knowledge of radiation safety. In addition, a substantial component of the cost of testing is a one-time cost to NRC to certify the organizations approved to conduct the testing.

7.2 Decision rationale for PRM 20-24

1. All of the alternatives are acceptable according to generally accepted radiation protection principles, such as those expressed by NRC, NCRP, IAEA and ICRP (see Section 4.3, Evaluation of the Alternatives with Respect to Accepted Radiation Protection Principles).
2. Alternative 1 (status quo) is the least expensive to the public compared to Alternative 2, but Alternative 1 also conveys the least physical and emotional benefit to the patient. If the qualitative benefits of increased visitor-patient access is overlooked, a benefit which has not been expressed in dollar terms, the additional cost of Alternative 2 relative to Alternative 1 is about \$334,800 per year. The preponderance of this additional cost is associated with badging visitors and providing ALARA instruction.
3. Alternative 1 and Alternative 3 have essentially the same relative licensee costs. The major difference is the qualitative benefits that the patient and visitor receive under Alternative 3.
4. Alternative 3 relative to Alternative 2 also has a net cost differential of \$334,800 per year, mostly due to less prescriptive nature of the alternative in that there is no requirement to provide dosimetry and basic radiation safety instruction for each visitor and there are reduced recordkeeping requirements. Also, both Alternative 2 and Alternative 3 bestow similar qualitative benefits to the patient and visitors because of the increased visitor access. Thus, Alternative 3 is more cost effective in comparison with Alternative 2.

8. IMPLEMENTATION

No impediments to implementation of any of the alternatives have been identified.

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ATTACHMENT 9

Draft Environmental Assessment

**DRAFT ENVIRONMENTAL ASSESSMENT
FOR PROPOSED AMENDMENTS TO 10 CFR PART 35
"MEDICAL USE OF BYPRODUCT MATERIAL" AND
PETITION FOR RULEMAKING
"REVISION OF DOSE LIMIT FOR MEMBERS OF THE
PUBLIC EXPOSED TO HOSPITALIZED PATIENTS"
(PRM 20-24)
FINDING OF NO SIGNIFICANT IMPACT**

1. Background

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the medical use of byproduct material. The NRC has examined the issues surrounding its medical use program, and is now undertaking a comprehensive revision of Part 35. The proposed revision is one component of the Commission's overall program for revising its regulatory framework for medical use. The overall goals of this program are to focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, to make the regulatory requirements more risk-informed, performance-based, and to reduce the prescriptive nature of some of the current requirements. The proposed rule is intended to provide greater flexibility to licensees in providing high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician, while also providing for protection of patients and the public. In addition, as a result of the development of new medical uses involving byproduct material, certain portions of the existing regulations in Part 35 need to be updated or expanded.

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 1,900 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. In addition, there are approximately 5,000 State licenses in Agreement States authorizing the medical use of byproduct material. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients, and recognizes that nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. The Commission's regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interests of their patients.

The major features of the proposed amendments address: (1) restructuring of Part 35 to incorporate all of the requirements that are specific for a modality into the same subpart; (2) elimination of the requirement for a Radiation Safety Committee to allow a licensee more flexibility in carrying out the responsibilities for the radiation safety program; (3) requirements for written directives

to provide high confidence that the physician's prescription is administered in accordance with the physician's directions and to focus on those requirements that are essential for patient safety; (4) reporting of medical events and precursor events; (5) reduction of requirements in Part 35 that are in other parts of 10 CFR, particularly Part 20; (6) reduction in the number and type of licensing actions required under Part 35; (7) revision of the training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists to focus more on radiation safety; (8) reductions in recordkeeping and/or reporting requirements when there would be no health and safety impact; and (9) revisions to the decay-in-storage provisions of Part 35.

2. Need for the Amendment

First, amendments to Subpart B - General Administrative Requirements, Subpart C - General Technical Requirements, and to Subparts D through H are needed to reduce the prescriptive nature of certain requirements of Part 35, which result in costs to licensees without commensurate health and safety benefits. Although licensees currently can seek, through license amendments, to adopt exemptions or alternatives to some prescriptive requirements, such licensing actions are costly both to the licensee and to NRC.

Second, amendments to Subparts D through H are needed for certain established medical uses, such as high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery. Regulation of these technologies currently is primarily through license conditions.

Third, amendments to Part 35 are needed to provide for the licensing of new medical uses in a timely manner. Currently, new medical uses must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for medical uses that are not specifically addressed in Part 35.

Fourth, the regulations in 10 CFR 35.2 regarding thresholds for "misadministrations" are not entirely dose based. Also, new medical uses are not addressed under the current criteria, and the current requirements do not address "patient intervention" or provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, the regulations currently do not require the identification and reporting of precursor events. This reduces the likelihood that NRC is informed of conditions or incidents that would result in a medical event involving a patient or human research subject, worker or member of the public.

Sixth, regarding training and experience, Subpart J includes requirements for clinical experience in all modalities, even though diagnostic procedures present a lower overall risk than that

presented by therapeutic procedures. Therefore, NRC requirements for clinical experience may not be necessary for most diagnostic procedures.

Seventh, the regulations permit medical use licensees to hold byproduct material with a physical half-life less than 65 days for decay-in-storage, if it holds the byproduct material for decay before disposal in ordinary trash for a minimum of ten half-lives. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

Finally, a Petition for Rulemaking (PRM 20-24) received by the Commission requests a revision from 1mSv (0.1 rem) to 5mSv (0.5 rem) of the public dose limit for specified visitors of radiation therapy patients who are not released in accordance with §35.75.

In its Staff Requirements Memorandum (SRM)-COMSECY-96-057, "Materials/Medical Oversight (SDI 7 dated March 20, 1997, the Commission directed the NRC staff to revise 10 CFR Part 35, the NRC's regulations for the use of byproduct materials in medicine; associated guidance documents; and, if necessary, the Commission's 1979 Medical Policy Statement. The Commission's SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. During development of the rule and associated guidance, the Commission directed the NRC staff to consider the following:

- (1) Focusing Part 35 on those procedures that pose the highest risk;
- (2) Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures;
- (3) The best way to capture not only medical events, but also precursor events that could lead to a medical event;
- (4) The need to change from the term "misadministration" to "medical event" or other comparable terminology;
- (5) Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;
- (6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety; and
- (7) The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC's needs.

The staff identified the following issues that also needed to be addressed:

- (1) Radiation Safety Committee (RSC) requirements;
- (2) Threshold for reportable events; and
- (3) Training and experience requirements for authorized users, Radiation Safety Officers, authorized nuclear pharmacists, and authorized medical physicists.

3. Alternatives

The following alternatives were considered in this rulemaking:

Alternative One: Status quo.
Continue 10 CFR Part 35 without revision. Deny PRM 20-24 and retain the 1mSv (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the 5mSv (0.5 rem) annual dose limit for visitors of radiation patients.

Alternative Two: Comprehensive revision of Part 35.
Promulgate comprehensive proposed amendments that focus NRC regulation of medical uses of byproduct material on those medical procedures that pose the highest risk, restructure the regulatory requirements into more risk-informed, performance-based standards, and relax or eliminate certain prescriptive requirements currently contained in Part 35. Promulgate new requirements pertaining to low dose-rate, pulsed dose-rate, and high dose-rate remote afterloaders, gamma stereotactic radiosurgery units, and mobile remote afterloaders. Promulgate a new dose limit of 5mSv (0.5 rem) for visitors of radiation patients, as requested under PRM 20-24.

The no-action alternative is not favored because, based on the information presented to it, the Commission believes that its current regulations may be unnecessarily prescriptive and are not sufficiently risk-informed and performance-based. The Commission believes that greater flexibility can be provided, while continuing adequate protection of public health and safety.

4. Impact on the Public and the Environment

The proposed amendments would have no significant impact on the public and the environment.

The proposed amendments to the general administrative requirements and general technical requirements, and to Subparts D through H of Part 35, reducing the prescriptive nature of certain sections of Part 35, and deleting requirements that are covered in other parts of NRC's regulations will have no significant impact on public health and safety, occupational health and safety, or the environment. First, 10 CFR Part 20 continues to require medical licensees to develop ALARA programs; possess, use, calibrate, and check instruments; conduct surveys for contamination and ambient radiation exposure; and ensure the control of volatiles and gases. Reliance on 10 CFR Part 20 is expected to have no significant impact on public health and safety, occupational health and safety, or the environment. Second, the amendments to Part 35 reducing the overly prescriptive nature of certain requirements and making them more risk-informed and performance-based will allow licensees greater flexibility in the development and implementation of their radiation safety programs associated with the use of byproduct materials in medicine, but the amendments are expected to result in no significant impact on public health and safety, occupational health and safety, or the environment.

The proposed amendments to Subparts D through H that place the basis for regulation of high dose-rate brachytherapy, low dose-rate brachytherapy, pulsed dose-rate brachytherapy, and gamma stereotactic radiosurgery units into the requirements in Part 35 will codify existing license conditions. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The proposed amendments to Part 35 regarding new medical uses provide information that is needed for submittal of a license application, which should result in expedited licensing for new medical uses. This is expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The proposed amendments to the requirements for reporting medical events and precursor events would have a positive impact on public health and safety and the environment by helping to ensure that affected persons and the NRC are informed about conditions or incidents that have caused, or could cause, a medical event involving a patient or human research subject, worker or member of the public.

The proposed amendments to the training and experience requirements in Part 35 focus on knowledge and experience that is integral to radiation safety. These changes are expected to have no significant impact on public health and safety, occupational health and safety, and the environment.

The proposed amendment of § 35.92, pertaining to decay-in-storage, provides that byproduct material with a physical half-life of less than 120 days may be held for decay-in-storage and

eliminates the requirement that such material be held for a minimum of ten half-lives. Licensees will be required to monitor the material at the container surface before disposal to verify that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set at its most sensitive scale and with no interposed shielding. These changes are expected to have no significant impact on public health and safety, occupational health and safety, or the environment.

The proposed amendment in 10 CFR 20.1301 to permit, on a case-by-case basis, visitors to individuals who are not released in accordance with 10 CFR 35.75 to receive up to 5mSv (0.5 rem) is expected to result in an increase in radiation exposure to the public. However, this alternative is consistent with generally accepted radiation protection principles, such as those expressed by the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the International Atomic Energy Agency (IAEA).

Therefore, with the exception of the proposed amendment to 10 CFR 20.1301, the proposed amendments to Part 35 will not lead to any increase in radiation exposure to the public, health care workers, or the environment. Revisions to the regulatory specifications to reduce the prescriptiveness of the requirements are not expected to lead to any increase in radiation exposure to the public, health care workers, or the environment, beyond the exposures currently resulting from the administration of byproduct material or radiation from byproduct material. Revisions to the requirements to focus on those requirements that are essential for patient safety will not lead to any increase in radiation exposure to the public, health care workers, or to the environment. These revisions would not increase radiation exposure because the proposed performance-based regulations would provide for adequate protection. Reduction or elimination of duplication or overlaps between Part 35 and other parts of 10 CFR, including particularly Part 20, will not lead to any increase in radiation exposure to the public, health care workers, or to the environment.

5. List of Agencies and Persons Consulted and Identification of Sources Used

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. The NRC published an announcement of its proposed revision of Part 35 and a request for public input on NRC's medical use program in a Federal Register notice on August 6, 1997 (62 FR 42219). In response, NRC received numerous written comments, which are reflected in the proposed revision.

To ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking alternatives, the Commission convened or participated in a number of public workshops to discuss the fundamental approaches and issues to be addressed in the proposed rulemaking. NRC participated in a Part 35 workshop held during the Organization of Agreement States' 1997 All Agreement State meeting on October 18, 1997 in Los Angeles, California. (See 62 FR 52513; October 8, 1997) The All Agreement States workshop was attended not only by representatives of the 30 Agreement States, but also by the public. NRC convened two facilitated public workshops,

in Philadelphia, Pennsylvania on October 28, 29, and 30 and in Chicago, Illinois on November 12, 13, and 14, 1997. (See 62 FR 53249; October 14, 1997) These workshops were attended by nuclear medicine physicians; radiation oncologists; other specialists (e.g., cardiologists, radiologists); radiation safety officers; medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients' rights advocates; Agreement States; Federal agencies; and members of the public. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an NRC advisory committee, discussed the issues raised by the proposed rulemaking in its semiannual meetings on September 25 and 26, 1997, and March 1 and 2, 1998. Both of the ACMUI meetings were open to the public. Finally, NRC staff participated in meetings with numerous groups representing physicians, pharmacists, medical physicists, technicians, and other stakeholders, including the following:

Interactions with Medical Professional Societies

Date	Location	Society
6/4/97	San Antonio, TX	Society of Nuclear Medicine American College of Nuclear Physicians
6/11/97	Lake Tahoe, CA/NV	American College of Medical Physicists
9/7/97	Atlanta, GA	American College of Radiology
9/16/97	Rockville, MD	American College of Radiation Oncology
9/26/97	San Francisco, CA	American Association of Clinical Endocrinologists
9/97	Professional Journal Notice	Oncology Nursing Services
10/16/97	Chicago, IL	American Hospital Association
10/18/97	Los Angeles, CA	Organization of Agreement States American Hospital Association
10/20/97	Orlando, FL	American Society of Therapeutic Radiology and Oncology
10/22/97	Bethesda, MD	American College of Cardiology American Society of Nuclear Cardiology
12/2/97	Chicago, IL	Radiation Society of North America
12/18/97	Rockville, MD	Society of Nuclear Medicine
2/1/98	Las Vegas, NV	Society of Nuclear Medicine

Public input also was obtained by holding open meetings of the government groups developing the revised rule language; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops.

In addition, the rulemaking process is using a working group, steering group, and guidance consolidation team that includes not only members from the NRC Headquarters offices, but also members from the regional licensing and inspection staff that are in frequent contact with NRC's

medical licensees. Representatives of two Agreement States and a non-Agreement State are members of the groups developing the rule and guidance. The Agreement State representative on the working group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process will enhance development of corresponding rules in State regulations and will provide an early opportunity for State input. In addition, it will allow the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance are noted in the NRC meeting announcements and are open to the public.

The NRC has benefitted from all of the comments and interactions during development of the proposed revision of Part 35, and has planned public workshops during the 75-day public comment period on the rulemaking.

6. Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the proposed amendments, if adopted, would be a major Federal action but would not significantly affect the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendments would relax certain requirements and eliminate other procedural restrictions associated with the medical use of byproduct material. The Commission believes these proposed amendments would provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this proposed rule, if adopted, would not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

ATTACHMENT 10

Congressional Letters



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, D.C. 20555-0001

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed rulemaking, to be published in the Federal Register for a 75-day public comment period (Enclosure 1). A copy of the press release for the rulemaking provided in Enclosure 2.

The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise its regulations in 10 CFR Part 35, "Medical Uses of Byproduct Material," as part of an overall program to revise the Commission's regulatory framework for medical use. The goal of this proposed rulemaking is to restructure Part 35 into a risk-informed, more performance-based regulation that focuses the regulations on those medical procedures that pose the highest risk, from a radiation safety aspect, with a subsequent decrease in the oversight of low-risk activities. Another component of the program, revision of NRC's 1979 "Medical Use Policy Statement," is being separately published and transmitted to the Subcommittee.

The process used to revise Part 35 has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and an early "strawman" revision of the draft proposed rule on the Internet and in NRC's Public Document Room; and convening public workshops. The staff benefitted from these interactions and received many useful comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Representative Ralph Hall



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the Subcommittee's information is a copy of a notice of a proposed rulemaking, to be published in the Federal Register for a 75-day public comment period (Enclosure 1). A copy of the press release for the rulemaking is provided in Enclosure 2.

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The process used to revise Part 35 has provided more opportunity for input from potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards; putting background documents, options for the more significant regulatory issues associated with the rulemaking, and an early "strawman" revision of the draft proposed rule on the Internet and in NRC's Public Document Room; and convening public workshops. The staff benefitted from these interactions and received many useful comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:

1. Federal Register Notice
2. Press Release

cc: Senator Bob Graham

ATTACHMENT 11

Press Release

Draft press release -- 5/20/98, 10:35 a.m.

**NRC PROPOSES EXTENSIVE REVISIONS TO REGULATIONS
ON MEDICAL USES OF RADIOACTIVE MATERIAL**

The Nuclear Regulatory Commission is proposing extensive revisions to its regulations on medical uses of radioactive material. The revisions, designed to be risk-informed and performance-based, focus regulation on the medical procedures that pose the highest risk from a radiation safety aspect.

The NRC regulates the use of radioactive material in medical diagnosis and treatment, as well as research. The material is administered to about eleven million patients a year.

In developing the proposed changes to the regulations, the NRC provided extensive opportunities for public input. Publicly announced meetings and workshops were held last year and this year where rulemaking alternatives for significant "cross-cutting issues" were discussed. The alternatives for the cross-cutting issues were discussed with the NRC's Advisory Committee on the Medical Uses of Isotopes, as well as with state regulators, medical professional societies, and the public at meetings in Philadelphia and Chicago. In addition, the rulemaking alternatives and an early "strawman" version of the NRC staff's proposed revisions to the regulations were made available for comment on the Internet and in the NRC's Public Document Room in Washington, DC.

In general, the proposed changes to the regulations reflect an overall change in regulatory philosophy to make the regulations performance based and to delete some of the more detailed requirements. An applicant for an NRC medical-use license would have to develop and implement procedures, but would no longer be required to submit

those procedures as part of the license application. Further, licensees would have maximum flexibility in developing their procedures, because most of the requirements in the proposed changes to the regulations are stated in terms of the objectives to be achieved, rather than stated with a list of prescriptive details.

The significant cross-cutting issues that were identified, and their resolutions in the proposed revisions to the regulations, are:

(1) Patient notification/reportable events -- The requirements in the current regulations for notifying individuals following a misadministration would remain unchanged, with the exception of substituting the term “medical event” for “misadministration.” The term, defined in detail in the proposed revisions to the regulations, generally refers to the administration of radioactive materials or radiation in a manner that differs substantially from the physician’s direction. Using “medical event” responds to objections that the term “misadministration” has possible connotations of carelessness and harm, which is not always the case. In addition, “medical event” is consistent with terms used to characterize events in non-medical activities regulated by the NRC. The proposed regulations would continue to require that, when a medical event occurs, licensees must notify the NRC, the referring physician and the affected patient -- unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. If the patient is a minor, or is unconscious and incapable of comprehending the information, it is expected that the licensee would report to the patient’s responsible relative or guardian rather than to the patient.

(2) Radiation safety committee -- The proposed revisions to the regulations delete the requirement for a medical institution licensee to have a radiation safety

committee, with specified membership and duties, to oversee the use of radioactive material. The key functions of the committee would be transferred to licensee management. The proposed regulations specify the responsibilities for and functions to be accomplished by the radiation safety program, including some of the functions previously listed as those of the radiation safety committee.

(3) Quality management program -- Provisions in this area have been revised to focus more on patient safety. Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the proposed revisions to the regulations require licensees to have written directives for procedures involving greater risk. Licensees would also have to develop, implement and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician's written directive. This proposed revision not only eliminates unnecessary details, but is more consistent with the recently proposed revision to the agency's NRC's medical policy statement, which states that "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides in accordance with the physician's directions."

(4) Training and experience -- Requirements in both the current regulations and the proposed revisions differ for diagnostic versus therapeutic uses of nuclear material. The proposed regulations basically retain the current training requirements for therapeutic uses of sealed sources of radioactive material because of the high risk associated with the types of material in such uses. However, the proposed revisions would reduce some of the training requirements for diagnostic and therapeutic procedures using radioactive materials in unsealed form, because of the lower risk

associated with these procedures. Training and experience were the primary concerns expressed by the public comments during development of the proposed changes to the regulations. Most of the commenters thought the current requirements should be retained. Under the proposed revisions, the current training requirements would stay in effect for two years to allow licensees time to implement the new requirements. During the intervening period, licensees would have the option of meeting either the current or the revised requirements.

(5) Precursor events -- The proposed revisions to the regulations require licensees to notify the NRC after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), radioactive material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer or an authorized user, could lead to a medical event.

The proposed changes to the regulations also address a petition for rulemaking filed by the University of Cincinnati. The petition requests a 500-millirem radiation dose limit for certain individuals visiting patients who are required to be confined to the hospital while receiving radiation treatment, where the visitors are determined by the physician to be necessary for the patient's emotional or physical support. The current limit of 100 millirems for visitors is the same as for members of the public under other circumstances. The proposed regulations would respond to this petition by allowing licensees the discretion to permit visitors to receive up to 500 millirems in a year from exposure to hospitalized radiation patients.

In addition, the proposed changes add a requirement for reporting unintended radiation exposure of an embryo, fetus, or nursing child, and add specific requirements for medical uses of radiation by a licensee at temporary job sites and for specific

technologies that are not currently addressed in the regulations. They also add a section to allow easier licensing of new medical procedures that use radioactive material or radiation.

Details of these and other aspects of the proposed changes to the regulations are contained in a Federal Register notice to be published shortly. Interested persons are invited to submit comments within 75 days of publication of the Federal Register notice to the Secretary, U.S. Nuclear Regulatory Commission, Attention: Rulemakings and Adjudications Staff.

The NRC plans to hold three public meetings in August and September to discuss the proposed revisions to the regulations. Details of time and place will be announced later.

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ATTACHMENT 12

OMB Clearance Package

FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)
AND
NRC FORM 313
APPLICATION FOR MATERIAL LICENSE, AND
SUPPLEMENTAL FORMS
NRC FORM 313A, TRAINING AND EXPERIENCE AND
NRC FORM 313B, PRECEPTOR STATEMENT
(3150-0120)
AND
10 CFR PART 20
STANDARDS FOR PROTECTION AGAINST RADIATION
(3150-0014)

COMPLETE REVISION OF PART 35

Description of the Information Collection

Part 35 of Title 10 of the Code of Federal Regulations contains the Nuclear Regulatory Commission's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material.

This clearance package covers the requirements for all sections of Part 35. It reflects the elimination of 10 CFR §§ 35.32 and 35.33, currently cleared under OMB clearance number 3150-0171, "Quality Management Program and Misadministrations." It also incorporates the burden approved for the final rule for 10 CFR §35.75, "Criteria for the Release of Individuals Administered Radioactive Material," which was approved subsequent to the last Part 35 extension renewal. The recordkeeping and reporting requirements of Part 35 have been centralized into two Subparts: Subpart L - Records (§§ 35.2024-2655) and Subpart M - Reports (§§ 35.3045-3067). Cross references to the recordkeeping requirements appear in other related portions of the Part 35 rule, but these cross references do not constitute additional recordkeeping requirements.

This clearance package covers the requirements of Subpart J, "Training and experience requirements," which is part of the current Part 35 (§§ 35.900 - 35.980), as well as proposed new training and experience requirements in Subparts B and D-H of the proposed rule. Licensees will have the option to comply with the training and experience requirements in Subpart J or those in the proposed Subparts B and D-H until two years after the effective date of the final rule. At that time Subpart J will be deleted from Part 35.

The burden for the training and experience requirements under the current Subpart J, as well as the proposed new training and

experience requirements in Subparts B and D-H of the proposed rule, are related as appropriate to the clearance for NRC Form 313, "Application for Material License," OMB clearance number 3150-0120, or to this clearance package for Part 35 requirements. Burdens not captured in the current clearance for NRC Form 313, including the supplemental forms 313A and 313B, are identified in the current clearance. Subsequent references to "NRC Form 313" are intended to refer to "NRC Form 313, including the supplemental forms 313A and 313B." Part 35 burdens, including burdens previously existing but not previously included in clearance for Part 35, also are identified in the current clearance.

General requirements for radiation protection that are applicable to all NRC licensees are contained in 10 CFR Part 20. There are no burden changes to 10 CFR Part 20.

A. Justification

Part of the NRC's function is to license and regulate the use of byproduct materials, as required by the Atomic Energy Act as amended, in order to provide for the radiation safety of workers, the general public, and patients. The NRC requires licensees to perform certain tasks to ensure fulfillment of their obligations. The records required by Part 35 are the least burdensome way for licensees to demonstrate compliance with NRC's requirements. Occasionally, safety matters are of such significance that personnel need to be aware of the information in order to perform their jobs or work in a safe manner. In such cases, reports are required.

1. Need for and Practical Utility of the Collection of Information

§35.6 Provisions for research involving human subjects.

This section would require a licensee that conducts research involving human subjects using byproduct material whose research is not conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects to apply for and receive approval of a specific amendment to its NRC license before conducting such research. This information is needed to enable the Commission to evaluate the licensee's compliance with the requirements for the protection of human subjects.

This section also would require all licensees that conduct research involving human subjects to obtain informed consent from the human subjects. This informed consent is needed to ensure that the human subjects understand the risks, if any, to them associated with the research and voluntarily agree to participate.

This section also would require all licensees that conduct research involving human subjects to obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of those terms as defined and described in the Federal Policy for the Protection of Human Subjects. This information is needed to evaluate the licensee's compliance with the requirements for the protection of human subjects.

§35.12 Application for license, amendment, or renewal.

Paragraphs 35.12(b) and (c) would require that applicants for license renewals and amendments submit an original and one copy of a completed NRC Form 313, "Application for Material License." The form elicits an orderly description of the applicant's complete radiation safety program. The request also may be submitted in letter format.

Paragraph 35.12(d) would require that applicants for a license for medical use of byproduct material described in §35.1000 submit an original and one copy of a completed NRC Form 313. Because this license application is for a new medical use, not included in the provisions of Part 35, a licensee also would be required to provide additional information regarding any radiation safety aspects of the medical use of the material that is not addressed in the general requirements of Subparts A through C of Part 35. The licensee also would be required to provide specific information necessary for (1) radiation safety precautions and instructions, (2) training and experience of proposed users, (3) methodology for measurement of dosages or doses to be administered to patients or human research subjects, and (4) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. The applicant or licensee also would be required to provide any other information requested by the Commission in its review of the application to enable the Commission to evaluate a license application for a new medical use of byproduct material. This information is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material.

The burden for Section 35.12 is included in the information collection burden for NRC Form 313, including supplemental forms 313A and 313B. NRC Form 313 is cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

§35.13 License amendments.

This section would require that licensees apply for and receive a license amendment before receiving or using material for a clinical procedure that is permitted under Part 35, but is not authorized by the licensee's current license under this part; before permitting authorized users, authorized nuclear

pharmacists, or authorized medical physicists who do not meet certain requirements to work under the license; before changing Radiation Safety Officers (RSO); before ordering more byproduct material or a different radionuclide or form than authorized by the license; before changing the area of use authorized for use of byproduct material under §§ 35.100 and 35.200; and before changing the addresses of authorized places of use. The triggering events are critical indicators of a potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection of the licensee's program. The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety.

The burden for Section 35.13 is included in the information collection burden for NRC Form 313.

§35.14 Notifications.

Paragraph 35.14(a) would require that licensees provide to the Commission a copy of the board certification and license or permit for each individual no later than 30 days after the date the licensee permits the individual to work as an authorized user (AU), as an authorized nuclear pharmacist (ANP), or as an authorized medical physicist (AMP). The information is required so that the NRC can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and has the facilities and equipment necessary to assure protection of public health and safety.

Paragraph 35.14(b) would require that licensees notify the NRC by letter no later than 30 days after an ANP, AU, AMP, or RSO ends his association with the licensee or has a name change; when the licensee's mailing address changes; when the licensee has a name change that is not a change in control of the license; or when licensees authorized for use of byproduct material under §§ 35.100 and 35.200 have a change in the areas of use. The report for AU and AMP is required in order to maintain the licensee's file with a current record of individuals authorized to use or prepare radioactive material. The report for changes in "key" workers is required because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure the safety of all licensed users. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use radioactive material safely. The NRC needs to be aware of name and mailing address changes to ensure that the licensee continues receiving correspondence such as information notices, bulletins, and other safety related documents. The NRC needs to be aware of changes

of areas of use so that NRC can determine if the facilities are adequate to assure protection of public health and safety.

The burden to the licensee for submission of the notifications required by §35.14(b) is included in the information collection burden for NRC Form 313.

§35.24 Authority and responsibilities for the radiation protection program.

Paragraph 35.24(a) would require a licensee's management to approve requests for license application, renewal, or amendment prior to submittal; any individual, prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and radiation protection program changes that do not require an amendment and are permitted under §35.26. Management approval is necessary to ensure that actions affecting the radiation protection program have been reviewed by responsible licensee officials.

Paragraph 35.24(b) would require licensees with multiple modalities or multiple users to develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Procedures for interdepartmental/interdisciplinary coordination of the radiation protection program provide assurance both to the licensees and to NRC that all of the different departments and diverse professional staff are aware of changes, needs, and issues related to the licensee's radiation protection program.

Paragraph 35.24(d) would require a licensee to establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer. The statement is needed so that the duties, and responsibilities of the Radiation Safety Officer are clearly defined, and the Radiation Safety Officer is provided sufficient authority to assure that the licensee's radiation safety activities are being performed in accordance with regulatory requirements.

Paragraph 35.24(f) would require that a record of actions taken pursuant to paragraphs (a) and (d) be retained in accordance with §35.2024. A description of the contents of the record and the need for the record is provided under §35.2024.

§35.26 Radiation protection program changes.

Paragraphs 35.26(a)(3) and (4) would allow a licensee to revise its radiation protection program without Commission approval if the revisions do not require an amendment under §35.13 and if the revisions have been reviewed and approved by the Radiation Safety Officer and licensee management, and the affected individuals are instructed on the revised program before the changes are implemented. Review and approval by licensee management will allow a licensee to make some changes in their radiation safety

program, provided that the changes do not reduce radiation safety.

Paragraph 35.26(b) would require a record of each change to be retained in accordance with §35.2026. A description of the contents of the record and the need for the record is provided under §35.2026.

§35.27 Supervision.

Paragraph 35.27(a) would require a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by §35.11(b) in addition to instructing the supervised individual in the licensee's written radiation protection procedures, to instruct the individual regulations in 10 CFR Part 35, and license conditions with respect to the use of byproduct material. This instruction will ensure that the supervised individual is aware of all regulatory requirements and license conditions.

Paragraph 35.27(c) would require a licensee to develop, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from the authorized user or authorized nuclear pharmacist, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any questions about the instructions and requirements provided them in accordance with paragraphs (a) and (b) of §35.27. This policy will ensure that the supervised individual secures clarification, as needed, about radiation safety procedures that affect the health and safety of the public.

§35.40 Written directives.

Paragraph 35.40(c) would require licensees who, prior to certain specified medical administrations or procedures, have prepared a written directive containing the patient or human research subject's name and certain specified information pertaining to the administration or procedure, as specified in §35.40(b), to retain the written directive in accordance with §35.2040. A description of the contents of the record and the need for the record is provided under §35.2040.

§35.41 Procedures for administrations requiring a written directive.

This section would require licensees to develop, maintain, and implement written procedures for any administration requiring a written directive that will provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. These procedures are necessary to

ensure that administrations that require a written directive are given as directed by the authorized user physician.

§35.50 Training for Radiation Safety Officer.

Paragraph 35.50(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.50(b)(1) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.50(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this requirement is included in the licensee burden table.

Paragraph 35.50(b)(2) would require that an individual obtain a written certification signed by a preceptor Radiation Safety Officer before the individual can be qualified as a Radiation Safety Officer. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.50(b)(2) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.50(b)(3) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed the examination is necessary to ensure that the individual has sufficient knowledge in radiation safety commensurate with the medical uses of byproduct material. This record is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material.

The information required by §35.50(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.51 Training for an authorized medical physicist.

Paragraph 35.51(a) would require the licensee to require the authorized medical physicist to be certified by a specialty board

whose certification process satisfies the training and experience requirements of §35.51(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

The information required by §35.51(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.51(b)(2) would require the individual to have obtained a written certification signed by a preceptor authorized medical physicist before the individual can be qualified as a authorized medical physicist. This statement is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a medical physicist.

The information required by §35.51(b)(2) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.51(b)(3) would require the individual to have demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed an examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of byproduct material.

The information required by §35.51(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.55 Training for an authorized nuclear pharmacist.

Paragraph 35.55(a) would require the licensee to require the authorized nuclear pharmacist who has been certified as a nuclear pharmacist by a specialty board whose certification process satisfies the requirements of §35.55(b) and whose certification has been approved by the Commission. The certification is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.55(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for

NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.55(b)(2) would require the nuclear pharmacist to have obtained a written certification signed by a preceptor authorized nuclear pharmacist before the individual can be qualified as a nuclear pharmacist. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.55(b)(2) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the certification by the applicant will be a burden under Part 35.

Paragraph 35.55(b)(3) would require the nuclear pharmacist to be an individual who has demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual has successfully passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of the medical use of radiopharmaceuticals.

The information required by §35.55(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the information by the applicant will be a new burden under Part 35.

§35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

Paragraph 35.57(c) would require a licensee to apply for and receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. This record is necessary to ensure that the NRC has reviewed the training and experience of an individual who, as a result of experience, is not required to comply with the training and experience requirements of §35.55(b) or §35.980 and §35.59 to qualify as an authorized nuclear pharmacist, and determined that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The information required by §35.57 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313

due to this added requirement is included in the licensee burden table.

§35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.

Paragraph 35.60(b) would require licensees to develop, maintain, and implement written procedures for proper operation of instruments to measure the activity of photon-emitting radionuclides. These procedures are required to show that the instruments are functioning correctly because confirmation of a dosage or adjustment of dosages must be based on properly-calibrated equipment.

Paragraph 35.60(e) would require licensees to retain a record of checks and tests required by §35.60(b) in accordance with §35.2060. A description of the contents of the record and the need for the record is provided under §35.2060.

§35.61 Calibration and check of survey instruments.

Paragraph 35.61(a)(3) would require that the licensee conspicuously note on a survey instrument the date that the instrument was calibrated. This information is necessary to show that survey instruments were calibrated and operational.

Paragraph 35.61(b) would require the licensee to attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent. This information is necessary to enable instrument users to make necessary corrections.

Paragraph 35.61(d) would require licensees to retain a record of the survey instrument calibrations in accordance with §35.2061. A description of the contents of the record and the need for the record is provided under §35.2061.

§35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

Paragraph 35.62(b) would require licensees to develop, maintain, and implement procedures for the use of instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. Part 35 licensees may use procedures provided by the manufacturer of the instrumentation. These procedures are necessary to ensure that licensees use the instrumentation correctly, and that the instruments that are used to measure the dosages have been checked and are operating correctly.

Paragraph 35.62(d) would require licensees to retain a record of each annual accuracy and linearity test and each day of use check for constancy and proper operation required by this section in accordance with §35.2060. A description of the contents of the record and the need for the record is provided under §35.2060.

§35.63 Determination of dosages of unsealed byproduct material for medical use.

Paragraph 35.63(e) would require licensees to retain a record of each radiopharmaceutical dosage determination in accordance with §35.2063. A description of the contents of the record and the need for the record is provided under §35.2063.

§35.67 Requirements for possession of sealed sources and brachytherapy sources.

Paragraph 35.67(a) would require licensees to read, understand, and maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources for the duration of source use. These instructions are required so that individuals who handle sources can determine the specific safety measures appropriate for each kind of source used.

Paragraph 35.67(d) would require licensees to retain a record of sealed source leak tests in accordance with §35.2067. A description of the contents of the record and the need for the record is provided under §35.2067.

Paragraph 35.67(e)(2) would require licensees to file a report with the NRC within 5 days if leakage of a sealed source is detected in accordance with §35.3067. A description of the contents of the record and the need for the record is provided under §35.2067.

Paragraph 35.67(g) would require licensees to conduct a semi-annual sealed source and brachytherapy source inventory and retain the inventory record in accordance with §35.2067. A description of the contents of the record and the need for the record is provided under §35.2067.

§35.69 Labeling and shielding of vials and syringes.

This section would require licensees to develop, maintain, and implement procedures for labeling each syringe, syringe radiation shield, or vial shield. Labeling is needed because review of misadministration reports has indicated that in many cases misadministrations are caused by inadvertent transposition of syringes or by drawing a dosage from the wrong vial of radioactive material. These procedures are necessary to ensure that licensees use the syringes, syringe shields, and vial shields correctly, to document the procedures, and to enable NRC to evaluate the procedures and make a determination that the procedures are sufficient for radiation safety.

§35.70 Surveys for ambient radiation exposure rate.

This section would require licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive

were prepared for use or administered. Licensees would be required to retain a record of each survey in accordance with §35.2070. A description of the contents of the record and the need for the record is provided under §35.2070.

§35.75 Release of individuals containing radiopharmaceuticals or implants.

Paragraph 35.75(b) would require licensees to provide an individual who has been administered radiopharmaceuticals or implants containing radioactive material and who is being released from the licensee's control in accordance with §35.75(a) with instructions on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). The licensee must provide special instructions to the released individual if the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem), assuming there is no interruption of breast feeding. These instructions are needed to ensure that the released individual is aware of the recommended actions to maintain doses to other persons as low as reasonably achievable (ALARA).

Paragraph 35.75(c) would require licensees to maintain a record of the basis for authorizing the release of an individual, in accordance with §35.2075(b). A description of the contents of the record and a statement of need for the record is provided under §35.2075.

Paragraph 35.75(d) would require licensees to maintain a record that instructions were provided to breast-feeding women in accordance with §35.2075(b). A description of the contents of the record and a statement of need for the record is provided under §35.2075.

§35.80 Provision of mobile service.

Paragraph 35.80(a) would require a licensee providing mobile service to obtain a letter signed by the management of each client that permits the use of byproduct material at the client's address of use and delineates the authority and responsibility of each entity. This record is necessary to show that the client's management has permitted this work.

Paragraph 35.80(f) would require that the letter required in §35.80(a) and a record of the surveys required in §35.80(e) be retained in accordance with §35.2080. A description of the contents of the record and the need for the record is provided under §35.2080.

§35.92 Decay-in-storage.

Paragraph 35.92(b) would require licensees to retain a record of disposal of waste that was decayed in storage and retain the

record in accordance with §35.2092. A description of the contents of the record and the need for the record is provided under §35.2092.

§35.204 Permissible molybdenum-99 concentration.

Paragraph 35.204(c) would require licensees to measure the molybdenum-99 concentrations in eluates from a molybdenum-99/technetium-99m generator and retain the record in accordance with §35.2204. A description of the contents of the record and the need for the record is provided under §35.2204..

§35.290 Training for uptake, dilution, and excretion studies.

Paragraph 35.290(a) would require the licensee to require an authorized user of a radiopharmaceutical for the use of unsealed byproduct material for uptake, dilution, and excretion studies to be a physician who has been certified by a specialty board whose certification process satisfies the training and experience requirements of §35.290(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the physician has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for uptake, dilution, and excretion studies.

The information required by §35.290(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the certification by the applicant will be a burden under Part 35.

Paragraph 35.290(b)(2) would require the licensee to require an authorized user to be a physician who has obtained a written certification signed by a preceptor before the physician can independently function as an authorized user of a diagnostic radiopharmaceutical for uptake, dilution, and excretion studies. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of radiopharmaceuticals for uptake, dilution, or excretion studies.

The information required by §35.290(b)(2) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the preceptor certification by the applicant will be a new burden under Part 35.

Paragraph 35.290(b)(3) would require the licensee to require an authorized user to be a physician who has demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in

accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using radiopharmaceuticals for uptake, dilution, or excretion studies.

The information required by §35.290(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the information by the applicant will be a new burden under Part 35.

§35.292 Training for imaging and localization studies.

Paragraph 35.292(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.292(b) and whose certification has been approved by the Commission. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators for therapeutic administration for which a written directive is required.

The information required by §35.292(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the certification by the applicant will be a burden under Part 35.

Paragraph 35.292(b)(2) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of diagnostic radiopharmaceuticals and generators for imaging and localization studies. This record is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of diagnostic radiopharmaceuticals and generators for therapeutic administration for which a written directive is required.

The information required by §35.292(b)(2) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the preceptor certification by the applicant will be a burden under Part 35.

Paragraph 35.292(b)(3) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using diagnostic radiopharmaceuticals and generators

for therapeutic administration for which a written directive is required.

The information required by §35.292(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table. Obtaining a copy of the information by the applicant will be a burden under Part 35.

§35.310 Safety instruction.

Paragraph 35.310(b) would require licensees to retain a record of radiation safety instruction given to personnel who care for radiopharmaceutical therapy patients or human research subjects, in accordance with §35.2310. A description of the contents of the record and the need for the record are provided under §35.2310.

§35.315 Safety precautions.

Paragraph 35.315(a)(2) would require that the licensee post a radiopharmaceutical therapy patient's or human research subject's room with a "Radioactive Materials" sign and note in the patient's chart how long visitors may stay in the patient's room. This provides notice to hospital workers and the public that there is radioactivity in the room and is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules.

Paragraph 35.315(b) would require that the licensee promptly notify the Radiation Safety Officer, or his designee, if the patient dies or has a medical emergency. This notification is required so that the Radiation Safety Officer or his designee can take whatever actions are necessary to prevent radioactive contamination. The Radiation Safety Officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

§35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.

Paragraph 35.390(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.390(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for therapy or to use unsealed byproduct material that requires a written directive.

The information required by §35.390(a) will be submitted on NRC Form 313 as a license amendment application, which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.390(b)(3) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic radiopharmaceuticals for the uses requiring a written directive. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of unsealed byproduct material for therapy.

The information required by §35.390(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.390(b)(4) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using unsealed byproduct material for therapy.

The information required by §35.390(b)(4) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.404 Radiation surveys of patients or human research subjects treated with implants.

Paragraph 35.404(c) would require a licensee to retain a record of the patient or human research subject surveys required by §35.404(a) after an implant and §35.404(b) after removing the implant in accordance with §35.2404. A description of the contents of the record and the need for the record is provided under §35.2404.

§35.406 Brachytherapy sources inventory.

Paragraph 35.406(c) would require licensees to make a record of brachytherapy source accountability in accordance with §35.2406. A description of the contents of the record and the need for the record is provided under §35.2406.

§35.410 Safety instruction.

Paragraph 35.410(b) would require licensees to retain a record of radiation safety instruction for personnel who care for patients or human research subjects who are undergoing implant therapy, in accordance with §35.2310. A description of the contents of the record and the need for the record is provided under §35.2310.

§35.415 Safety precautions.

Paragraph 35.415(a) would require that the licensee post the patient's room with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room. This posting is required to help protect against excessive radiation exposure to visitors.

Paragraph 35.415(c) would require that the licensee promptly notify the Radiation Safety Officer, or his designee, and authorized user if the patient dies or has a medical emergency. This notification is required so that the Radiation Safety Officer, or his designee, or authorized user can take whatever actions are necessary to prevent a spread of radioactive contamination or loss of sources containing byproduct material. The Radiation Safety Officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

§35.432 Full calibration measurements of brachytherapy sources.

Paragraph 35.432(f) would require licensees who perform full calibration measurements on brachytherapy sources before the first medical use of the source or the source/applicator configuration to retain a record of each calibration in accordance with §35.2432. A description of the contents of the record and the need for the record is provided under §35.2432.

§35.490 Training for use of manual brachytherapy sources.

Paragraph 35.490(a) would require licensees to require the authorized user of a manual brachytherapy source for the uses listed in §35.400 to be a physician certified by a specialty board whose certification process satisfies the requirements of §35.490(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.

The information required by §35.490(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.490(b)(3) would require licensees to require the authorized user to be a physician who has obtained a written certification signed by a preceptor before the individual can independently function as an authorized user of manual brachytherapy sources. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for manual brachytherapy.

The information required by §35.490(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.490(b)(4) would require licensees to require the authorized user to have demonstrated sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. A record that the individual passed the examination is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using manual brachytherapy.

The information required by §35.490(b)(4) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.590 Training for use of sealed sources for diagnosis.

Paragraph 35.590(a) would require the licensee to require the authorized user of a diagnostic sealed source for use in a device listed in §35.500 to be a physician, dentist, or podiatrist who has been certified by a specialty board approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user of sealed sources for diagnosis.

The information required by §35.590(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.

Paragraph 35.604(b) would require licensees who use sealed sources in devices for therapeutic medical uses and who immediately after retracting the source from the patient into its

shielded position in the device have performed a radiation survey of the patient or human research subject as required by §35.604(a) to retain a record of the survey in accordance with §35.2404. A description of the contents of the record and the need for the record is provided under §35.2404.

§35.605 Installation, maintenance, and repair.

Paragraph 35.605(d) would require licensees to retain a record of each installation, maintenance, and repair of a therapeutic medical device in accordance with §35.2605. A description of the contents of the record and the need for the record is provided under §35.2605.

§35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.

Paragraph 35.610(a) would require licensees to develop, maintain, and implement specified safety procedures. These procedures are necessary because of the complexity and higher radiation risk associated with these units.

Paragraph 35.610(b) would require licensees to physically locate a copy of the procedures at the unit console. These safety procedures are necessary to ensure that workers at the console have physical access to the procedures.

Paragraph 35.610(c) would require licensees to post instructions for individuals who operate the devices at the device console providing the locations of the procedures and emergency names and telephone numbers. These instructions are necessary to inform workers of the procedures and to serve as a quick reference in case of emergencies or equipment malfunction.

Paragraph 35.610(e) would require licensees to make a record of initial instruction, refresher training, and practice drills for individuals who operate devices and retain the record in accordance with §35.2310. A description of the contents of the record and the need for the record is provided under §35.2310.

§35.630 Dosimetry equipment.

Paragraph 35.630(c) would require licensees to retain a record of each calibration, intercomparison, and comparison of calibrated dosimetry equipment in accordance with §35.2630. A description of the contents of the record and the need for the record is provided under §35.2630.

§35.632 Full calibration measurements on teletherapy units.

Paragraph 35.632(g) would require licensees to retain a record of full calibration measurements on teletherapy units in accordance

with §35.2632. A description of the contents of the record and the need for the record is provided under §35.2632.

§35.633 Full calibration measurements on remote afterloaders.

Paragraph 35.633(h) would require licensees to retain a record of full calibration measurements on remote afterloaders in accordance with §35.2633. A description of the contents of the record and the need for the record is provided under §35.2633.

§35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

Paragraph 35.635(g) would require licensees to retain a record of full calibration measurements on gamma stereotactic radiosurgery units in accordance with §35.2635. A description of the contents of the record and the need for the record is provided under §35.2635.

§35.642 Periodic spot-checks for teletherapy units.

Paragraph 35.642(c) would require that the authorized medical physicist review and report the results of teletherapy unit output spot-checks promptly to the licensee. This report is needed to assure the licensee that the results of each spot-check have been reviewed by an expert.

Paragraph 35.642(f) would require licensees to retain a copy of each report of monthly teletherapy unit output spot-checks and each monthly teletherapy unit safety spot-checks in accordance with §35.2642. A description of the contents of the record and the need for the record is provided under §35.2642.

§35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.

Paragraph 35.643(b) would require licensees to have the authorized medical physicist establish procedures for performing periodic spot-checks on high dose-rate and pulsed dose-rate remote afterloaders. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.643(h) would require licensees to retain a copy of each report of weekly and daily spot-checks in accordance with §35.2643. A description of the contents of the record and the need for the record is provided under §35.2643.

§35.644 Periodic spot-checks for low dose-rate remote afterloaders.

Paragraph 35.644(c) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on low dose-rate remote afterloaders prior to each

patient treatment and after each source installation. The authorized medical physicist is the most qualified individual to ensure that the procedures are in accordance with published recommendations of nationally recognized bodies. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.644(e) would require licensees to retain a copy of each report of spot-checks on low dose-rate remote afterloaders in accordance with §35.2643. A description of the contents of the record and the need for the record is provided under §35.2643.

§35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

Paragraph 35.645(b)(1) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on gamma stereotactic radiosurgery units monthly and prior to each day of use. The authorized medical physicist is the most qualified individual to ensure that the procedures are performed in accordance with published recommendations of nationally recognized bodies. These procedures are necessary to document the licensee's radiation protection program and to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(b)(2) would require licensees to have the authorized medical physicist review the results of each spot-check of a gamma stereotactic radiosurgery unit within three days of each spot-check. This review is necessary to ensure that the dose limits in 10 CFR Part 20 are not exceeded.

Paragraph 35.645(g) would require licensees to retain a record of each spot-check in accordance with §35.2645. A description of the contents of the record and the need for the record is provided under §35.2645.

§35.647 Additional technical requirements for mobile remote afterloaders.

Paragraph 35.647(e) would require licensees to retain a record of each check of mobile remote afterloaders prior to each change of address of use as required by §35.647(b) in accordance with §35.2647. A description of the contents of the record and the need for the record is provided under §35.2647.

§35.652 Radiation surveys.

Paragraph 35.652(c) would require that licensees who make radiation surveys as required by §35.652(b) at installation of a new source and following repairs to the source(s) shielding, source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding

around the source(s), or compromise the radiation safety of the device or the sources, to retain a record of the radiation surveys in accordance with §35.2652. A description of the contents of the record and the need for the record is provided under §35.2652.

§35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

Paragraph 35.655(c) would require licensees to keep a record of the teletherapy unit and gamma stereotactic radiosurgery unit 5-year inspection and servicing required by §35.655(a) in accordance with §35.2655. A description of the contents of the record and the need for the record is provided under §35.2655.

§35.690 Training for use of therapeutic medical devices.

Paragraph 35.690(a) would require an individual to be certified by a specialty board whose certification process satisfies the requirements of §35.690(b) and whose certification has been approved by the Commission. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

The information required by §35.690(a) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.690(b)(3) would require an individual to obtain a written certification signed by a preceptor before the individual can independently function as an authorized user of therapeutic medical device. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic medical devices.

The information required by §35.690(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

Paragraph 35.690(b)(4) would require an individual to demonstrate sufficient knowledge in radiation safety by passing an examination given by an organization or entity approved by the Commission in accordance with Appendix A. This record is necessary to ensure that the individual has sufficient knowledge of the radiation safety aspects of using therapeutic medical devices.

The information required by §35.690(b)(3) will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The increase in burden for NRC Form 313 due to this added requirement is included in the licensee burden table.

§35.900 Radiation Safety Officer.

Paragraph 35.900(a) would require that, except as provided in §35.57 with respect to training for an experienced Radiation Safety Officer, a licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who is certified by one of nine listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a Radiation Safety Officer.

The information required by §35.900 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.910 Training for uptake, dilution, and excretion studies.

Paragraph 35.910(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a radiopharmaceutical in §35.100(a) to be a physician who is certified by one of five listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for uptake, dilution, and excretion studies.

The information required by §35.910 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.920 Training for imaging and localization studies.

Paragraph 35.920(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a radiopharmaceutical, generator, or reagent kit in §35.200(a) to be a physician who is certified by one of five listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for imaging and localization studies.

The information required by §35.920 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB

Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.930 Training for therapeutic use of unsealed byproduct material.

Paragraph 35.930(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of radiopharmaceuticals in §35.300 to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for therapeutic use of unsealed byproduct material.

The information required by §35.930 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.940 Training for use of brachytherapy sources.

Paragraph 35.940(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a brachytherapy source listed in §35.400 for therapy to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for brachytherapy sources.

The information required by §35.940 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.950 Training for use of sealed sources for diagnosis.

Paragraph 35.950(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a sealed source in a device listed in §35.500 to be a physician, dentist, or podiatrist who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for use of sealed sources for diagnosis.

The information required by §35.950 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.960 Training for teletherapy.

Paragraph 35.960(a) would require that, except as provided in §35.57 with respect to training for an experienced authorized user, a licensee must require the authorized user of a sealed source listed in §35.600 in a teletherapy unit to be a physician who is certified by one of four listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized user for teletherapy.

The information required by §35.960 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.961 Training for teletherapy physicist.

Paragraph 35.961(a) would require that the licensee shall require the teletherapy physicist to be an individual who is certified by one of two listed certifying organizations. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as a teletherapy physicist.

The information required by §35.961 will be submitted on NRC Form 313 as a license amendment application which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this added requirement is included in the current clearance for Form 313.

§35.980 Training for authorized nuclear pharmacist.

Paragraphs 35.980(a) and (b)(2) would require that the licensee shall require the authorized nuclear pharmacist to be a pharmacist who is certified by a listed certifying organization or has obtained another certification signed by a preceptor who is an authorized nuclear pharmacist that the applicants training has been satisfactorily completed. This certification is necessary to ensure that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

The information required by §35.980 will be submitted on NRC Form 313 as a license amendment application, which is cleared under OMB Clearance No. 3150-0120. The burden for NRC Form 313 due to this requirement is included in the current clearance for Form 313.

§35.2024 Records of authority and responsibilities for radiation protection programs.

Paragraph 35.2024(a) would require licensees to retain a record of actions taken in accordance with §35.24(a) for five years.

This record must include a summary of actions taken and the signature of licensee management for requests for license application, renewal, or amendment; approvals or disapprovals of requests to allow an individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and approval or disapproval of radiation protection program changes that do not require an amendment. This record is needed to document these actions and the basis for them because they are important to the licensee's radiation safety program.

Paragraph 35.2024(b) requires that licensees maintain for the life of the license a current copy of the authorities, duties, and responsibilities of the radiation safety officer as required by §35.24(d). The record must include the signature of the radiation safety officer and licensee management. This record is important to show that the RSO has sufficient authority, time, resources, and management prerogative to ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

§35.2026 Records of radiation safety program changes.

This section would require licensees to retain a record of each radiation protection program change as required by §35.26(a) for five years. The record must include a copy of the old and new procedures and the signatures of the radiation safety officer and licensee management that reviewed and approved the change. This record is needed to document what radiation safety factors were considered before implementing the minor change. This record facilitates the Commission's evaluation of the nature and appropriateness of the minor changes during inspections prior to renewal, and provides the licensee with a complete record of the radiation safety program changes until the changes are incorporated into the license when renewed.

§35.2040 Records of written directives.

This section would require licensees to retain a copy of each written directive as required by §35.40 for three years. Preparation of a written directive is necessary to provide high confidence that byproduct material will be administered as directed by the authorized user physician. Retention of the written directives and records of each administration for three years after the date of the administration will allow NRC to ensure that administrations were in accordance with the written directives by reviewing a sample of written directives and records during an NRC inspection.

§35.2045 Records of medical events and precursor events.

This section would require licensees to maintain a record of medical events and precursor events reported pursuant to §§ 35.3045 and 35.3046 for three years. The record must contain the licensee's name; names of all the licensee's personnel

involved, and the affected or potentially affected individual's social security number or other identification number if one has been assigned, a brief description of the medical event or precursor event, why it occurred, the effect on the individual, and the actions taken to prevent recurrence. This record is needed to document medical events and precursor events for licensee and Commission review, so that the Commission can ascertain whether medical events have been investigated by the licensee and that corrective actions have been taken.

§35.2060 Records of instrument calibrations.

This section would require licensees to retain a record of instrument calibrations performed in accordance with §§ 35.60 and 35.62 for three years. The records must include:

- (1) For constancy, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the activity measured, and the name of the individual who performed the check.
- (2) For accuracy, the model and serial number of the instrument, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test, and the name of the individual who performed the test.
- (3) For linearity, the model and serial number of the instrument, the calculated activities, the measured activities, and the date of the test, and the name of the individual who performed the test.
- (4) For geometric dependence, the model and serial number of the instrument, the configuration of the source measured, the activity measured for each volume measured, and the date of the test, and the name of the individual who performed the test.

The records of the checks and tests in §§ 35.60 and 35.62 are necessary to demonstrate that the instruments used to measure the activity of alpha-, beta-, and photon-emitting radionuclides are functioning correctly and are capable of accurately measuring dosages; to establish trends in equipment performance; and to show compliance with regulatory requirements.

§35.2061 Records of radiation survey instrument calibrations.

This section would require licensees to retain a record of radiation survey instrument calibrations required by §35.61 for three years. The record must include:

- (1) A description of the calibration procedure; and

- (2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the name of the individual who performed the calibration.

This record of calibration of survey instruments is required to show that survey instruments were calibrated and are functioning correctly.

§35.2063 Records of dosages of unsealed byproduct material for medical use.

This section would require licensees to retain a record of dosage determinations required by §35.63 for three years. The record must contain the radionuclide, radiopharmaceutical and its lot number; patient's or human research subject's name, or identification number; prescribed dosage and activity at the time of determination, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); date and time of the determination; and name of the individual who determined the dosage.

This record is required for demonstrate that licensees are maintaining control of the use of radiopharmaceuticals.

§35.2067 Records of possession of sealed sources and brachytherapy sources.

Paragraph 35.2067(a) would require licensees to retain records of leak tests required by §35.67(b) for three years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, a description of the method used to measure each test sample, the date of the test, and the name of the individual who performed the test. This record is required to demonstrate that the leak test was done as required, and that the source was not leaking.

Paragraph 35.2067(b) would require that licensees retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by §35.67(g) for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, the activity of each test sample, location of each source, and the name of the individual who performed the survey. This inventory record is needed to show that possession of sealed sources did not exceed the amount authorized by the license.

§35.2070 Records of surveys for ambient radiation exposure rate.

This section would require licensees to retain a record of each survey required by §35.70 for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area of the removable contamination in each area, the instrument used to make the survey or analyze the samples, and the name of the individual who performed the survey. The records are needed to document that the surveys were performed, and that the ambient radiation exposure rates are below the limits set for protection of workers and the public.

§35.2075 Records of the release of individuals containing radiopharmaceuticals or implants.

Paragraph 35.2075(a) would require that licensees retain records of the release of individuals containing radiopharmaceuticals or implants in accordance with §35.75 for three years after the date of release. Retention of the release records for three years after the date of the release will allow NRC to ensure that releases were in accordance with the criteria for release by reviewing a sample of the records during an NRC inspection.

Paragraph 35.2075(b) would require a licensee to retain a record that describes the basis for authorizing the release of individuals if the total effective dose equivalent is calculated by using the retained activity rather than the activity administered; using an occupancy factor less than 0.25 at 1 meter; using the biological or effective half-life; or considering the shielding by tissue.

These records are necessary to document the basis for releasing individuals containing radiopharmaceuticals or implants from the control of licensees, and into situations where they could expose members of the general public.

Paragraph 35.2075(c) would require licensees to retain a record that the instructions required by §35.75(b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem). This record is necessary to show that nursing mothers have been provided with necessary information to ensure that an infant or child does not receive excess exposure to radiation.

§35.2080 Records of administrative and technical requirements that apply to the provision of mobile services.

Paragraph 35.2080(a) would require that licensees providing mobile services retain a copy of the letters signed by the management of each client as required by §35.80(a) for three years after the last provision of service. The letter must delineate the authority and responsibility of each entity. These

records are necessary to show that the licensees had permission to use byproduct material at the client's address of use.

Paragraph 35.2080(b) would require licensees to retain a record of each survey required by §35.80(e) for three years. The record must include the date of the survey, a plan of each area surveyed, the measured dose rate at several points in each area of use, the instrument used to make the survey, and the name of the individual who performed the survey. These records are needed to show that the required surveys were made.

§35.2092 Records of waste disposal.

This section would require licensees to retain records of the disposal of licensed materials made pursuant to §35.92 for three years. The records must include the date of disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. These records are needed to show that materials were decayed for the required length of time, that their radioactivity cannot be distinguished from background radiation levels, and that a proper survey of each waste container was made prior to disposal. These records are also needed to show that radioactive material is not disposed of as ordinary waste.

§35.2204 Records of molybdenum-99 concentration.

This section would require licensees to retain records of molybdenum-99 concentration tests required by §35.204(b) for three years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the name of the individual who made the measurement. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

§35.2310 Records of instruction and training.

This section would require licensees to retain records of instructions and training required by §§ 35.310, 35.410, and 35.610 for three years. The record must include a description of the instruction, the date of instruction, and the name(s) of the individual(s) giving and attending the training. This record is needed to show that the required initial and refresher training was given and that the drills were performed so that individuals are aware of the safety procedures to be used in caring for patients and human research subjects treated with byproduct material or radiation therefrom.

§35.2404 Records of radiation surveys of patients and human research subjects.

This section would require licensees to retain a record of the radiation surveys of patients and human research subjects required by §§ 35.404 and 35.604 for three years. Each record must include the date and results of the survey, an identifier for the patient or the human research subject, the survey instrument used, and the name of the individual who made the survey. This record is used to show that all sources were removed from the patient or human research subject, and that no sources have been misplaced.

§35.2406 Records of brachytherapy source inventory.

This section would require licensees to retain records of brachytherapy source accountability required by §35.406 for three years. For temporary implants, the record must include: (1) the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; (2) the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage. For permanent implants, the record must include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources returned to storage, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is alerted and can take appropriate action.

§35.2432 Records of full calibrations of brachytherapy sources.

This section would require licensees to retain records of full calibrations on brachytherapy sources required by §35.432 for three years after the last use of the source. The record must include the date of calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the signature of the authorized medical physicist. These records are needed to document that the brachytherapy sources have been calibrated.

§35.2605 Records of installation, maintenance, and repair.

This section would require licensees to retain records of installation, maintenance and repair of therapeutic medical devices required by §35.605 for three years. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individuals who performed the work. This record is necessary to

show that the devices are properly installed, maintained, and repaired, to establish trends in device performance, and to establish a service history that may be used in evaluation of generic equipment problems.

§35.2630 Records of dosimetry equipment.

This section would require licensees to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with §35.630 for the duration of the license. For each calibration, intercomparison, or comparison, the record must include: the date, the model numbers and serial numbers of the instruments, the correction factor; and the names of the individuals who performed the calibration, intercomparison, or comparison. This record is needed to show that calibrations of medical devices were made with properly calibrated instruments.

§35.2632 Records of teletherapy full calibrations.

This section would require licensees to retain records of teletherapy full calibrations required by §35.632 for three years. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for the teletherapy unit, the source, and instruments used to calibrate the teletherapy unit; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; an assessment of timer accuracy and linearity; the calculated on-off error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the teletherapy unit.

§35.2633 Records of remote afterloader full calibrations.

This section would require licensees to retain records of remote afterloader full calibrations required by §35.633 for three years. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the high dose-rate remote afterloader, source, and instruments used to calibrate the unit; the source output; an assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, source retraction functionality; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from remote afterloader devices.

§35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.

This section would require licensees to retain records of gamma stereotactic radiosurgery full calibrations required by §35.635 for three years. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit; the unit output; an assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and the signature of the authorized medical physicist who performed the full calibration. This record is needed to show that the calibrations were done so that licensees did not inadvertently administer incorrect radiation doses to patients from the gamma stereotactic radiosurgery unit.

§35.2642 Records of periodic spot-checks for teletherapy units.

This section would require licensees to retain a record of each periodic spot-check for teletherapy units required by §35.642 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring or localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and the signature of the individual who performed the periodic spot-check. This record is needed to show that the spot-checks were performed and that the units are operating correctly.

§35.2643 Records of periodic spot-checks for remote afterloaders.

This section would require licensees to retain records of each spot-check for remote afterloaders required by §§ 35.643 and 35.644 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the remote afterloader, source, and instrument used to measure the output of the remote afterloader; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the periodic

spot-check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

This section would require licensees to retain records of each spot-check for gamma stereotactic radiosurgery units required by §35.645 for three years. The record must include the date of the spot-check; the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, the manufacturer's name, model number and serial number of the instrument used to measure the output of the unit; the measured source output and source output against computer calculations; notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff switches and stereotactic frames and localizing devices (trunnions); and the signature of the individual who performed the periodic spot-check. This record is necessary to show that the spot-checks were performed and that the units are operating correctly.

§35.2647 Records of additional technical requirements for mobile remote afterloaders.

This section would require licensees to retain records of each check for mobile remote afterloaders required by §35.647 for three years. The record must include the date of the check; the manufacturer's name, model number, and serial number for the remote afterloader; notations accounting for all sources before departing from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and the signature of the individual who performed the check. This record is necessary to show that the checks were performed and that the units are operating correctly.

§35.2652 Records of surveys of therapeutic treatment units.

This section would require licensees to retain records of radiation surveys of treatment units made in accordance with §35.652 for the duration of use of the unit. The record must include the date of the measurements, the manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels, and each dose rate measured around the source while the unit is in the off position and the average of all measurements, and the signature of the Radiation Safety Officer. This record is necessary to show that the surveys were performed and that the units do not exceed occupational dose levels with the sources in the shielded position.

§35.2655 Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

This section would require licensees to retain records of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by §35.655 for the duration of use of the unit. The record must contain the inspector's name, the inspector's radioactive materials license number, the date of inspection, the manufacturer's name and model number and serial number for both the treatment unit and source, a list of components inspected, and a list of components serviced, and the type of service, and the signature of the inspector. This record is needed to document the type of service that was performed and that any required work was done.

§35.3045 Reports of medical events.

Paragraph 35.3045(b) would require licensees to notify NRC by telephone no later than the next calendar day after discovery of a medical event that involves an administration of byproduct material or radiation therefrom that meets or exceeds the dosage criteria in §3045(a) and is not the direct result of intervention by the patient that could have been reasonably prevented by the physician. This reporting requirement is needed to ensure that NRC is aware of medical events to be able to promptly take any necessary actions based on the circumstances.

Paragraph 35.3045(c) would require licensees to submit a written report to NRC within 15 days of the discovery of the medical event. The report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian) and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it appears the precipitating event might be generic.

Paragraph 35.3045(d) would require the licensee to notify the referring physician and the individual affected by the medical event, or that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Paragraph 35.3045(e) would require the licensee to furnish a written report of the medical event to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect the individual. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee. This report is needed to ensure that patients obtain a written report as a record of information furnished to them verbally.

§35.3046 Reports of precursor events.

Paragraph 35.3046(a) would require that licensees notify the NRC Operations Center by telephone no later than the next calendar day after identifying any defects, exclusive of ordinary equipment failures, in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the Radiation Safety Officer or authorized user, could lead to a medical event. This report is needed to ensure that NRC is aware of defects that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

Paragraph 35.3046(b) would require the licensee to submit a written report within 15 days after discovery of the precursor event to the appropriate NRC Regional Office. The report must include the licensee's name; a brief description of the event; why the event occurred; what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. This written report will ensure that NRC is aware of events that could lead to a medical event and enable NRC to promptly take any necessary actions based on the circumstances.

§35.3047 Report of a dose to an embryo/fetus or a nursing child.

Paragraph 35.3047(a) would require the licensee to report any administration of byproduct material or radiation therefrom to a pregnant woman unless the administration was specifically approved, in advance, by the authorized user if the administration results in a dose that is greater than 5mSv (500 mrem) total dose equivalent to a nursing child. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(b) would require the licensee to report any administration of byproduct material to a breast feeding woman, unless the administration was specifically approved, in advance, by the authorized user, if the administration results in a dose that is greater than 5mSv (500 mrem) total dose equivalent to a

nursing child. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) as amended, which requires NRC to submit reports of unintended radiation exposure.

Paragraph 35.3047(c) would require the licensee to notify by telephone the NRC Operation Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Paragraph 35.3047(d) would require the licensee to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). The written report must include the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect on the affected individual(s); what improvements are needed to prevent recurrence; and actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

§35.3067 Reports of leaking sources.

This section would require that licensees report detection of a leaking source by submitting a written report within 5 days after a leakage test reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office. The report must include the model number and serial number, if assigned, of the leaking source; radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample, and the date of the test. This will enable NRC to promptly determine if the necessary follow-up actions are necessary following discovery of the leaking source.

Appendix A

Appendix A would specify the requirements for an independent organization or entity that submits an application for approval of the Commission to examine individuals pursuant to §§ 35.50(b)(3), 35.51(b)(3), 35.55(b)(3), 35.290(b)(3), 35.292(b)(3), 35.390(b)(4), 35.490(b)(4), or 35.690(b)(4). Each such organization or entity that submits an application shall:

Appendix A, Part I, item 1 would require the independent organization to make its examination

process available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability. This ensures that the independent organization will uphold 10 CFR Part 4, Subpart A -- Regulations Implementing Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974 with respect to prohibiting discriminatory actions.

Appendix A, Part I, item 2 would require the independent organization to have an adequate staff, a viable system for financing its operations, and a policy- and decision-making review board. This would ensure that the organization will have the resources to maintain an adequate program.

Appendix A, Part I, item 3 would require the independent organization to have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies. This would ensure that the independent organization has a program in place for monitoring and enforcing its by-laws and policies.

Appendix A, Part I, item 4 would require the independent organization to have a committee, whose members can carry out their responsibilities impartially, to review and approve the examination guidelines and procedures, and to advise the organization's staff in implementing the examination program. This would ensure that the organization has a mechanism in place for ensuring the technical quality of the examination.

Appendix A, Part I, item 5 would require the independent organization to have a committee, whose members can carry out their responsibilities impartially, to review complaints by examined individuals. This would ensure that the independent organization will provide a mechanism to resolve disputes concerning the examination results.

Appendix A, Part I, item 6 would require the independent organization to have written procedures describing all aspects of its examination program, maintain records of the current status of each individual's examination and the administration of its examination program. The procedures are needed to ensure that the examination program is adequate to identify properly trained individuals and to ensure that the examination results are maintained in case of inquiry.

Appendix A, Part I, item 7 would require the independent organization to have procedures to ensure that examinations are not given to individuals who have also been instructed by the examining organization in the same subject area. The procedures are needed to ensure that the organization provides an independent and objective assessment of the candidate's qualifications.

Appendix A, Part I, item 8 would require the independent organization to have procedures to ensure that examined individuals are provided due process with respect to the administration of its examination program, including the process of being examined. The procedures are needed to ensure that the independent organization provides individuals adequate due process.

Appendix A, Part I, item 9 would require the independent organization to have procedures for proctoring examinations, including qualifications for proctors. The procedures are needed to help ensure fairness in the examination process.

Appendix A, Part I, item 10 would require the independent organization to exchange information about examined individuals with the Commission and other independent examining organizations and/or Agreement States and allows periodic review of its examination program and related records. The exchange of information and periodic review are to ensure that all individuals' certifications are current and valid.

Appendix A, Part I, item 11 would require the independent organization to provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment. The procedures are needed to ensure that the independent certifying organization provides for appropriate examination sites and environments.

Appendix A, Part I, item 12 would require the independent organization to submit its request to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. Submission of the request is necessary so that the request can be reviewed by NRC.

Appendix A, Part II, item 2 would require all examination programs to include procedures to ensure that all examination questions are protected from disclosure. The purpose of these procedures is to ensure the fairness of the examination.

Appendix A, Part III, item 2 would require all examinations to have test items drawn from a question bank containing psychometrically valid questions based on the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations. The purpose of this question bank is to ensure that the test questions adequately address knowledge and understanding of the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations.

Appendix A, Part III, item 3 would require sample questions from all examinations to be submitted to the Commission for review initially and every 5 years. The purpose of this submission is to enable NRC to verify that the test questions adequately address knowledge and understanding of the material in §§ 35.50(b)(1); 35.51(b)(1); 35.55(b)(1); 35.290(b)(1); 35.292(b)(1); 35.390(b)(1); 35.490(b)(1); or 35.690(b)(1), or equivalent Agreement State regulations.

2. Agency Use of Information

The NRC uses the records and reports required in this part to ensure that licensees' medical use programs are adequate to protect health and minimize danger to life and property and to ensure that licensees' personnel are aware of the information needed to perform their jobs and work in a safe manner. The staff makes use of the records and reports to determine whether the licensee has individuals with adequate training and experience to safely use radioactive material in the treatment of patients or human research subjects, and has the facilities and equipment necessary to assure protection of public health and safety. NRC also uses the information to develop reports to inform the public about the measures taken to provide for the radiation safety of workers, the general public, and patients and to alert licensees to issues of general concern. Reports of medical events and precursor events that NRC is notified of significant events. These reports also allow NRC to determine whether to take actions, such as to conduct inspections, or to alert other medical use licensees, to prevent similar events that may have generic implications.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information, the applications and reports do not lend themselves readily to the use of automated information technology for submission. Section 35.5 of the rule would provide that records under Part 35 may be stored in electronic media.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. In general, information required by the NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. Portions of the needed information might also be contained in other information submittals to the NRC or other Federal agencies. However, duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

5. Effort to Reduce Small Business Burden

While a number of medical licensees are considered small businesses under the NRC's current definitions, the health and safety consequences of improper use of radioactive material are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures while maintaining the required level of safety.

6. Consequences to Federal Program or Policy Activities if the Collection is Not Conducted or is Conducted Less Frequently

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the possession, use, or transfer of byproduct material.

Applications are required to be submitted for the initial license, for amendments, and for renewals. The application process requires that applicants and licensees perform a comprehensive review of their entire radiation safety program to assure that all activities will be or are being conducted safely and in accordance with NRC regulations. The review and submission of the information required for the application is essential to NRC's determination of whether the applicant has the training, experience, equipment, and facilities that are adequate to protect the public health and safety. Other reporting and recordkeeping requirements are occasioned by specific events, such as inventories of licensed material, calibrations and checks of medical devices, medical events, and precursor events. Collection of information at the required frequency from licensees that use byproduct material in the treatment of patients or human research subjects is essential to protect the health and safety of workers and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

Section 35.24(b) would require licensees with multiple modalities or multiple users to develop, document, and implement administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.27(c) would require licensees to develop, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from the authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done, and from the authorized user and authorized nuclear pharmacist about the instructions and requirements provided in accordance with paragraphs (a) and (b) of §35.27. Such policies would be retained for the life of the license, or until superseded by new or revised policies, in order to ensure that they remain available for reference.

Section 35.41(a) would require licensees to develop, maintain, and implement written procedures for any administration requiring a written directive that will provide high confidence that the patient or human research subject's identity is verified prior to each administration and that each administration is in accordance with the written directive. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.60(b) would require licensees to develop, maintain, and implement written procedures for proper operation of instruments to measure the activity of photon-emitting radionuclides. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.62(b) would require licensees to develop, maintain, and implement procedures for the use of instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. Part 35 licensees may use procedures provided by the manufacturer of the instrumentation. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain

available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.67(a) would require licensees to read, understand, and maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources for the duration of source use. Such instructions would be retained for the duration of source use, in order to ensure that they remain available for reference.

Section 35.67(e)(2) would require licensees to file a report within five days of the leakage test in accordance with §35.3067. The justification for this variation from OMB guidelines is provided under §35.3067.

Section 35.69(a) would require licensees to develop, maintain, and implement procedures for labeling each syringe, syringe radiation shield, or vial shield. Retaining such procedures for the life of the license, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.315(b) would require licensees to notify the Radiation Safety Officer, or his designee, and the authorized user immediately if the patient dies or has a medical emergency. This immediate notification is necessary to permit the Radiation Safety Officer and authorized user to ensure that the necessary radiation safety precautions are used for handling an individual who has been treated with unsealed byproduct material for a therapeutic medical use.

Section 35.415(c) would require licensees to notify the Radiation Safety Officer, or his designee, immediately if the patient dies or has a medical emergency. This immediate notification is necessary to permit the Radiation Safety Officer to ensure that safety requirements are met for removal or disposal of the implanted radioactive material.

Section 35.610(a) would require licensees to develop, maintain, and implement safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.610(b) would require licensees to physically locate a copy of the procedures at the unit console. These safety procedures would be retained for the life of the license or the devices, or until superseded by new or revised procedures, in order to ensure that they remain available for reference.

Section 35.610(c) would require licensees to post instructions for individuals who operate the devices at the device console. These instructions would be retained for the life of the license or the devices, or until superseded by new or revised instructions, in order to ensure that they remain available for reference.

Section 35.643(b) would require licensees to have the authorized medical physicist establish procedures for performing periodic spot-checks on high dose-rate and pulsed dose-rate remote afterloaders. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.644(c) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on low dose-rate remote afterloaders prior to each patient treatment and after each source installation. Retaining such procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would enable the NRC to evaluate the nature and appropriateness of the procedures during inspections.

Section 35.645(b)(1) would require licensees to have the authorized medical physicist establish procedures for performing spot-checks on gamma stereotactic radiosurgery units monthly and prior to each day of use. Retaining these procedures for the life of the license or the devices, or until superseded by new or revised procedures, would ensure that they remain available for reference and would allow the NRC to evaluate the nature and appropriateness of such procedures during inspections.

Section 35.2024(a) would require licensees to retain a record of actions taken by licensee's management in accordance with §35.24(a) for five years. Maintaining this record for five years would allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2024(b) would require licensees to maintain a current copy of the authorities, duties, and responsibilities of the Radiation Safety Officer in accordance with §35.24(d). Maintaining a current copy of the authorities, duties, and responsibilities would ensure that they remain available for reference and would allow the NRC to evaluate the nature and appropriateness of such actions during inspections.

Section 35.2026 would require licensees to retain a record of radiation safety program changes in accordance with §35.26 for five years. Maintaining this record for five years would allow the NRC to evaluate the nature and appropriateness of such changes during inspections.

Section 35.2630 would require licensees to retain a record of each calibration, intercomparison, and comparison of dosimetry equipment done in accordance with §35.630 for the duration of the license. These records are necessary to show throughout the period of use of the equipment that calibrations of medical devices were made with properly calibrated equipment.

Section 35.2652 would require licensees to retain a record of radiation surveys of treatment units made in accordance with §35.652 for the duration of use of the unit. These records are necessary throughout the period of use of the unit to provide assurance that the source was properly installed or repaired and that the unit did not exceed occupational dose levels with the sources in the shielded position. They would also be necessary in reconstruction following an incident involving the unit.

Section 35.2655 would require licensees to keep a record of five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by §35.655 for the duration of use of the unit. This record is required throughout the period of use of the unit to show that the required work was done and to establish a service history that may be used in incident investigations and evaluation of generic equipment problems.

Section 35.3045(b) would require licensees to report an administration of byproduct material or radiation therefrom that meets or exceeds the criteria in §35.3045(a) for a medical event within one calendar day after discovery of the medical event. This requirement is the minimum frequency to inform the NRC about a medical event so that any follow-up action can be taken. In addition, prompt notification is necessary because a medical event may present a radiation hazard to a member of the public that might be mitigated by NRC assistance.

Section 35.3045(c) would require licensees to submit a written report to the appropriate NRC Regional Office listed in §30.6 within 15 days after discovery of the medical event. This written report is necessary to provide a detailed record of the medical event. The report also may be used to satisfy the requirements of §35.3045(e)(1).

Section 35.3045(d) would require licensees to notify the referring physician and the individual affected by the medical event, or to that individual's responsible relative or guardian when appropriate, no later than 24 hours after its discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. This requirement is the minimum frequency to inform the individuals and their referring physician(s), or the individual's responsible relative or guardian, of the medical event in order to allow them to make timely decisions regarding possible health care needs.

Section 35.3045(e) would require that if the individual affected by the medical event has been notified orally of the medical

event, the licensee must furnish a written report of the medical event to the patient within 15 days after the discovery of the medical event. This requirement is the minimum frequency to ensure that complete written information is furnished to an individual so that adequate followup to the medical event can be provided, if needed.

Section 35.3046(a) would require licenses to notify by telephone the NRC Operations Center no later than the next calendar day after identifying any precursor events. Submission of the notice no later than the next calendar day is necessary so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.3046(b) requires licensees to file a report with the NRC within 15 days of any precursor event. Submission of written report is necessary to provide a detailed record of the precursor event, to support any necessary followup actions by NRC to notify other licensees, and to address the root causes of the precursor event.

Section 35.3047(c) would require licensees to notify by telephone the NRC Operation Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). Notification within five days is necessary to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Section 35.3047(d) would require licensees to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §35.3047(a) or (b). Submission of a written report is needed to provide detailed information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Section 35.3067 would require licensees to file a report with the NRC within 5 days if a leakage test required by §35.67 reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination. This report is necessary so that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee up to five days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

8. Consultations Outside the Agency

The program for revising Part 35 and the associated guidance documents has involved more interactions and consultations with

potentially affected parties (the medical community and the public) than is provided by the typical notice and comment rulemaking process. Early public input was solicited through several different mechanisms: requesting public input through Federal Register notices; holding open meetings of the government groups developing the revised rule language; meeting with medical professional societies and boards (listed below); putting background documents, options for the more significant regulatory issues associated with the rulemaking, and a "strawman" draft proposed rule on the Internet; and convening public workshops. Participants from the broad spectrum of interests that may be affected by the rulemaking were invited to attend the public workshops in Philadelphia, PA and Chicago, IL, held in October and November 1997. The public was also welcome to attend these workshops, as well as the Part 35 Workshop that was held in conjunction with the All Agreement States Meeting in October 1997 and the NRC's Advisory Committee on the Medical Uses of Isotopes meetings in September 1997 and March 1998.

In addition, the rulemaking process is using a working group, steering group, and guidance consolidation team that includes not only members from the NRC headquarters offices, but also members from the regional licensing and inspection staff that are in frequent contact with NRC's medical licensees. Representatives of two Agreement States and a non-Agreement State are members of the groups developing the rule and guidance. The Agreement State representative on the working group is also a member of the Conference of Radiation Control Directors' Suggested State Regulation Committee on Medical Regulation, which is working toward parallel development of suggested State regulations. State participation in the process will enhance development of corresponding rules in State regulations and will provide an early opportunity for State input. In addition, it will allow the State staff to assess the potential impacts of NRC draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States. The meetings of the groups developing the rule text and the associated guidance are noted in the NRC meeting announcements and are open to the public.

The NRC has benefitted from all of the comments received during these interactions, as well as the written comments received in response to the request for input in the Federal Register notice.

Interactions with Medical Professional Societies

Date	Location	Society
6/4/97	San Antonio, TX	Society of Nuclear Medicine American College of Nuclear Physicians
6/11/97	Lake Tahoe, CA/NV	American College of Medical Physicists
9/7/97	Atlanta, GA	American College of Radiology
9/16/97	Rockville, MD	American College of Radiation Oncology
9/26/97	San Francisco, CA	American Association of Clinical Endocrinologists
9/97	Professional Journal Notice	Oncology Nursing Services
10/16/97	Chicago, IL	American Hospital Association
10/18/97	Los Angeles, CA	Organization of Agreement States
10/20/97	Orlando, FL	American Society of Therapeutic Radiology and Oncology
10/22/97	Bethesda, MD	American College of Cardiology American Society of Nuclear Cardiology
12/2/97	Chicago, IL	Radiation Society of North America
12/18/97	Rockville, MD	Society of Nuclear Medicine
2/1/98	Las Vegas, NV	Society of Nuclear Medicine

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

This information is usually not confidential. If it were, the information would be handled as proprietary in accordance with 10 CFR 2.790 of the NRC regulations.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:

The total annual burden is estimated to be about 494,211 hours per year (about 259 hours per licensee) for the 1,902 licensees covered by 10 CFR Part 35. The details are shown in Tables 1 and 2. The total cost for the NRC licensees is estimated at \$59,799,531 (494,211 hours x \$121.00 per hour).

NRC estimates that the burden for §§ 35.50, 35.51, 35.55, 35.290, 35.292, 35.390, 35.490, or 35.690, or equivalent Agreement State regulations will be somewhat smaller than estimated over the 3-year period for this clearance package. Existing training and

experience requirements for licensees under Subpart J are expected to be phased out over an approximately 2-year period following the effective date of the rule. The burden for those requirements is less than the burden for the requirements being substituted by the proposed rule. The difference in burden will be determined by the period of time required for certifying organizations to submit applications and for the NRC to review and approve them.

Agreement State Licensees:

This rule has several compatibility categories. Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of their health and safety requirement. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Part 35. A category "A" designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. Category "A" designated Agreement State requirements should be essentially identical to those of the NRC. A category "B" designation means the requirement has significant direct transboundary implications. Category "B" designated Agreement State requirements should be essentially identical to those of the NRC. A category "C" designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplication or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A category "D" designation means the requirement does not need to be adopted by an Agreement State for purposes of compatibility. The Health and Safety (H&S) Category identifies requirements which are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program. The Agreement States are encouraged to adopt similar regulations, but are not required to have any degree of uniformity between the NRC regulations and the State regulations. The burden for Agreement State licensees is calculated on the basis of Agreement States having similar regulations for medical use programs.

The total annual burden for Agreement States licensees if all requirements are enacted is estimated to be about 1,235,318 hours per year (about 259 hours per licensee) for the estimated 4,760 licensees covered by equivalent regulations. The details are shown in Tables 3 and 4. The total cost for the Agreement State licensees is estimated at \$149,473,478 (1,235,318 hours x \$121.00 per hour).

Source of Burden and Cost Data and Method of Estimating and Cost

The burden estimates are based on the staff's best estimate of the time required to perform information collection activities. NRC received information on information collection activities during the public workshops and meetings described above. Cost estimates are based on the rate used in NRC's license fee rule.

13. Estimate of Other Additional Costs

None. For licensees under 10 CFR Part 35, it is most likely that purchases of equipment and services were already acquired as part of customary and usual business or private practices.

14. Estimated Annualized Cost to the Federal Government

Application review activities are attributable to and reported under NRC Form 313, "Application for Material Licensee," OMB Clearance No. 3150-0120.

Annual Cost of NRC staff review for activities other than application review (Professional effort is 33,272 hours @ \$121.00 per hour) = \$4,025,912.

15. Reasons for Changes in Burden and Cost

NRC Licensees:

The revision is a net upward adjustment in burden of 2,633 hours. As a result of a comprehensive revision of the Part 35 requirements to eliminate prescriptive requirements, at least 10 reporting requirements were eliminated as a result of rulemaking since the last burden was calculated. (Sections 35.60(b), 35.61(b), 35.70(d), 35.70(g), 35.315(a)(6), 35.610(a), 35.643(a)(3), 35.643(b), 35.645, and 35.980(b)(2).) Three recordkeeping requirements were eliminated (35.20, 35.22(a)(4) and (5), and 35.32) and numerous other requirements were revised. However, revisions to the training and experience requirements and estimates relating to the number of certain radiation safety activities to be undertaken by licensees offset these reductions.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

Not Applicable

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

Table 1- Reporting Requirements
NRC Licensees

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.6	1,644	1	8	13,152
35.12(b)	OMB Clearance 3150-0120			
35.12(c)	OMB Clearance 3150-0120			
35.12(d)	2	1	4	8
35.13	OMB Clearance 3150-0120			
35.14(a)	OMB Clearance 3150-0120			
35.14(b)	73	1	0.25	18
35.27(a)	1,902	1	1	1,902
35.27(b)	1,902	1	1	1,902
35.67(e)(2)	Burden calculated in 35.3067			
35.75(b)	1,066	24	0.17	4,247
35.315(b)	16	1	1	16
35.415(c)	73	1	1	73
35.642(c)	63	12	0.25	189
35.3045(b)	30	1	0.50	15
35.3045(c)	30	1	8	240
35.3045(d)	30	1	2	60
35.3045(e)	30	1	2	60
35.3046(a)	50	1	4	200
35.3047(a)	1	1	8	8
35.3047(b)	1	1	2	2
35.3047(c)	1	1	0.5	0.5
35.3047(d)	1	1	8	8
35.3067	2	2	2	8
Appendix A, Part I, Item 11	39	1	0.5	20
Appendix A, Part I, Item 12	39	1	120	4,680
Appendix A, Part III, Item 3	39	1	120	4,680
Total:	7,034	57	294	31,488

Table 2- Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.24(a)	1,216	5	0.5	3,040	5 years
35.24(b)	1,277	1	0.5	639	Duration of license
35.24(d)	1,216	1	0.5	608	Duration of license
35.24(f)	Burden calculated in 35.2024				
35.26(a)(3)+(4)	1,902	1	0.5	951	5 years
35.26(b)	Burden calculated in 35.2026				
35.27(c)	1,902	1	0.5	951	Duration of license
35.40	Burden calculated in 34.2040				
35.41(a)	1,902	1	0.5	951	Duration of license
35.50(a)	47	1	0.5	24	
35.50(b)(2)	5	1	0.5	3	
35.50(b)(3)	5	1	0.5	3	
35.51(a)	47	1	0.5	24	
35.51(b)(2)	5	1	0.5	3	
35.51(b)(3)	5	1	0.5	3	
35.55(a)	1	1	0.5	1	
35.55(b)(2)	1	1	0.5	1	
35.55(b)(3)	1	1	0.5	1	
35.57(c)	50	1	0.25	0	
35.60(b)	1,902	1	1	1,902	Equipment duration
35.60(e)	Burden calculated in 35.2060				
35.61(a)(3)	1,902	1	0.03	57	Equipment duration
35.61(b)	1,902	1	0.03	57	Equipment duration
35.61(d)	Burden calculated in 35.2061				
35.62(b)	52	1	0.5	26	Equipment duration
35.62(d)	Burden calculated in 35.2060				
35.63(e)	Burden calculated in 35.2063				
35.67(a)	1,346	1	0.5	673	Source duration
35.67(d)	Burden calculated in 35.2067(a)				
35.67(g)	Burden calculated in 35.2067(b)				
35.69(a)	1,707	1	0.5	854	Duration of license
35.70	Burden calculated in 35.2070				

Table 2- Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.75(c)	Burden calculated in 35.2075(a)				
35.75(d)	Burden calculated in 35.2075(b)				
35.80(a)	40	20	1	800	3 years after last service
35.80(e)	Burden calculated in 35.2080				
35.80(f)	Burden calculated in 35.2080				
35.92(b)	Burden calculated in 35.2092				
35.204(c)	Burden calculated in 35.2204				
35.290(a)	285	1	0.5	143	
35.290(b)(2)	3	1	0.5	2	
35.290(b)(3)	3	1	0.5	2	
35.292(a)	285	1	0.5	143	
35.292(b)(2)	3	1	0.5	2	
35.292(b)(3)	3	1	0.5	2	
35.310(b)	Burden calculated in 35.2310				
35.315(a)(2)	1,066	3	0.2	640	Duration of treatment
35.390(a)	332	1	0.5	166	
35.390(b)(3)	37	1	0.5	19	
35.390(b)(4)	37	1	0.5	19	
35.404(c)	Burden calculated in 35.2404				
35.406(c)	Burden calculated in 35.2406				
35.410(b)	Burden calculated in 35.2301				
35.415(a)	454	18	0.2	1,634	Duration of treatment
35.432(f)	Burden calculated in 35.2432				
35.490(a)	39	1	0.5	20	
35.490(b)(3)	4	1	0.5	2	
35.490(b)(4)	4	1	0.5	2	
35.590	360	1	0.5	162	
35.604(b)	Burden calculated in 35.2404				
35.605(d)	Burden calculated in 35.2605				
35.610(a)	195	1	0.5	98	Duration of use of unit
35.610(b)	195	1	0.03	6	Duration of use of unit
35.610(c)	195	1	0.5	98	Duration of use of unit

Table 2- Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.610(e)	Burden calculated in 35.2310				
35.630(c)	Burden calculated in 35.2630				
35.632(g)	Burden calculated in 35.2632				
35.633(h)	Burden calculated in 35.2633				
35.635(g)	Burden calculated in 35.2635				
35.642(c)	63	12	0.25	189	Duration of use of unit
35.642(f)	Burden calculated in 35.2642				
35.643(b)	114	1	0.5	57	Duration of use of unit
35.643(h)	Burden calculated in 35.2643				
35.644(c)	29	1	0.5	15	Duration of use of unit
35.644(e)	Burden calculated in 35.2643				
35.645(b)(1)	9	1	0.5	9	Duration of use of unit
35.645(b)(2)	9	260	0.25	585	Duration of use of unit
35.645(g)	Burden calculated in 35.2645				
35.647(e)	Burden calculated in 35.2647				
35.652(c)	Burden calculated in 35.2652				
35.655(c)	Burden calculated in 35.2655				
35.690(a)	39	1	0.5	20	
35.690(b)(4)	4	1	0.5	2	
35.690(b)(5)	4	1	0.5	2	
35.2024(a)	1,216	5	0.25	1,520	5 years
35.2024(b)	1,216	1	0.08	97	Duration of license
35.2026	1,902	1	0.25	476	5 years
35.2040	1,902	21	0.16	6,391	3 years
35.2045	30	1	0.25	8	3 years
35.2060	1,902	400	0.2	152,160	3 years
35.2061	1,902	1.5	0.5	1,427	3 years
35.2063	1,757	290	0.16	81,525	3 years
35.2067(a)	1,346	2	0.16	431	3 years
35.2067(b)	1,346	2	0.5	1,346	3 years
35.2070	1,757	260	0.25	114,205	3 years
35.2075(a)	1,066	24	0.08	2,047	3 years

Table 2- Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.2075(b)	1,066	3	0.16	512	3 years
35.2075(c)	1,066	2	0.13	277	3 years
35.2080(a)	40	20	0.03	24	3 years after last service
35.2080(b)	40	20	6.5	5,200	3 years
35.2092	1,757	88	0.16	24,739	3 years
35.2204	674	52	0.08	2,804	3 years
35.2310	1,066	1	0.25	267	3 years
35.2404	621	29	0.25	4,502	3 years
35.2406	454	25	0.16	1,816	3 years
35.2432	454	25	0.16	1,816	3 years
35.2605	521	1	2	1,042	3 years
35.2630	521	1	0.5	261	3 years
35.2632	63	1.5	4	378	3 years
35.2633	143	3	4	1,716	3 years
35.2635	9	1.2	4	43	3 years
35.2642	63	12	0.5	378	3 years
35.2643	143	260	1	37,180	3 years
35.2645	9	260	1	2,340	3 years
35.2647	0	0	0	0	3 years
35.2652	195	1	0.5	98	Duration of use of unit
35.2655	65	0.2	2	26	Duration of use of unit
Appendix A, Part I, Item 1	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 2	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 3	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 4	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 5	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 6	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 7	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 8	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 9	39	1	0.16	6	Indefinite
Appendix A, Part I, Item 10	39	1	0.16	6	Indefinite
Appendix A, Part II, Item 2	39	1	0.16	6	Indefinite

Table 2- Recordkeeping Requirements
NRC Licensees

Section	No. of NRC Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
Appendix A, Part III, Item 2	39	1	0.16	6	Indefinite
Total:	48,984	2,187	55	462,723	

Table 3- Reporting Requirements
Agreement State Licensees

Section	Number of Agreement State Licensees	Number of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.6	4,110	1	8	32,880
35.12(b)	OMB Clearance 3150-0120			
35.12(c)	OMB Clearance 3150-0120			
35.12(d)	5	1	4	20
35.13	OMB Clearance 3150-0120			
35.14(a)	OMB Clearance 3150-0120			
35.14(b)	183	1	0.25	46
35.27(a)	4,755	1	1	4,755
35.27(b)	4,755	1	1	4,755
35.67(e)(2)	Burden calculated in 35.3067			
35.75(b)	2,665	24	0.17	10,617
35.315(b)	40	1	1	40
35.415(c)	183	1	1	183
35.642(c)	158	12	0.25	473
35.3045(b)	75	1	0.5	38
35.3045(c)	75	1	8	600
35.3045(d)	75	1	2	150
35.3045(e)	75	1	2	150
35.3046(a)	125	1	4	500
35.3047(a)	3	1	8	20
35.3047(b)	3	1	2	5
35.3047(c)	3	1	0.5	1
35.3047(d)	3	1	8	20
35.3067	5	2	2	20
Appendix A, Part I, Item 12	98	1	120	11,700
Appendix A, Part III, Item 3	98	1	120	11,700
Total:	17,488	56	294	78,672

Table 4- Recordkeeping Requirements
Agreement State Licensees

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record-keeping Hours	Record Retention Period
35.24(a)	3,040	5	0.5	7,600	5 years
35.24(b)	3,193	1	0.5	1,596	Duration of license
35.24(d)	3,040	1	0.5	1,520	Duration of license
35.24(f)	Burden calculated in 35.2024				
35.26(a)(3)+(4)	4,755	1	0.5	2,378	5 years
35.26(b)	Burden calculated in 35.2026				
35.27(c)	4,755	1	0.5	2,378	Duration of license
35.40	Burden calculated in 34.2040				
35.41	4,755	1	0.5	2,378	Duration of license
35.50(a)	Not effective during clearance period.				
35.50(b)(2)	Not effective during clearance period.				
35.50(b)(3)	Not effective during clearance period.				
35.51(a)	Not effective during clearance period.				
35.51(b)(2)	Not effective during clearance period.				
35.51(b)(3)	Not effective during clearance period.				
35.55(a)	Not effective during clearance period.				
35.55(b)(2)	Not effective during clearance period.				
35.55(b)(3)	Not effective during clearance period.				
35.57(c)	Not effective during clearance period.				
35.60(b)	4,755	1	1	4,755	Equipment duration
35.60(e)	Burden calculated in 35.2060				
35.61(a)(3)	4,755	1	0.03	143	Equipment duration
35.61(b)	4,755	1	0.03	143	Equipment duration
35.61(d)	Burden calculated in 35.2061				
35.62(b)	130	1	0.5	65	Equipment duration
35.62(d)	Burden calculated in 35.2060				
35.63(e)	Burden calculated in 35.2063				
35.67(a)	3,365	1	0.5	1,683	Source duration
35.67(d)	Burden calculated in 35.2067(a)				
35.67(g)	Burden calculated in 35.2067(b)				
35.69	4,268	1	0.5	2,134	Duration of license
35.70	Burden calculated in 35.2070				
35.75(c)	Burden calculated in 35.2075(a)				

**Table 4- Recordkeeping Requirements
Agreement State Licensees**

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.75(d)	Burden calculated in 35.2075(b)				
35.80(a)	100	20	1	2,000	3 years after last service
35.80(e)	Burden calculated in 35.2080				
35.80(f)	Burden calculated in 35.2080				
35.92(b)	Burden calculated in 35.2092				
35.204(c)	Burden calculated in 35.2204				
35.290(a)	Not effective during clearance period.				
35.290(b)(2)	Not effective during clearance period.				
35.290(b)(3)	Not effective during clearance period.				
35.292(a)	Not effective during clearance period.				
35.292(b)(2)	Not effective during clearance period.				
35.292(b)(3)	Not effective during clearance period.				
35.310(b)	Burden calculated in 35.2310				
35.315(a)(2)	2,665	3	0.2	1,599	Duration of treatment
35.390(a)	Not effective during clearance period.				
35.390(b)(3)	Not effective during clearance period.				
35.390(b)(4)	Not effective during clearance period.				
35.404(c)	Burden calculated in 35.2404				
35.406(c)	Burden calculated in 35.2406				
35.410(b)	Burden calculated in 35.2301				
35.415(a)	1,135	18	0.2	4,086	Duration of treatment
35.432(f)	Burden calculated in 35.2432				
35.490(a)	Not effective during clearance period.				
35.490(b)(3)	Not effective during clearance period.				
35.490(b)(4)	Not effective during clearance period.				
35.590	Not effective during clearance period.				
35.604(b)	Burden calculated in 35.2404				
35.605(d)	Burden calculated in 35.2605				
35.610(a)	488	1	0.5	244	Duration of use of unit
35.610(b)	488	1	0.03	15	Duration of use of unit
35.610(c)	488	1	0.5	244	Duration of use of unit
35.610(e)	Burden calculated in 35.2310				
35.630(c)	Burden calculated in 35.2630				

Table 4- Recordkeeping Requirements
Agreement State Licensees

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.632(g)	Burden calculated in 35.2632				
35.633(h)	Burden calculated in 35.2633				
35.635(g)	Burden calculated in 35.2635				
35.642(c)	158	12	0.25	473	Duration of use of unit
35.642(f)	Burden calculated in 35.2642				
35.643(b)	285	1	0.5	143	Duration of use of unit
35.643(h)	Burden calculated in 35.2643				
35.644(c)	73	1	0.5	36	Duration of use of unit
35.644(e)	Burden calculated in 35.2643				
35.645(b)(1)	23	1	0.5	9	Duration of use of unit
35.645(b)(2)	23	260	0.25	1,463	Duration of use of unit
35.645(g)	Burden calculated in 35.2645				
35.647(e)	Burden calculated in 35.2647				
35.652(c)	Burden calculated in 35.2652				
35.655(c)	Burden calculated in 35.2655				
35.690(a)	Not effective during clearance period.				
35.690(b)(4)	Not effective during clearance period.				
35.690(b)(5)	Not effective during clearance period.				
35.900(a)	132	1	0.5	66	
35.910(a)	793	1	0.5	397	
35.920(a)	793	1	0.5	397	
35.930(a)	900	1	0.5	450	
35.932(a)	10	1	0.5	5	
35.934(a)	10	1	0.5	5	
35.940(a)	107	1	0.5	54	
35.941(a)	5	1	0.5	2.5	
35.950(a)	900	1	0.5	450	
35.960(a)	107	1	0.5	54	
35.961(a)	132	1	0.5	66	
35.980(a)	3	1	0.5	2	
35.2024(a)	3,040	5	0.25	3,800	5 years
35.2024(b)	3,040	1	0.08	243	Duration of license
35.2026	4,755	1	0.25	1,189	5 years

Table 4- Recordkeeping Requirements
Agreement State Licensees

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
35.2040	4,755	21	0.16	15,977	3 years
35.2045	75	1	0.25	19	3 years
35.2060	4,755	400	0.2	380,400	3 years
35.2061	4,755	1.5	0.5	3,566	3 years
35.2063	4,393	290	0.16	203,812	3 years
35.2067(a)	3,365	2	0.16	1,077	3 years
35.2067(b)	3,365	2	0.5	3,365	3 years
35.2070	4,393	260	0.25	285,513	3 years
35.2075(a)	2,665	24	0.08	5,117	3 years
35.2075(b)	2,665	3	0.16	1,279	3 years
35.2075(c)	2,665	2	0.13	693	3 years
35.2080(a)	100	20	0.03	60	3 years after last service
35.2080(b)	100	20	6.5	13,000	3 years
35.2092	4,393	88	0.16	61,846	3 years
35.2204	1,685	52	0.08	7,010	3 years
35.2310	2,665	1	0.25	666	3 years
35.2404	1,553	29	0.25	11,256	3 years
35.2406	1,135	25	0.16	4,540	3 years
35.2432	1,135	25	0.16	4,540	3 years
35.2605	1,303	1	2	2,605	3 years
35.2630	1,303	1	0.5	651	3 years
35.2632	158	1.5	4	945	3 years
35.2633	358	3	4	4,290	3 years
35.2635	23	1.2	4	108	3 years
35.2642	158	12	0.5	945	3 years
35.2643	358	260	1	92,950	3 years
35.2645	23	260	1	5,850	3 years
35.2647	0	0	0	0	3 years
35.2652	488	1	0.5	244	Duration of use of unit
35.2655	163	0.2	2	65	Duration of use of unit
Appendix A, Part I, Item 1	N/A				
Appendix A, Part I, Item 2	N/A				
Appendix A, Part I, Item 3	N/A				

**Table 4- Recordkeeping Requirements
Agreement State Licensees**

Section	No. of Agreement State Recordkeepers	Number of Records per Licensee Year	Hours per Record	Total Record- keeping Hours	Record Retention Period
Appendix A, Part I, Item 4	N/A				
Appendix A, Part I, Item 5	N/A				
Appendix A, Part I, Item 6	N/A				
Appendix A, Part I, Item 7	N/A				
Appendix A, Part I, Item 8	N/A				
Appendix A, Part I, Item 9	N/A				
Appendix A, Part I, Item 10	N/A				
Appendix A, Part I, Item 11	N/A				
Appendix A, Part II, Item 2	N/A				
Appendix A, Part III, Item 2	N/A				
Total:	121,160	2,161	46	1,156,646	

**Table 5-Form 313 Additional Burden
to NRC Licensees for Submission of Credentials for New Staff to NRC**

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.50(a)+(b)	185	1	1	185
35.51(a)+(b)	185	1	1	185
35.55(a)	5	1	1	5
35.290(a)+(b)	110	1	1	110
35.292(a)+(b)	110	1	1	110
35.390(a)+(b)	1,290	1	1	1,290
35.490(a)+(b)	150	1	1	150
35.690(a)+(b)	150	1	1	150
Total:	2,185	8	8	2,185

Table 6-Part 35 Overlooked Burden for Obtaining Copy of Certification by 90 Percent of Applicants

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.50(a)	167	1	1	167
35.51(a)	167	1	1	167
35.55(a)	5	1	1	5
35.290(a)	99	1	1	99
35.292(a)	99	1	1	99
35.390(a)	1,161	1	1	1,161
35.490(a)	135	1	1	135
35.690(a)	135	1	1	135
Total:	1,967	8	8	1,967

Table 7-Part 35 New Burden for Obtaining Preceptor Statement and Test Result by 10 Percent of Applicants

Section	Number of NRC Licensees	Number of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.50(b)	19	1	1	19
35.51(b)	19	1	1	19
35.55(b)	1	1	1	1
35.290(b)	11	1	1	11
35.292(b)	11	1	1	11
35.390(b)	129	1	1	129
35.490(b)	15	1	1	15
35.690(b)	15	1	1	15
Total:	219	8	8	219