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RULE ON MEDICAL USE OF BYPRODUCT
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ANN RILEY & ASSOCIATES, LTD.
1025 Connecticut Avenue, NW, Suite 1014
Washington, D.C. 20036
(202) 842-0034

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

OFFICE OF THE SECRETARY

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BRIEFING ON PART 35

RULE ON MEDICAL USE OF BYPRODUCT MATERIAL

Room 1F-16

One White Flint North

11555 Rockville Pike

Rockville, Maryland

Thursday, October 21, 1999

The Commission met in open session, pursuant to notice, at 9:36 a.m., Greta J. Dicus, Chairman, presiding.

COMMISSIONER'S PRESENT:

GRETA J. DICUS, Chairman of the Commission

NILS J. DIAZ, Commissioner (Via Speaker Phone)

EDWARD McGAFFIGAN, JR., Commissioner

JEFFREY S. MERRIFIELD, Commissioner

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1025 Connecticut Avenue, NW, Suite 1014
Washington, D.C. 20036
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P R O C E E D I N G S

[9:36 a.m.]

CHAIRMAN DICUS: Good morning again, ladies and gentlemen.

On behalf of my fellow Commissioners, I would like to welcome the staff from the Office of Nuclear Materials Safety and Safeguards, as well as representatives from the Advisory Committee on the Medical Use of Isotopes.

Today's presentation will discuss many of the proposed major revisions to NRC's 10 CFR Part 35, the medical use of byproduct material.

The Commission's last briefing on this subject was on March 25, 1999, and since that time, the staff has continued to listen and work with our stakeholders to modify and to revise the draft final rule.

Some of the more important issues that we will hear about today is the training and experience requirements for authorized users, reporting thresholds for unintended exposures, and potential notification following a medical event.

This draft final rule illustrates the ability by staff, members of the public, the medical community, licensees, and the agreement states to be able to effectively communicate and work together to develop a draft final rule that is both risk-informed and performance-based,

which is a vast improvement over the existing 10 CFR Part 35.

More important, however, is the focus that the rule continues to ensure the patient's health and safety, while using past operating experience from medical facilities across the United States to make risk-informed changes to the regulations which reduce unnecessary regulatory burden for very low-risk procedures.

The many weekends, week-nights, and holidays that the staff of the Division of Industrial and Medical Nuclear Safety has worked have not gone unnoticed. The staff is to be highly commended for these efforts in bringing a well-balanced and well-written paper to the Commission. It is, indeed, a job well done.

Since August of 1997, seven facilitated public workshops have been held, for of which were during the public comment period of the proposed rule.

I note that the staff has made more than 20 formal presentations to professional societies on the particular items of interest to them, such as training and experience, T&E, requirements.

In addition, both the Organization of Agreement States and the Conference of Radiation Control Program Directors were directly involved with the preparation and development of the proposed and draft final rules.

While the information presented today is quite extensive, we will try to let you get through your presentations with minimum interruption and save our general questions until the end of each of the two major presentations.

In other words, the staff present first and then we will have a period of questions, and then the advisory committee to present, with a series of questions, and if time allows, we might have everybody at the table toward the end.

If there are additional questions, as I mentioned, we will try to have everyone together at the end.

Do any of my fellow Commissioners have any opening remarks they wish to express?

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: I want to echo your compliments to the staff. I think they've done an outstanding job here. I think this is a major improvement over the existing Part 35.

I also want to thank ACMUI, the members who put in a large number of hours plowing through large numbers of drafts, and I think we have a good product. Is it a perfect product? No. There will be dissatisfied people. But it is a vast improvement over the previous Part 35, and I compliment the staff for the effort.

CHAIRMAN DICUS: I thank you for those comments.

Commissioner Merrifield?

COMMISSIONER MERRIFIELD: I'd like to join in that sentiment.

Cathy Haney, Diane Flack, and the rest of the Part 35 team have done an outstanding job. I know there are some areas where some stakeholders still have concerns. We'll work through those, but overall, it's a tremendous amount of effort on the part of the staff, and we do recognize that and thank you.

CHAIRMAN DICUS: We do really, very much, as all of us have mentioned, appreciate the effort. We know this has been a major effort. I know how long this has been on the books, and I also appreciate the work of ACMUI and what you have done in giving your time to this effort.

So, without any further ado, Dr. Paperiello, if you would introduce the staff, and we will get started.

DR. PAPERIELLO: Thank you, Madam Chairman and Commissioners.

As you noted, the purpose of the meeting today is to brief the Commission on the revision of Part 35, medical use of byproduct material.

Before the staff starts the actual briefing on the issues associated with rule-making, I'd like to note that the draft final rule before the Commission is the

culmination of extensive effort that began in 1993, when the Commission examined the issues surrounding the medical use program.

In 1997, the Commission stated that it supported the ongoing medical use regulatory program, with improvement, decreased oversight of low-risk activities, and continued emphasis on high-risk activities.

That direction from the Commission has resulted in a draft final rule that significantly reduces the requirements for medical use licensees, especially for diagnostic uses.

In addition to other Commission guidance over the past two years, the staff has also benefitted from extensive interactions with the advisory committee on medical uses of isotopes, medical professional societies, and other stakeholders, and in particular, as we heard from yesterday, the agreement states and the Conference of Radiation Control Program DIrectors.

The staff has kept the Commission apprised of the key issues associated with rule-making through SECY papers and previous briefings.

Our presentation today will focus on the issues where the staff has requested Commission guidance, in SECY 99-201, in order to finalize the rule-making.

However, the staff is prepared to discuss other

issues in the draft final rule, as well as the public comments on the proposed rule and the comparison of current requirements in Part 35 with the requirements in the draft final rule.

Members of the Commission's ACMUI will follow their comments -- with their comments on the staff's proposed resolutions of the key issues.

Following the formal presentations, the staff will be glad to respond to questions.

Seated the table with me are William Kane, Director of the Office of Nuclear Material Safety and Safeguards; Dr. Donald Cool, Director of the Division of Industrial, Medical, and Nuclear Safety; and Cathy Haney, Chairperson of the Part 35 Working Group.

Ms. Haney will be presenting the staff's position on the key issues.

Following the staff's presentation, Dr. Manuel Cerqueira, Ms. Nekita Hobson, Ms. Ruth McBurney, and Dr. Louis Wagner will present the ACMUI's position on the key issues.

Cathy Haney will now begin the staff's briefing on Part 35.

MS. HANEY: Good morning. Thank you.

If I could have view-graph number one, I would like to first go through what I would like to discuss with

the Commission first.

That would be just a brief discussion on the background, some of the extra information that is included in SECY 99-201, identify the key issues for the Commission's consideration, also look into our implication -- what we consider to be implications of implementing the rule in the licensing, inspection, and enforcement program, and then, finally, to give you our best estimate of the time-table for completion of this project and also the resources needed to complete the task before us.

Next view-graph, please.

With background, as has been indicated, we're really starting back with the March 20, 1997, SRM from the Commission that asked that we revise Part 35 into a more risk-informed performance-based regulation, and again, as indicated previously, we have had continuous interactions with the public, with stakeholders, agreement states, non-agreement states, and the ACMUI, and that's why I believe we were able to really put this package before you with considering all these comments.

It was very advantageous to us to have this interaction with the stakeholders.

The next view-graph -- I'd like to note just a couple of things on this.

Obviously, the main reason for providing you with

SECY 99-201 was to provide the draft final rule language to you, but we also used this as a mechanism for closing out previous requests from the Commission on some of the outstanding issues.

One such example would be the need for a formal risk assessment, which we'll discuss in a minute.

The other thing was to provide the Commission with our understanding of where the draft final rule package differs from that of the SR-6 committee, the SR-6 committee being a committee that's under the Conference of Radiation Control Program Directors that is developing a suggested state regulation for the medical area.

In view-graph four, there are several issues that we would like to highlight for the Commission's decision. They are noted on this slide.

There are numerous other issues associated with this project, but knowing that I couldn't have you for eight hours to talk to you about them, we identified just the key ones that we wanted to put before you, the first one being --

CHAIRMAN DICUS: Do you think you can get all the key issues just in eight hours?

MS. HANEY: No.

COMMISSIONER MERRIFIELD: That's reading them.

MS. HANEY: It's not telling you the background.

COMMISSIONER McGAFFIGAN: Madam Chairman, I just might note -- I forget whether we've said it already. This paper has been available to the public since early August, and we've been pouring over it and getting briefed on it bit by bit.

So, this is the tip of the iceberg of the Commission's involvement in this paper and, I think, the public involvement, as well.

COMMISSIONER MERRIFIELD: I'd actually, just for a second, like to jump in on that.

I think all of the Commissioners, or at least all the Commissioners present, have also had separate briefings from the staff on this, and there are a number of questions that I had that have already been answered, and I'll try to give the flavor of some of those today, but you know, normally, I might have more questions than perhaps I may have today, and that's not as a result of not having questions, it's a result of having answers.

CHAIRMAN DICUS: I think we're all in the same boat. I do have the questions that I'll ask on behalf of Commissioner Diaz, but we're going to let you go ahead and get through. You're going very well.

MS. HANEY: Thank you.

All right.

The first topic would be the need for a risk

assessment, and the issue here is whether we need to perform a formal risk assessment.

After the March briefing, the Commission asked us to provide the pros and cons associated with doing a formal risk assessment at this time.

The pros, obviously, would be that there would be additional information and that it would be responsive to some of the public comments.

However, there are several down-sides to doing it at this point, and this has to do with the significant delay in providing a final rule to either the Commission or putting a final rule in the Federal Register. It also would be significantly resource-intensive.

We believe what we've provided you with is a risk-informed rule and that we have made significant reductions in unnecessary burden associated with the use of byproduct material.

Another thing to note, too, is that some of the data that would be needed to perform a formal risk assessment would be problematic, and this goes back to information that appeared in the NAS -- the National Academy of Science Institute of Medicine report, when they did look at NRC's role in regulating in this particular area.

As I said earlier, we have made significant reductions in unnecessary burden.

Just to give you an example of a few of them for consideration would be as the reduction in the radiation safety committee, your diagnostic users would no longer be required to have a radiation safety committee, some of the quality assurance tests that are done on generators. We have reduced requirements in for surveys in the department, relying on Part 20 as the governing regulation, as compared to Part 35, and also, we've made some changes in the requirements for what a licensee would need to -- when they would need to come in for a license amendment. All of those things considered, we do think that the rule has reduced the burden -- unnecessary burden.

Moving on to the next view-graph on radiation safety committee, this was a very interesting issue, and really, the issue is what is the impact of deleting the radiation safety committee? Does it reduce the licensee's radiation safety program effectiveness?

We took into consideration the risks associated with use of material at the facilities, as well as public comments.

Public comments really were from the standpoint of medical physicist, radiation safety officer, they believe a very strong importance for the safety committee, where others believed that it was more important to have flexibility.

Our recommendation would be that the radiation safety committee is only required if there are two or more different types of uses under the sub-parts E, F, and H, and what that translates into is, if you're using unsealed byproduct material for therapy, something such as I-131, remote after-loaders, gamma stereotactic radiosurgery units, teletherapy, or manual brachytherapy. If you have two or more of those types of units, then you would need to have a radiation safety committee.

Also, in subpart H -- subpart H is really medical devices, and we believe that, if you have two or more units under that particular subpart, that it was important to have a radiation safety committee.

For example, if you had a remote after-loader, those tend to be in your oncology department. If you had a gamma stereotactic radiosurgery unit, that tends to be in your neurosurgery units.

The concept of -- the need for a radiation safety committee is to bring departments together so that they can speak, and that's why we believe that this was important here.

We also believe this is a very good example of where we considered risk in reducing requirements.

Next view-graph, seven, has to do with training and experience requirements, and this was probably the

biggest issue that we had to address under this particular rule-making. It also received the most comments.

We believe that our regulation should be focused on the safe handling of the radioactive material and that it's important to note that being a licensed, authorized user under NRC, in the case of a physician, is saying the individual is competent to handle materials safely. it is not assessment of their clinical proficiency.

We do have some global recommendations in this particular area, and that is, as I said, we focus on radiation safety, and also, we rely on the preceptor form and the hours of -- that are required by the rule to assure that the individual has safe handling of the material.

Slide seven, please. Thanks.

If you remember back in the proposed rule, we had proposed that an exam be required, and also, in March, when I spoke with you, we asked that -- and we were considering NRC getting into a situation where we would approve training programs, but when we went back and looked at the implications and the assurance that we would gain from both of those particular items, we felt that we really didn't need to go to that extreme, that it would be sufficient to just require -- increase the number of hours in some areas of training over that in the proposed rule and also to rely on the preceptor form.

Now if you can move to page eight, the other thing I would like to point out about changes in the training and experience is that, in the case of the diagnostic users of material -- that's the 35.200 use of material -- that we no longer have the breakdown in the number of classroom hours and the number of work experience hours. We've grouped that together and asked that the individual have 700 hours of training, total, and we specify in the rule what we would want the individual to know.

So, this is, again, a step at us becoming less prescriptive and focusing in on performance, telling the licensees what we want them to know.

The other particular item that is a change in this area is that we have reinstated the current requirements for the use of strontium-90 for eye applicators.

Again, an example of looking at risk in this particular area, at the proposed rule we asked that the hours be increased to that required for radiation oncology. However, we were concerned about the impact on the profession by doing this.

We were also aware that there were a significant number of misadministrations in this particular area, but we asked ourselves whether increasing the training was really the solution to the problem, and our suggestion is that, in this case, it may not be.

The cause of the misadministrations were sources that had not been calibrated properly and had not been decayed.

So, we did put a prescriptive requirement into the rule that the sources would -- the licensee would need to have them calibrated to NIST and also that an authorized medical physicist perform the calculation.

Again, we recognize it is a prescriptive requirement, but because of the risk associated with the use of this material, we do believe that it is warranted.

Moving on to view-graph nine, this issue has to do with the reporting threshold for unintended exposure to the embryo/fetus and nursing child.

The issue here is that we do have a requirement to report to Congress when an embryo/fetus or nursing child receives an exposure greater than 5 rem or if there is a situation where there's been unintended permanent functional damage to an organ.

As a result, we proposed at the proposed rule stage that the threshold be slightly less than the AO criteria that we come -- that our rules require reporting at 500 millirem, rather than 5 rem, so that we would hear about information in advance of having to report it Congress.

We have changed -- based on public comment, staff is recommending that we increase the level from that

proposed in the proposed rule to the 5-rem limit, which would put it right at the limit of the AO criteria.

Now, if we go on to view-graph 10, some of the reasons that we are doing this are because of the impact on the medical profession if the threshold were left at 500 millirem.

We received comments to the point that, even in a diagnostic area, there are a significant number of procedures that would trip the 500-millirem level, and as a result, the practice of medicine would have to be changed somewhat to address this, because the question is would it be adequate any longer just to merely ask the patient if they were pregnant or would we get into a situation where they were having to do pregnancy tests all the time?

Another concern would get into the cost of who would be paying for this, whether it would be covered for insurance or not. Would the patient be able to go to the same facility to get the blood-work that they would need to that they would get the nuclear medicine procedure?

Also, it could actually impact the care of the individual, because the physicians might be leary to do this procedure, and therefore -- because they might have to report to NRC -- and therefore order tests that would not be as good as the nuclear medicine test as a diagnostic tool.

We consider this in light of the risks associated

with exposure between 500 millirem and 5,000 millirem, and what was -- you know, was the baby or embryo/fetus going to be negatively impacted?

We considered reports put out by the National Council on Radiation Protection and the American Association of Physicists in Medicine, and based on the information in that document, we felt justified in coming back to the Commission with the request to raise this level to 5 rem, also realizing that this is a reporting requirement and not a dose limit, and that is a very important distinction on this particular item.

Lou Wagner, who is on the ACMUI, is prepared to discuss the effects of the -- on the embryo/fetus and the nursing child between these two particular levels.

This is one of the areas where I would like to point out that there is a concern -- that there was a concern raised by the SR6 committee in this area, believing that the dose limit should not be at the 5-rem level, it would be better if it was at a lower threshold.

View-graph number 11 gets us into the next topic area, and that is notification following a medical event or exposure to the embryo/fetus or nursing child.

The issue here is should there be an NRC requirement that would require the licensee, referring physician, or the authorized user to notify either the

patient, the responsible relative, or the mother if an event did occur?

The public comments that we received were very much against a requirement from the standpoint of NRC having a requirement, indicating that it is the standard of car, standard of practice to inform the individual when an event such as this has occurred.

However, we have chosen, based on previous Commission positions, I guess is the best way to put it, that we would continue to require this notification in the rule.

We did, however, provide in the SECY paper some alternative rule text for this particular area, and that was in response to the SRM that we received after the March briefing.

So, what I would like to just run through real briefly with you are the pros and cons of the alternative text, recognizing that the alternative text would only require that the licensee certify to us that the individual would told.

We would go no further. We would not care whether a report was given to the mother nor would we ask if a report was given; it's merely licensee certify to us that you told them.

From the pros associated with this alternative, we

do believe that it is more consistent with the medical policy goals. We believe that it does put a greater reliance on the patient/physician relationship.

We would like to recognize that it is consistent with the Federal patient -- with other Federal patient notification requirements, that being FDA's, and then it also -- one could argue that it is stepping more into a more risk-informed situation than the current text is right now.

However, there are cons associated with that, and they are that it does not ensure that the patient is notified, is fully informed of the event. That's probably the biggest one.

The other is that it is not consistent with other NRC requirements, that being the Part 20 requirements that require the licensee to notify a member of the public or an occupationally-exposed individual if they receive doses in excess of the limits.

So, as I said, we have -- the draft final rule text has the current requirements in it, but you do have the alternative text, if you would like to consider that.

There are two additional concerns raised by the SR6 committee.

One has to do with criteria for releasing individuals, slide 14, and that being that there are two cases where -- two items that they would suggest going into

the suggested state regulations.

Under this particular item, the states would have the authority to be more restrictive in this because of the compatibility designation associated with it.

One is that the authorized user would be required to sign the document that authorizes the release of the individual.

The other is that they would like to include a statement that the licensees would have continued responsibility for contaminated articles even though the patient had been released under the regulations.

The other issue has to do with safety precautions associated with brachytherapy treatments. The draft final rule you have before you would allow a licensee to quarter two patients in the same room that had both received unsealed byproduct material for a therapy situation.

We believe that the dose that one would be receiving from the other would be inconsequential in light of the dose or exposure that they are receiving as a result of their treatment. Therefore, we see no reason to preclude that.

However, the SR6 committee would so require a private room.

The other is that they would like to see some additional survey requirements in their equivalent to Part

35, where we feel confident that the licensee's radiation safety program under Part 20 would adequately address this.

View-graph 15 covers real briefly the implications in the licensing inspection and enforcement program.

We do believe that medical licensees should continue to receive a specific license because of the risks associated with the use of the material.

We have, however, made changes in what information, what amount of information must be submitted to us in order to receive that license.

Under the current rule and current policies, licensees need to submit procedures to us for handling material safely, for their training programs, for how they're going to calibrate their dose calibrator, very specific procedures, and that becomes part of their license application.

What we are proposing is that information no longer come in to the licensees.

The only information that we would need would be their name, their mailing address, who's going to be the authorized user, the training and experience for the authorized users, T&E for their radiation safety officer, and some information on their equipment, and that is all that we would be looking at, but the comments that I received were fine, Cathy, that sounds great, but you're

going to hit us on the inspection, you're come in and look at that, so all you're doing is shifting your resources from licensing to inspection, and that is not the case.

Our plan is not to go into reviewing these procedures at all, really, during an inspection, unless the situation warranted it -- for example, we were out investigating a medical event or some contamination getting out into a unrestricted area.

In that case, we would go in and look at these procedures.

So, it doesn't relieve the licensee from having them as part of their safety program, but from the standpoint of NRC reviewing them, we would not be doing that.

Also, there would be some needed revisions to the enforcement policy from a standpoint of there are some changes in terminology.

So, we would need to make some minor changes in some of the appendices for the enforcement policy, and that would really be it, because there are -- any changes in the overall enforcement policy are being handled under a separate effort.

View-graph number 16 addresses the resources and time-table for completion of the rule. My best guess is that it will take approximately three FTE to complete the

rule-making, recognizing that, when we do come back to you, we will be providing you with the medical policy statement in final, the NUREG document, which is the guidance document, a complete Federal register notice, regulatory analysis, and an OMB package.

As far as the due date for that, or the timing to do all of that, once we get that back to you and the rule would get published, we're looking at probably an effective date of early 2001.

That is assuming that we really -- we're waiting for direction from the Commission to go forward, and then we'll have about three to four months to do that.

Following that, we'll need a maximum of 90 days to get OMB clearance on the package. The rule would be published mid-next year, with a six-month effective period.

With that, I've gone through prepared remarks, at least.

CHAIRMAN DICUS: Okay.

Let me make a couple of observations.

First of all, I want to thank you for a succinct yet thorough review of where we are at the moment. I really personally don't have very many questions, because in fact, I think they've been answered in the slides themselves and from a pre-brief that I had. I will make a couple of observations, though.

The first one is on slide seven, and it's the last sub-bullet, where it says NRC recognition, especially boards, and I simply want to point out we are talking about recognizing, not approving.

MS. HANEY: Correct.

CHAIRMAN DICUS: So, there is a difference there.

And then I would go to slide 15 and the issue in the third bullet of inspections and the issue that you brought up as to whether or not we would be transferring licensing burden to inspection burden.

I just want to caution the staff to be sure that we don't do that, to be sure that we don't get inspection creep in this arena, that we are careful, that our review of procedures and inspection is related strictly to when it's found to be a reason that we need to go in to review those.

So, on behalf of Commissioner Diaz, who we did have problems having in on this briefing -- and I know he has a great deal of interest in this issue -- I would like to ask a question on his behalf, and it goes to slide eight, and his question is, "As noted in the SECY paper and as discussed yesterday at the OAS/CRCPD briefing, which we did get into Part 35, there is a concern about the number of hours of required training for the use of I-131. Would you please explain why 80 hours of training" -- and I realize you may have already done this, but I think, for the record,

for him -- "is sufficient for the safe administration of I-131?" That's question one.

"Should there be different requirements for large institutions versus endocrinologists' offices?" question number two, and question number three, in "In your discussion, would you please address health and safety issues of workers and the public in this regard?"

MS. HANEY: Okay. Let me address them in order. I think I can do that.

We did -- if you go back to where we were before the proposed rule, we had recommended that the number of hours for the endocrinologist be increased, and that was based on looking at hazards associated with the use of I-131 and recognizing that misadministrations have occurred with use of I-131 and noting that the way the rule was currently written, there were some hands-on performance sort of requirements that were not included in the requirements that were specific to the endocrinologist. So, we had recommended an increase.

We did have a lot of interactions with the endocrinology community, where they described in detail their training programs and how they handled material and asked that we look closer at the records -- the misadministration records associated with use of I-131 and reconsider whether an increase in this particular area was

warranted or not.

We did go back and do that, and according to our records, there were two misadministrations of I-131 that could be attributed to an endocrinologist as compared to another type of user, and really, what we've been hearing is look at the track records.

If material -- if things have been working well, why do you need to change them, and with that in mind, we went back and we really didn't feel like we had the basis to change the requirements, to increase the hours for the particular users.

We did modify the ruling somewhat to make sure that there were requirements in the rule for some of the more performance-oriented -- surveys, things like that -- to explicitly get them into the rule as compared to knowing that it takes place but it was not necessarily required by the rule change.

The other thing that -- change that we made in this area was the greater reliance on the preceptor.

Whether you're looking at someone preceptoring for use of I-131 or for a remote after-loader or a radiation safety officer, for that instance, under the current scenario the preceptor is merely saying yes, the individual took the training period. That's all that he's signing to.

Under our new proposal is the preceptor is

actually saying the individual took the training, but in his or her professional opinion, the individual is competent to handle the material safely.

So, because of that, we really felt that we could leave the training requirements at the same level as they are right now and not feel like there was any impact on either the patient or the occupational workers or the public as a result of these particular hours.

The second requirement about whether there should be different requirements for the large institutions versus the -- you know, whether you could have a different requirement for the endocrinologist -- if you asked me this question a year-and-a-half ago, I would have said no -- or I would have said yes, based on that information, but again, because of the benefit of having this level of interaction with the stakeholders, I really do think that there is a need for separate requirements in this particular area.

In the larger institutions, you have individuals that are -- you're supervising larger staff, so they're handling more material, so more things can go wrong, and they need to be able to have a little bit more experience to be able to make sure that either things don't go wrong or that, if they do go wrong, they know how to handle it, also recognizing that there are certain -- it's almost a -- well, it is a specialty, that they're only using iodine, majority

is only used in capsule form and, therefore, cutting down on the problems with potential contamination, and you're only dealing with one organ, and based on all of that, I think it's just a separate category for this particular type of user is warranted.

With regards to the question about did we consider the health and safety associated with use of the workers and the public -- and I'm going to assume this is specific to iodine -- yes, we did, and I believe that the regulations are in place that would provide for that.

Section 35.75, which has to do with the release criteria for when a patient can be released, is dose-based, and it is -- and the release is based on the dose to the maximally exposed individual.

So, from that standpoint, I think that that addresses one set of populations, really your public exposures.

Part 20 would address your occupational exposures, and again, the licensee still needs to comply with Part 20, so all of those requirements are still in place.

So, because of, you know, the combination of Part 35 and 25, I think that the public health and safety, as well as occupational health and safety, is protected by the draft final rule.

CHAIRMAN DICUS: Okay. Thank you for your

responses.

I know that the SR6 committee did have concerns with this and did surface them later.

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: I'm going to try to go through basically the SR6 concerns. I think I come down on the staff's side on all of them, but I just want you to have a chance, publicly, to talk about some of them.

The first slide he had yesterday -- and I'm talking about Mr. Walter from Alabama -- had to do with written procedures, and he basically, unlike our rule, wants to have all of the procedures submitted as part of the license and, you know, a fairly prescriptive requirement, rather than relying on spot inspections as needed. Tell me why you came down the way you came down, as opposed to the SR6 committee.

MS. HANEY: From the standpoint of the procedures being submitted at the time of licensing?

COMMISSIONER McGAFFIGAN: Yes.

MS. HANEY: The procedures are really the licensee's responsibility. We set the regulations, tell them what they need to do. We have requirements for assuring that they're properly trained, and that sort of information we would review.

So, we're looking at saying that you've got

properly trained individuals who know what they're supposed to do because it's in the requirements, and we don't need to look any further at the time of licensing.

We would expect the licensees to develop the procedures that are needed to comply with the regulations, and our review is not necessary.

Also, it gives the licensees maximum flexibility in those areas where we think, because of the risk, that it's warranted.

Any procedure that we've reviewed, they're tied to in their license. So, they cannot change that procedure unless they come in for a license amendment, which is yet another process they have to go through in dealing with NRC. So, this eliminates that need.

So, it has to do with flexibility for the licensee, but yet, at the same time, I don't think we're reducing any of the safety considerations.

COMMISSIONER McGAFFIGAN: I would think that OMB, when it did the paperwork reduction review --

MS. HANEY: They'll like us.

COMMISSIONER McGAFFIGAN: They'll like you on this particular item.

Authorized user duties was a slide he had yesterday, and he claimed there's a Catch-22 because there are no duties specified in Part 35 for the authorized user

unless a written directive is required.

It sounds like a technical point that he was making, but have you talked to him about this and can you explain why you are where you are?

MS. HANEY: Sure.

We have tried not to interfere with medical practice, following the medical policy statement. So, from the standpoint of selecting the patient, in my view, at least, is crossing that line a little bit too far.

I do believe that the needed duties are in Part 35. There is a requirement for the individuals handling the material, say at the technologist level, to follow the directions of the authorized user.

So, in essence, that is setting up a responsibility for the authorized user. I mean maybe it's a de facto one, but it is there.

The reference to whether there was a Catch-22 in the rule between our requirements really has to do with the unique situations that is in hospitals, where we -- the hospital is our licensee.

However, the authorized user is usually a contract employee, and now you have got a contract employee in a situation where they're directing a member of the licensee's staff.

So, the relationship between 35.11 and 35.27,

which he cited in his view-graph, is really needed to make sure that NRC -- that the licensee is clear that they're ultimately responsible for the safe handling of the material but yet making sure that, at the technologist level or the user level, that they are aware that they have to follow what the authorized user says.

COMMISSIONER McGAFFIGAN: Let me just mention -- and I don't want to go through them all, because you've gone through several in your presentation. Technologist T&E -- he says the SR6 will include technologist training and experience requirements which we don't have and I don't think at any point in the process we ever had. So, this is a new idea.

Why have we not considered training and experience requirements for technologists?

MS. HANEY: The working group considered having training and experience requirements for technologists back in late '97, on one of the first drafts that we issued.

We received a lot of early comments from the technologists on this particular area, and those comments really went along the line of they were very concerned that if we put a requirement for the training and experience in our rule and it was only focused on radiation safety, that we might actually be negatively impacting the medical practice, the handling of it, because licensees are always

going to be looking for ways of saving money, and if our rule says you only need 100 hours of training to handle the material at a technologist level, they're going to go out and look for individuals that have 100 hours of training, and the technologists really are doing -- going much further than just the radiation safety handling.

There's imaging. There's positioning. There's a lot more than just the world of NRC that the technologists have to do.

So, the techs are very concerned that that might be an impact of having that.

Also, the Part 35 working group stepped back and said, you know, who's responsible here, and it's the licensees that's responsible for the safe handling of the material, not at the technologist level.

There are requirements in the rules for the licensee to make sure that their technologists have -- well, actually, let me take it broader.

The licensee is responsible for assuring that their staff is properly trained, and under that particular requirement is we're making sure that the techs get the experience to -- and the training to handle material safely.

So, because of that, we don't really think that it's needed in Part 35.

COMMISSIONER McGAFFIGAN: I'll leave it there.

There's some other questions I'll pursue with the ACMUI.

CHAIRMAN DICUS: Okay.

Commissioner Merrifield.

COMMISSIONER MERRIFIELD: Going to slide five, I just wanted for you to expand a bit.

You mentioned that there were significant costs and staff impacts related to performing a full-blown risk assessment.

I was wondering if you could perhaps expand a little bit more on that in terms of detail, because I think there are some out there who wanted us to do that, who expected us to go through a risk-based rather than a risk-informed process, and I think having a little better understanding of why we chose the direction we did for those reasons would be helpful.

MS. HANEY: Okay.

Our estimate is that, in order to do a formal risk assessment and to carry that into regulations could take approximately 10 FTE to do, and we're looking at five years to complete that project, again, we're looking at a very thorough assessment here. It also could take several million dollars to do that.

Our concern is that this rule does provide immediate relief to some of the diagnostic users, and if we were to wait and hold this rule to complete that, we

actually are negatively impacting the stakeholders, because they would not be allowed to start implementing and reducing their requirements right now, because they'd be waiting for another five years while we completed this risk assessment.

COMMISSIONER MERRIFIELD: There's nothing about moving forward with this rule that would preclude outside stakeholders on their own from obtaining additional information and bringing that to us later on, after this rule-making is completed, for us to consider additional changes, is there?

MS. HANEY: Nothing.

COMMISSIONER MERRIFIELD: Okay.

On slide 11, you spoke about the concerns relative to some of the notification requirements, and you mentioned something, that there was significant -- we received a significant number of public comments related to this requirement.

To what extent did those public comments include comments of persons other than those who would be impacted by the rule change -- i.e., individuals not in the medical community?

MS. HANEY: I don't believe we received any comments from your average patient commenting on whether this was a good requirement or a bad requirement. I mean we didn't get comments either way. We didn't hear from that

population at all.

We do have a patients rights advocate on the ACMUI that will be -- when they get to this -- when they come up to the table, will be discussing it with you, but we did hear, during the process, at the public meetings -- we had two patients rights advocates come, and they did not believe there should be an NRC requirement for this type of -- for the notification.

Their view was this was between the patient and the physician and it was just not needed to have the NRC step in, but they were, you know, two people sitting at the table.

COMMISSIONER MERRIFIELD: I'm reminded of experience that I had working in the United States Senate dealing with -- although it's a completely different issue dealing with right-to-know requirements under some of our environmental laws, and I know changes to that which would take away the right of individuals to be aware of materials brought with it significant comments.

Whether the greater patient community was aware of what we were doing or not remains to be seen. I leave that for further comments.

On slide 14, one of the issues that was raised yesterday when we met with the agreement states, one that Commissioner McGaffigan didn't mention, related to the

possibility -- the impacts that this would have on individuals in the medical community or -- I guess the example that was used was nursing homes.

If you had multiple patients who were in a nursing home who were subject to these release criteria, how would that impact a nurse or other nursing home attendant who had to deal with multiple patients and multiple exposures over the course of a year?

Did we factor that into our thinking?

MS. HANEY: This was factored into the thinking when we revised the rule back in 1990, the early '90s, when we did go from an activity-based rule to a dose-based rule, and the belief at that time, and as continues on, was that the requirement stating the 500 millirem to the maximally exposed individual was sufficient to protect the public as well as any individuals.

Now, in the case of, you know, the nursing home situation, I can't tell you that we actually went back and -- I have not gone back and looked at the reg analysis or the supporting statement for that rule specifically on were releases to a nursing home considered.

I would like to believe they were, but I can't tell you that they were definitely.

COMMISSIONER MERRIFIELD: Thank you.

CHAIRMAN DICUS: Let me follow up on slide 11 on

the patient notification, and I'm asking, again, on behalf of Commissioner Diaz, and this question is actually to the General Counsel on his behalf. It has to do with the alternatives, verbal notification of patient as opposed to written notification.

Does the Office of General Counsel have specific concerns with the alternative that would allow verbal notification?

MR. BURNS: Any one of the alternatives, I think the question really is whether a rationale can be developed for it and can be supported. So, from that sense, there's not a legal bar to alternative formulations that are under consideration.

The alternative here, one would have to, I think, harmonize in terms of the rule-making notice and the Commission's ultimate adoption of the alternative, would want to harmonize it with other notification requirements the Commission has, because if you look at Part 19 and Part 20 for both routine exposures, occupational but also public exposures, both routine as well as extreme or accidental exposures, there are notification requirements that we routinely require to be made under those regulations.

So, I think the answer is really that the Commission could adopt alternatives. It would have to articulate the rationale for them, and the special case

would probably be you'd have to articulate the rational in the context of other notification requirements the Commission has adopted.

The other thing we noted, too, is although it's not -- it doesn't drive us particularly as a requirement, the Commission can look at -- there are notification requirements in another Federal statute, the Mammography Quality Standards Act, which are comparable or in the same ballpark, let me say, as, I think, what the staff's proposal is, but alternatives could be considered.

CHAIRMAN DICUS: Okay. Thank you.

I think, in the interest of time, we'll go ahead now and hear from ACMUI.

I want to thank the staff again for your presentation, and we may, in fact, have additional questions after the ACMUI presentation.

DR. CERQUEIRA: Good morning, Chairman Dicus. My name is Manuel Cerquiera, and I'm going to be presenting the presentation for the ACMUI.

We have other members of the committee that are currently present: Dr. Louis Wagner, who is representing the nuclear medicine and the physicist community; Nicky Hobson, who is the patient rights and care advocate; and Ruth McBurney, who's representing the agreement states.

What I'd like to do, as Cathy Haney also

demonstrated, was to just go through our presentation. You've had the overhead slides available to you, and at the end of my overview, then we will take specific questions on the specific issues.

If we could have the briefing outline, we will make some general comments, we will then deal with the radiation safety committee, the training and experience issue, medical event, unintentional exposure to the embryo/fetus and a nursing child, patient notification, and then some challenges to implementing the Part 35 revision as we understand it at present.

In terms of my general comments, I think that all of us have had an opportunity to share in this effort and feel that it's been a very thorough process that I think, in general, has been able to maintain the safety to the users, to the public, and to the patients.

It is really taking a step in the right direction towards decreased the regulatory burden for the regulated community, and I think as a result of this very thorough process, it will definitely increase the public confidence in what we as medical professionals are current doing, and I think, as a result of all these changes, we've also managed to increase the efficiency and the effectiveness of the radiation regulations.

Again, it's our belief that the draft rule is

risk-informed, it's more performed-based, and as a result of the process, we've really been able to get the stakeholders involved.

The meetings that were held with public input and all the letters and things that were reviewed thoroughly by the staff as well as the committee have really taken the public input, both the user community and as much of the public as we could get, and as a result of that, I think it's allowed us to make those four points up front that we've been able to achieve as a result of this.

Slide three, please.

In terms of the radiation safety committee, I think Cathy has done a very good summary of our feeling son this.

The ACMUI endorses the draft rule which basically allows institutions that have higher risk to require some degree of safety oversight from the radiation safety committee while at the same time allowing the single office practice that's providing diagnostic services to have a more limited overview with the radiation safety officer but without the need for a radiation safety committee.

So, I think that this -- it's a prospective system that will allow the assurance that safety is appropriately provided at the various facilities.

Slide four.

The training and experience has in many ways been one of the more debated issues, and I think the current proposal maintains the safety aspects and deals with some of the issues that have been brought forth by the community while at the same time allowing the opportunity for emerging technologies to be regulated at a later point in terms of the training and experience requirements.

It's the feeling of the committee as well as the staff that the training needs to be obtained in a clinical environment, because all of these will be set up in a clinical programs, and it's very important to make certain that the training is going to be obtained in situations where it's going to be used.

We've endorsed the alternative pathway for training and experience for the AU, AMP, ANP, and the RSO, because the preceptor statement we feel will provide some assurance. This is not just a mere signing off. We really feel that the people that are doing the training assume responsibility to make certain that the material is fully mastered.

We believe that the NRC recognition of the specialty boards is going to be a very important process. It sort of widens the opportunity for people who have not taken traditional programs but who have gotten the appropriate clinical and radiation safety experience to

become authorized users.

There was some concerns expressed by the committee in terms of national standards for training and experience. I think the agreement state meeting yesterday -- some of these issues may have been brought up, but currently there's 31 agreement states.

So, we are implementing a national policy that's going to be, in effect, in a much smaller percentage of states than those that are actually going to be regulated, and if you look at the current regulations, they vary considerably from state to state, and even within states, there are some regulations that differ within New York City versus New York State.

So, it's the feeling of the committee that a uniform national policy, certainly with regards to training and experience, would be very important, especially for the people that are coming in through the alternative pathway, through the experience requirements without the boards, that by just allowing the NRC states to have these new modifications, people involved in training programs are going to be very much stretched in order to provide training that will allow people to practice wherever they have the opportunity to do so.

We also feel that -- and this was an issue that came up several times in terms of emerging technologies.

Intravascular brachytherapy for prevention of restonosis was one thing that came up, and this is a technology where the information as to which of the multiple alternatives will actually be available for clinical use is not known, and it wasn't felt that there was sufficient data at this point to set very definite training requirements.

35.1000, which deals with the emerging technology, will allow some of these techniques to be evaluated and recommendations made specific for the applications that are developed.

Slide five.

The medical events -- the ACMUI endorses the dose thresholds that are in the draft final rule. We feel that this adequately captures the events of concern and safety.

The dose thresholds will help to reduce the unnecessary regulatory burden for things such as wrong treatment site or patient intervention that are not really within the control of the medical community.

Events occurring as a result of patient intervention should not be reported to the NRC unless unintended permanent functional damage to an organ or physiological system has occurred.

Slide five.

Unintentional exposure to the embryo/fetus or the nursing child -- I think Cathy has gone over in some great

deal -- there were specific questions related to this.

It's the feeling of the committee that the risks are really very low and that the 5-rem reporting limit is probably too high, but given all of the issues and concerns around this, the ACMUI endorses the 5-rem as an appropriate reporting threshold.

We feel that, again, it has minimal impact on the patient and physician relationship in this format and has minimal impact on the current standard of car and cost, and some of these issues will be brought up during the discussion.

Slide seven, notification following medical event or exposure to embryo/fetus and nursing child -- and again, this was brought out. The ACMUI does not support any regulation requiring notification of physicians and patients, as this is redundant to the existing standards of care for medical practice.

You know, all of us believe that these types of things are essential for good medical care to be performed, but they're not regulated in other areas, and we feel that certainly diagnostic levels of radiation, that the current practice of medicine standards are effective.

The alternative rule language provided by the staff -- it was preferred over the existing requirements. We heard some of the legal counsel issues that were brought

up related to this.

And the final overhead is really the implementation challenges to this -- the revised Part 35.

We feel that it is very important that the NRC and the staff begin the process of recognizing the medical specialty boards that have sufficient requirements and assess competence in radiation safety and knowledge of radiation for approval for becoming an authorized user.

If we wait until this rule is fully implemented, a lot of the regulated community and people coming out of training will have some difficulty in getting appropriately licensed.

We also believe that, as Part 35 is being revised, there's going to have to be a considerable mind-set within the NRC reviewers and inspectors on how they perform their evaluation, and you know, we're really, at this point, trying to make it risk-based, and areas that are very low-risk, that really don't contribute to the safety of the public, the users, or the patients, really need to be recognized as such.

We also feel that it's very important to develop the guidance document.

We don't see this as de facto regulation but, rather, provides the user the opportunity to see -- look at some models, especially those less sophisticated sites.

This will give them some informed basis upon which to send their applications.

We believe, also, that implementation of the rule will continue to require some -- quite a bit of oversight from the ACMUI committee.

We were joking yesterday that we think we've gone through the hard part, but once these rules become implemented, there will obviously be quite a bit of contention into the actual implementation.

So, this really concludes our presentation in terms of the recommendations of the ACMUI, and at this time, I'd like to open it for questions from the Commissioners.

CHAIRMAN DICUS: Okay. Thank you very much.

Let me begin with a question on implementation. It's on behalf of Commissioner Diaz, but I think it would be my question, as well.

The intent is to try to have these new rules -- when and if, but I think I can say when this becomes a final rule, to have the new requirements in place within six months of the rule becoming final, and I guess my question is, is six months sufficient time for the specialty boards and the NRC itself -- and the NRC may want to come to the table on this one, as well -- to process the necessary certifications and actually meet the requirements of the rule?

Can we do this in six months? From your perspective, can it be done in six months? And then I might ask the staff if they think they can be prepared to do this in six months.

DR. CERQUEIRA: Again, in terms of reviewing the boards, I think that there's probably a limited number of boards that are going to apply, and I think as Cathy pointed out in her overhead, with enough FTEs, we should be able to get this done.

I think the interested boards have already met with the NRC, and they have actually initiated within their own organizations steps for applying.

So, I think that six months is adequate.

You know, this rule has been evolving over several years, so it's not completely novel. So, I think six months would be adequate time.

CHAIRMAN DICUS: Okay.

Cathy?

MS. HANEY: Six months is adequate time for the licensees to adopt the new regulation, recognizing that the majority of what's in the rule is actually a reduction. So, they're not going to -- they'll have to go back and just review some procedures, but they're not going to have to start over from scratch in developing new procedures.

I would say that the one key, though, is the early

recognition of the boards.

I do not think six months is effective, is going to give us enough time to actually get the boards approved, and then there's still an issue of whether we would need to notice in the Federal Register and things like that that we need to consider. So, that's why we're asking for this permission to start the recognition process early rather than later.

CHAIRMAN DICUS: What about getting the guidance documentation together?

MS. HANEY: Well, our plan right now is that, when the package comes back to you, that we would have the guidance document with it, and we have to make changes to it, but it matched the proposed rule.

But we will need to update it to match the final rule and then just to go through and double-check and make sure everything is in there and what shouldn't be is not in there.

So, I think we have adequate time for that, also.

CHAIRMAN DICUS: Okay.

I want to ask one more question on behalf of Commissioner Diaz, and we're in very good shape time-wise, so I think there will be sufficient time for some discussion, but this has to go with this kind of ticklish issue of the unintended dose to an embryo/fetus in excess of

the 500 millirem, and the question is to both the staff as well as ACMUI, again on behalf of Commissioner Diaz, and this was brought up, of course, yesterday, as we know, by Mr. Walter of the SR6 committee at the briefing we had.

His question is that, in the case of this -- of unintended dose, how would requiring that licensees report unintended doses in excess of 500 millirem hinder the practice of medicine? There was some indication that perhaps it would.

DR. CERQUEIRA: Lou, do you care to comment on this?

DR. WAGNER: Sure. I think there are several issues with regard to this.

First of all, as the rule currently stands, it is my understanding that, if there is a report to the NRC, there obviously has to be a written report to the patient.

Now, in terms of medical practice, what is a physician going to do in terms of medical decisions with regard to a dose like that? Okay.

Likely what he's going to do is go tell the patient, look, we reviewed everything, we don't have any real concerns here or any real risk, we're not going to do anything, we're not going to take any intervention, we're going to go on, but there's got to be a written report to the patient.

Then patient's going to get this report and say, okay, the NRC says I got to tell you all this. That's going to really tear down the confidence of the patient with their physician. That is a problem.

That is one essentially area where there would be a lot of difficulty with regard to the patient-physician relationship.

In addition, if you have this reporting rule, the NRC carries a lot of weight, and it can impact medicine by making some examinations not available to patients merely for the intention of avoiding this potential.

The question is what's unintentional, and the only place where it's really going to become a big issue is the early pregnancy, when they're not going to do that the patient's pregnant, patient comes back later and says, oh, I happened to be about four days past conception the day I got that examination, okay?

So, that's going to cause them a problem in regard to now I've got to report this to the NRC. Well, maybe I don't want to report that to the NRC. Maybe what I ought to do is just not do these examinations.

That will have an influence. It will change the way people practice medicine. So, there is a difficulty with regard to that.

Furthermore, what is going to happen with regard

to pregnancy testing? Are we going to require more and more pregnancy testing for women when they come in because they might be pregnant?

We might catch a few more, but pregnancy testing in itself is not foolproof and we still might not be able to catch all of them. What are we going to do now? Instigate a 10-day rule?

Are we going to say you have to have had your menstrual period within the past two weeks before we're going to do this exam on you? Now we're going to delay it. Okay, we delay it.

We find out later on, after we delay to find out if she is pregnant, that indeed she is pregnant. Then we so, oh, my gosh, I wish I'd done the study early, because now she's pregnant and she's at a certain stage which had advanced her risk time.

So, there's lots of areas now where this is going to have an impact on medical care as we currently practice it.

Now, if we look at the essence as to how medicine is practiced now with regard to standards of screening and how we take actions on things, they're in conflict with this rule and this reporting at 500-millirem, and it will have those kinds of changes on medicine, and I think that we have to come to an agreement on a reporting mechanism that

applies across the board for all the stages of pregnancy that is not going to impact the current standards of practice in medicine but will at the same time satisfy the need for the reporting requirement.

CHAIRMAN DICUS: Okay.

DR. CERQUEIRA: As, I guess, the only practicing physician on this group, as a practicing cardiologist and nuclear medicine physician, I feel it incumbent upon myself to notify patients when things happen that are not planned or are potentially dangerous, and as a cardiologist I can give medications that are 10 times more harmful than any radiation risks that could be given, even at therapeutic doses, and there's no regulation for my reporting misadministration of medications -- beta blockers, intravenous, or so on.

But I think within the practice of medicine, we basically regulate our own reporting of these things, so that this reporting mechanism is really beyond anything else that exists within the practice of medicine.

The risks that are involved, I think we've all agreed, certainly for diagnostic, are very low. So, I don't think it really adds to the safety of the patient.

It does create some difficulty in the patient-doctor relationship, and I think, you know, physicians are currently doing this as part of the standard

of care for medical practice, and to have it regulated like this doesn't really further the patient benefits.

CHAIRMAN DICUS: I know Commissioner Merrifield wants to weigh in. I've got another part of the question.

COMMISSIONER MERRIFIELD: It's very short. It's actually in the form of a statement in response.

CHAIRMAN DICUS: Okay.

COMMISSIONER MERRIFIELD: I've heard this argument before, and I'm sympathetic to it, but the response I would give is this:

If we sat around the room and we had a group of medical professionals and a group of scientists and experts in the NRC, I think we would recognize that, indeed, in a comparative manner, the risks associated with the uses of some of these radiological materials and the risks associated with some of the use of the other chemicals that you utilize is vastly different, but that's the issue that we have to deal with with all of the regulatory areas that we deal with as an agency.

When you compare some of the risks associated with some of the areas we do with chemical facilities out in the United States, there are some far greater risks in the safeguards, the security area, far great risks relative to those facilities than the reactors that we regulate, and we get the same complaint from our reactor operators, gee, you

have all these security requirements on us, and I got a chemical facility two blocks down the road that has nothing, and that's a far greater danger, and the fact is it's true, and the reason it's true is because there is a much greater public sensitivity to the areas in which you practice and we regulate than there is with chemicals, and I think that's a fact of life that we all have to recognize.

I mean, like I said, I think, sitting around a room, we could all recognize that perhaps there ought to be more balance, but I think there are external factors both to the regulated community as well as the regulators that affect the manner in which we have to go.

CHAIRMAN DICUS: Cathy -- oh, do you want to respond?

DR. CERQUEIRA: Well, again, I think we've had this discussion, you know, at our previous briefing in March, and you know, we're very sensitive to the public perception that surrounds radiation and, certainly, the failure to report, given all the public scrutiny that has gone on, but if we really try to make this, you know, risk-based, the risks are really very low.

It does interfere in the patient-physician interaction, and you're right, if we as physicians and scientists can come to an agreement, that sort of sets the level of risk, but then the public perception and the

regulation and all the other things are something that, you know, you have to make the decision on as Commissioners. The ACMUI has given you our recommendation on it, and we're aware of all the other things that need to be considered in the rule-making.

CHAIRMAN DICUS: Cathy, do you want to add anything?

MS. HANEY: No, I think Lou really addressed everything that we've heard so far.

CHAIRMAN DICUS: Okay.

DR. WAGNER: I'd like to make one comment with regard to that.

In the example that you just gave, you're talking about risks associated with the general public for which they are not seeking any benefit.

Here we're talking about patients who are sick. It's an entirely different situation. We're not talking about chemical risks versus radiation risks. We're talking about medical health care for patients. That's a totally different perspective, because we are going to intentionally expose this patient to radiation.

That is not something that was unintended. It is not something that's accidental.

It's a fact that that patient came to us because they had a medical need and we acted on that medical need,

and the conceptus of that patient has a similar stake in the benefits to the mother, and every time we irradiate a patient, we always have to take into consideration that they may or may not be pregnant, and we take that into full consideration every time when we do the screening properly.

So, this is not the same kind of analogy. Chemical versus x-ray versus others isn't the same. We're talking about risk-benefit. That's what we always talk about in medicine, and that's always what we have to look at, and in this case, you're interfering with that risk-benefit relationship between the physician and his patient or her patient.

COMMISSIONER MERRIFIELD: Well, I appreciate that comment. Again, I would argue, you're looking at it through the lens of a very well-trained professional who understands the risk.

What I'm trying to do is recognize that, relative to untrained individuals in Congress and public policy individuals in Washington, we've got to make decisions, and the general public, unfortunately, doesn't have the same level of understanding on these issues that either you or, to a lesser extent, I have, and so, what we've got to do is be reflective of the individuals who don't have that level of understanding and who have a higher sensitivity to the areas in which we regulate.

DR. WAGNER: I think your stakeholders in terms of members of the consumer rights advocates have given you some answers with regard to that, and I think you should listen to that.

CHAIRMAN DICUS: I want to go back to pursuing the issue of reporting, 500 millirem to 5 rem, and part of the basis, as I understand it, for -- and it's in one of your back-up slides from staff -- for a comfort level with the 5-rem reporting -- again, it is not a standard, it's not a dose that's allowable, it's a reporting requirement -- is based upon NCRP commentary number nine, I think, which indicates that, at 5-rem, there is not expected to be any deterministic effects and perhaps only a 1-percent stochastic effect to a fetus or conceptus at that rem.

Are you comfortable -- and I'd ask this, really, of both groups -- are you comfortable with the criteria that was used to come up with that conclusion in NCRP commentary nine?

MS. HANEY: From staff's standpoint, we were comfortable with that level, recognizing that there is a perceived difference between these reporting levels and that in Part 20, but because of these extenuating factors that Lou mentioned and the impact on medical care, we felt that it was warranted.

DR. CERQUEIRA: Lou, would you care to make a

comment on the selection of the level?

DR. WAGNER: Well, one of the important factors for the selection of this level is the fact that that is basically the level in medicine where if we have a situation where a woman has been exposed to radiation and either we find out that she's pregnant or we knew she was pregnant in the first place or whatever, that level is the level where we start considering the potential for medical intervention. Below that level, there are no recommendations for any medical intervention other than discussing with the patient, okay?

So, reporting in this level throws in -- reporting below that level throws in a level of uncertainty that erodes the patient-physician confidence again, by putting that reporting level in lower than that, and that's what we're trying to avoid here.

MS. McBURNEY: As a health physicist, I'm comfortable with the level of the 5-rem in accordance with the recommendations in NCRP number nine as a reporting level not as a dose limit.

CHAIRMAN DICUS: Commissioner Merrifield.

COMMISSIONER MERRIFIELD: I don't have any additional questions.

CHAIRMAN DICUS: Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: Well, let me just follow

up on this same line of questioning.

The SR6 committee -- this may go to Ms. McBurney as well as Mr. Wagner, but -- is basically saying that we should be treating the embryo/fetus and nursing child as a member of the public, and their recommendation is essentially going to be that -- not to include anything here but to force you to treat these people elsewhere in the model state regulations as a member of the public, so 100 millirem would be the limit, and I'm not advocating that at all, but I assume that your answer would be that that -- if the SR6 view takes hold in any of the 31 agreement states, that that would be even more impacting on the practice of medicine, because you -- as I understand it, the medical community believes that you treat a unit, you treat the mother and child, the mother and embryo as a unit, and you've just articulated what the action levels are, but how is the SR6 view, which is so far afield from any of the views that we've heard here today, going to move forward, and what is the -- how do stakeholders interact with the SR6 process, I might ask?

You could answer the first question. I mean, you know, I assume the answer is, if it was 100 millirems, there would be even more of an impact.

DR. WAGNER: I'll be happy to address that issue. I'll give you an example.

A woman comes into the emergency room. She's been in an automobile accident. She's a young woman. She might be pregnant. We don't know. She needs immediate medical care.

We're going to order a CT scan, because we consider that there may be some injury to her pelvis. We're going to do a CT scan of the whole abdomen. We need to have it done. We do it. Okay. Baby got about 4 rem from that exam. She turned out to be pregnant at the time.

Now, if that were a member of the general public, we'd have to report that as an overdose to a member of the general public from that radiation.

COMMISSIONER McGAFFIGAN: Even though CT scans aren't covered by us, the state regulations would cover it.

DR. WAGNER: Yeah. That's to give you the idea that we'd have to report it because it violates the member of the public being exposed to a level like that.

Now, how absurd is that? Clearly that baby is not a member of the general public.

Now, you can go on down to any other situation that you've got.

A woman presents herself in the doctor's office and says I'm sick, I'm feeling bad, here are my symptoms, etcetera.

The doctor works up the patient and continues to

work the patient up and finally decides, well, we're going to need this other study here, we're going to need this nuclear medicine study, okay? This is a sick patient.

If she is pregnant, that consideration is going to have be taken into account by the doctor in what he administers, what he prescribes, what he does, and the baby is going to be part of that. It's going to be in the baby's interest that this mother is going to be around for the baby. It's going to be in the baby's interest that the mother is healthy.

There is no way in the world anyone can argue that this baby, who's going to be intentionally exposed to radiation because the mother is sick, is rationally considered a member of the general public and should be restricted in terms of the dose that the baby is allowed to receive.

We don't do that, and rightfully so we don't do that. If we did that, we wouldn't be able to do any diagnostic exams on young women or women of childbearing potential.

COMMISSIONER McGAFFIGAN: I'm very proud of the process that we've gone through the last several years here, with your involvement, with the wider public's involvement, with massive public comments received and, I think, address honorably and well.

The SR6 process -- how does that work in the states?

Do you get a model of regulation and do a five-day notice and it's suddenly the rule, or how -- if the SR6 is, as eloquently as Mr. Wagner is talking, making a major mistake in its recommendation, how does that get resolved? Is it a state-by-state battle in 31 states?

MS. McBURNEY: Yes, sir. A short answer.

What the suggested state regulations provide is a model that the states can use in their rule-making process, but each state has to undergo the same -- well, a similar type of rule-making process that the Nuclear Regulatory Commission does.

We have to publish notice of the rule. In Texas, what we would do is take the suggested state regulations and the NRC regulations and pull from those, and there may be instances where we may add or subtract, and then, looking at the level of compatability, we take all those things into account in our rule-making.

Then it would go out to the public for comment. We have to address those comments the same way. As a regulator, we have to be sensitive, as Commissioner Merrifield mentioned, to the perceptions of radiation risk in our policy-making and the right to know, and from a regulatory standpoint, I feel that there should be some

notification at those medical event levels and that dose to the embryo/fetus.

However, I do recognize that --

COMMISSIONER McGAFFIGAN: At the 5-rem dose.

MS. McBURNEY: Right, at 5.

In medicine, there is a unique physician-patient relationship, and so, that would be in the medical records. That's why I think maybe the alternative language route might be an appropriate way to go where you're talking about the unique situation of a medical event, where it's not a general member of the public but in the unique situation -- and that could justify, then, the different language that's in Part 20.

MS. HANEY: Two points is that, with the suggested state regs, I believe some states are required to adopt them verbatim by their legislation. So, that's one thing that makes a suggested state's regs very important.

The other is that I believe the next step from where Dave is is that it does go out to all the states for comment and for their review, and while it's not something that's published in the Federal Register, it's something that Dave would come back and get based on the comments that he receives from the state and possibly make some changes in the suggested state regs.

MS. McBURNEY: Yeah, that was the other point I

was going to make, is that these suggested state regs, in draft form, have not gone out to the other states for peer review, only the states that have been involved or only the representatives involved on that working group have actually been involved.

COMMISSIONER McGAFFIGAN: In all honesty, I am sympathetic to the staff proposal and what you're endorsing in this area, in T&E, in whatever, and I believe that the model state regulation as it exists at the moment clearly impacts medical practice in a variety of areas more than what our staff is proposing.

Yet, I am worried about either this battleground in 31 states or some of the 31 having to, you know, just automatically, by their legislation, adopt standards. In T&E, I see Georgetown here. I mean, you know, you're going to train somebody who's going to be able to practice in the District and Virginia but not necessarily in Maryland, depending on if they decide they're going to do something more.

Yet, I think there's a reluctance, given the history of, you know, we're a Federal system, as my colleague from New Hampshire is quite apt to point out, and I fully acknowledge, and the states have, in, whether it's the practice of law or practice of medicine, they set the standards.

So, there is a chance for 32 different outcomes, you know, for 19 states ours, and for 31 others quite different outcomes on several of these issues.

Yet, I hope that the states will give some real weight to the process that we went through, in the openness and transparency and whatever.

Does the medical community have a chance to involve itself in SR6?

DR. CERQUEIRA: No, not really. It would have to be at the state level, and I'd sort of like to endorse your statements, as well, because this process has been very open, you've really sought input, not just from the medical community but from the public.

You've taken, you know, four major meetings, and so, I think this rule is very much -- has input from all of the stakeholders, and as such, the state process, even though it, you know, does involve a certain amount of review, especially with T&E, it's going to make it very difficult, and I think, right now, the NRC agreement state concordances is category C.

I think, for training and experience, making it a category B would really simplify the effort on the training programs and just physicians, because you really can't tell where you're going to be practicing.

So, you could be practicing, authorized in one

state, either by training or experience or boards, and go to another state and just not be able to do it, and so, this has been a very well-developed, thought-out process with a lot of input, and I really think that, in some form, it should be more of a Federal overall policy, and they've had three years in which to review the recommendations and take their own actions.

So, we're not going to have an instant resolution on the training and experience.

COMMISSIONER McGAFFIGAN: On patient release criteria, as I understood Mr. Walter yesterday -- and I haven't seen his draft regulation, but he wasn't necessarily against the 500-millirem patient release criterion, but he was stressing the requirement for ALARA training, ALARA training is critical in order to meet some of the concerns that he saw, but I think that was the thrust of his remarks yesterday.

Is there any need for something to be in the rule with regard to ALARA training for the patient, you know, adequate instruction? Or is there already something in the rule?

MS. HANEY: There is a requirement in the rule that, if you exceed 100-millirem, the authorized user needs to provide the patient with instructions, and it says explicitly instructions on how to minimize exposure. So,

that is going with the patient.

COMMISSIONER McGAFFIGAN: That goes with the patient. It goes with the loved ones of the patient, or the nursing home, for that matter, who will receive the patient. There's probably some written instructions that go with the patient.

MS. HANEY: Right. The rule says that the instructions would be provided to the patient.

Now, I believe what Dave is trying to bring out is, well, those instructions could get trashed on the way home, there's no requirement for the patient to follow what they're given, but even at that, the idea is that, if the instructions are not followed, you're still not going to exceed the 500 millirem.

COMMISSIONER McGAFFIGAN: Right.

CHAIRMAN DICUS: Commissioner Merrifield, comments?

COMMISSIONER MERRIFIELD: Yes, closing comments.

I do want to add my thanks to the other Commissioners' for this committee coming up and the amount of time that you've spent in going over these issues and providing your input.

It is very helpful and useful and certainly will weigh in my determination about how to move forward on this rule.

This is obviously an area where I think we've all spent a lot of time and effort in really trying to get ourselves up to speed so that we can make an informed decision about where we ought to go.

We had an enormous number of comments on this proposed rule, over 500 pages of material put together to answer some of those, I think is a recognition of the time we spent in considering those.

I think, for the vast majority, those are very thoughtful comments, and I think the staff has attempted to address those as much as possible.

I do have to note, since the time I have been here, this has been a rule-making which has had some enormous personal-directed comments that I have seen.

I think it would be -- I don't think I can let slide -- some of the comments that were made, which, frankly, coming from members of the medical community, I felt were quite unprofessional, and personal attacks on this Commission, our staff as well as the individual Commissioners.

Unfortunately, that's the case. That's why we take these positions, and we are what we are, but I was disappointed by some members of the medical community in the attacks that they made on us, in particular.

CHAIRMAN DICUS: Commissioner McGaffigan?

COMMISSIONER McGAFFIGAN: No further comment, except there's one member of the medical community, Carol Marcus, who is, I think, the main person you have in mind when you make that comment, and many of her comments are just so far off the mark that it's hard to read them.

CHAIRMAN DICUS: Anything else?

I'm going to refrain from making any comments. I think it's appropriate at the moment.

So, on behalf of my fellow Commissioners, I would certainly like to thank the staff from the Division of Industrial and Medical Nuclear Safety and certainly members of the Advisory Committee on the Medical Uses of Isotopes for this very informative briefing and for the good exchange that I think we have had.

It's very clear that all of you have worked extremely hard over the past couple of years and even beyond that on this rule-making, and you've made great progress in addressing the numerous stakeholder concerns with respect to training and experience requirements, the reporting thresholds, which we are still debating, obviously, the medical event notification, and unintended exposures, and revised radiation safety committee requirements, while taking into account, certainly, the implementation challenges that are going to face us as we put this rule into effect.

Part of this ongoing interaction includes a new direction and exchange of ideas for including more performance-based, risk-informed decision-making processes in our routine interactions with our stakeholders, as well as inclusion of these ideas into revised regulations, since the public's health and safety is paramount to all of our endeavors.

I think we obviously share that in common.

But we must take it upon ourselves to change the old way of developing regulatory strategies and instead use our technical competence, along with the insights drawn from past operating history, to better focus licensee and regulatory attention on design or operational issues commensurate with their importance to health and safety.

I believe it is paramount that the regulatory agencies in this country responsible for ensuring the public's health and safety for medical uses of ionizing radiation continue to focus all of our concerns on higher-risk activities to ensure that any revisions in the regulations are technically sound and are risk-based.

If we continue to work together in this manner, we will not only have a solid materials regulatory program that provides reassurance to our stakeholders but a sound uniform approach in regulating the safe use if ionizing radiation for medical purposes.

Do any of my fellow Commissioners have any other closing comments?

[No response.]

CHAIRMAN DICUS: Therefore, we stand adjourned.

Thank you very much.

[Whereupon, at 11:12 a.m., the briefing was concluded.]

CERTIFICATE

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

TITLE OF MEETING: BRIEFING ON PART 35
RULE ON MEDICAL USE OF
BYPRODUCT MATERIAL

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, October 21, 1999

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: Tamara Shipp

Reporter: Mark Mahoney

ACMUI ANNUAL COMMISSION BRIEFING

Manuel D. Cerqueira, M.D.
John Graham
Nekita Hobson
Ruth McBurney, M.S., CHP
Louis Wagner, Ph.D.

October 21, 1999

16 OCT 99

Briefing Outline

- General Comments
- Radiation Safety Committee
- Training and Experience
- Medical Event
- Unintentional Exposure to Embryo/Fetus/Nursing Child
- Notifications
- Implementation Challenges

General Comments

- Draft final rule is risk-informed, more performance based
  - Occupational, public, and patient safety maintained
  - Focus on higher risk procedures
  - Reduces unnecessary regulatory burden for low-risk procedures
- Stakeholder involvement
  - ACMUI, subcommittees
  - Regulated community

Radiation Safety Committee (§35.24)

- ACMUI endorses the draft final rule that requires RSC for two or more different types of uses under Subparts E, F, and H or two or more types of units under Subpart H
  - Provides the licensee flexibility in program management in environment of consolidating resources

Training and Experience

- NRC focus is on radiation safety
  - Training should be obtained in a clinical environment
- ACMUI endorses alternative pathway for training and experience requirements for AU, AMP, ANP, and RSO
  - Importance of preceptor statements
  - NRC recognition of specialty boards
    - Initiate recognition process immediately
- Encourages uniform national standards for training and experience
- T&E for emerging technologies

Medical Event (§30.3045)

- ACMUI endorses dose thresholds in draft final rule
  - Adequately capture events of concern
  - Dose thresholds will help to reduce unnecessary regulatory burden (wrong treatment site, patient intervention)
- Events occurring as result of patient intervention should not be reported to NRC unless unintended permanent functional damage to an organ or physiological system

Unintentional Exposure to Embryo/Fetus/Nursing Child (§35.3047)

- ACMUI endorses 50 mSv (5 rem) as an appropriate ***reporting*** threshold
  - Technical implications
  - Minimal impact on the patient/physician relationship
  - Minimal impact on current standard of care and cost

Notification Following Medical Event or Exposure to Embryo/Fetus/Nursing Child

- ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing standards of care
- Alternative rule language provided by staff preferred over existing requirements

Implementation Challenges

- Early recognition of medical specialty boards
- Focusing NRC license reviewers and inspectors on licensee performance and high risk procedures
- Use of guidance document

Revision of 10 CFR Part 35 Medical Use of Byproduct Material

October 21, 1999

Catherine Haney

Briefing Outline

- Background
- Purpose of SECY-99-201
- Key issues for Commission decision
- Implications for licensing, inspection, and enforcement programs
- Resources and timetable for completion of rulemaking

Background

- SRM-COMSECY-96-057, March 20, 1997, Commission directed the revision and restructuring of Part 35 into a risk-informed, more performance-based regulation
- Continuous interaction with public, stakeholders, Agreement States, non-Agreement States, and ACMUI

Purpose of SECY-99-201

- Provide draft final rule language for 10 CFR Part 35
- Summarize public comments and staff's draft responses to the comments
- Provide comparison of current rule to draft final rule
- Achieve closure on outstanding issues from previously issued SRMs
- Provide proposed Agreement State compatibility designations
- Provide CRCPD SR-6 Committee view on draft revision
- Request approval to complete final rulemaking package
- Request approval to begin notification process for specialty boards

Key Issues for Commission Decision

- Need for formal risk assessment
- Radiation Safety Committee
- Training and experience requirements
- Reporting threshold for unintended exposure to embryo/fetus/nursing child
- Notification following a medical event or exposure to embryo/fetus/nursing child
- Additional CRCPD SR-6 Committee concerns

Risk Assessment

- Issue - need to perform a formal risk assessment (SRM-SECY-98-263)
- Pros
  - Additional information
  - Responsive to public and Agreement State comments
- Cons
  - Significant delay in final rule
  - Resource intensive
  - Data necessary to perform a formal risk assessment may be either not available or be problematic
- Staff recommendation - proceed with Commission's direction to develop a risk-informed rule that is focused on radiation safety
- Draft final rule risk informed: reduction in unnecessary regulatory buden, especially in low risk diagnostic area

Radiation Safety Committee

- Issue - impact of the proposed deletion of the RSC on the licensees' effectiveness in carrying out radiation protection programs
- Considerations - risk, public comment
- Staff resolution - RSC only required for two or more different types of uses under Subparts E, F, and H, or two or more types of units under Subpart H

Training and Experience Requirements

- Issue - establish appropriate T&E requirements
- Considerations - public comments; risk; misadministration history
- Global recommendations
  - Focus on radiation safety
  - Reliance on preceptor statement vs. requirement for an examination or NRC approval of training program
  - NRC recognition of specialty boards

Training and Experience Requirements (cont)

- Changes in specific T&E since March 1999
  - Use of unsealed byproduct material
    - Requirement for total hours of training and experience versus breakdown of hours for classroom and laboratory training and supervised work experience
    - Requirements for oral administration of NaI (I-131) based on quantities used
  - Use of sealed byproduct material
    - Requirements added for ophthalmic use of Sr-90
- CRCPD SR-6 Committee concerns

Reporting Threshold for Unintended Exposure to an Embryo/Fetus/Nursing Child

- Issue - need for NRC to meet AO reporting criteria
- Considerations - impact on medical practices; public comments; reporting threshold, not dose limit; recommendations of radiation protection organizations; include reporting threshold in Part 35 or develop rulemaking plan to revise Part 20 or Parts 30, 40, and 70

Reporting Threshold for Unintended Exposure to an Embryo/Fetus/Nursing Child (cont)

- Staff resolution
  - Embryo/fetus - report any unintentional dose that exceeds 50 mSv (5 rem) dose equivalent
  - Nursing child - report any dose that is greater than 50 mSv (5 rem) TEDE; or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician

- CRCPD SR-6 Committee concerns

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child

- Issue - revision of the requirements to notify the patient, responsible relative, or mother
- Considerations - public comments; risk; alternative regulatory text provided in SRM
  - Verbal notification
  - Written documentation in patient's file
  - Written certification stating patient was notified

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child (cont)

- Pros of alternative text
  - More consistent with medical policy goals
  - Greater reliance on physician-patient relationship
  - Consistent with another Federal patient notification requirement
  - Responsive to SRM direction to be risk-informed and to public comments
- Cons of alternative text
  - Does not ensure patient is fully informed
  - Not consistent with other NRC requirements

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child (cont)

- Resolution - current requirements retained in draft final rule; alternative rule text provided for Commission consideration

Additional CRCPD SR-6 Committee Concerns

- Criteria for releasing individuals containing unsealed byproduct material or implants containing radioactive material
- Safety precautions associated with brachytherapy treatments

Implications for Licensing, Inspection, and Enforcement Programs

- Specific vs. general licensing
- Information to be submitted in support of licensing actions
- Inspection - review of procedures
- Revisions to the Enforcement Policy

Resources and Timetable for Completion of Rulemaking

- 3 FTE to complete rulemaking, MPS, and NUREG

- SRM will drive final due date - estimate final rule, including OMB approval, mid 2000; effective date early 2001

Back-up Slides

Proposed 10 CFR Part 35
Table of Sections Applicable to
Diagnostic and Therapeutic Nuclear Medicine

Section No. and Title		All Uses	35.100	35.200	35.300
Subpart A--General Information					
35.1	Purpose and scope.	✔			
35.2	Definitions.	✔			
35.5	Maintenance of records.	✔			
35.6	Provisions for the protection of human research 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.	✔			
35.18	License issuance.	✔			
35.19	Specific exemptions.	✔			

Section No. and Title		All Uses	35.100	35.200	35.300
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				✔
35.50	Training for Radiation Safety Officer.	✔			
35.55	Training for an authorized nuclear pharmacist.	✔			
35.57	Training for experienced RSO, teletherapy or medical physicist, authorized user, and nuclear pharmacist.	✔			
35.59	Recentness of training.	✔			
Subpart C--General Technical Requirements					
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.	✔			
35.61	Calibration of survey instruments.	✔			
35.63	Determination of dosages of unsealed byproduct material for medical use.	✔			
35.65	Authorization for calibration, transmission, and reference sources.	✔			
35.69	Labeling of vials and syringes.	✔			
35.70	Surveys of ambient radiation exposure rate.				✔

Section No. and Title		All Uses	35.100	35.200	35.300
35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material.	✔			
35.80	Provision of mobile medical service.	✔			
35.92	Decay-in-storage.	✔			
Subpart D--Unsealed Byproduct Material - Written Directive Not Required					
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion.		✔		
35.190	Training for uptake, dilution, and excretion studies.		✔		
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 imaging and localization studies.			✔	
Subpart E--Unsealed Byproduct Material - Written Directive Required					
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 which a written directive is required.				✔

Section No. and Title		All Uses	35.100	35.200	35.300
35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).				✔
35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).				✔
Subpart L--Records					
35.2024	Records of authority and responsibilities for radiation protection programs.	✔			
35.2026	Records of radiation program changes.	✔			
35.2040	Records of written directives.				✔
35.2045	Records of medical events.	✔			
35.2047	Record of a dose to an embryo/fetus or a nursing child	✔			
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.	✔			
35.2061	Records of radiation survey instrument calibrations.	✔			
35.2063	Records of dosages of unsealed byproduct material for medical use.	✔			
35.2070	Records of surveys for ambient radiation exposure rate.				✔
35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.	✔			
35.2080	Records of administrative and technical requirements that apply to the provision of mobile medical services.	✔			

Section No. and Title		All Uses	35.100	35.200	35.300
35.2092	Records of decay-in-storage.	✔			
35.2204	Records of molybdenum-99 concentrations.			✔	
35.2310	Records of instruction and training.	✔			
Subpart M--Records					
35.3045	Report and notification of a medical event.	✔			
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child.	✔			
Subpart N--Enforcement					
35.4001	Violations.	✔			
35.4002	Criminal penalties.	✔			

TRAINING AND EXPERIENCE REQUIREMENTS ON DRAFT FINAL RULE

	Requirements*
§ 35.190 - Training for uptake, dilution, and excretion studies *(Written directive is not required - § 35.100)*	- 60 hours training and experience (classroom and laboratory training and supervised work experience)
§ 35.290 - Training for imaging and localization studies *(Written Directive is not required - § 35.200)*	- 700 hours training and experience (classroom and laboratory training and supervised work experience)
§ 35.390 - Training for use of unsealed byproduct material *(Written Directive is required - § 35.300)*	- 700 hours training and experience (classroom and laboratory training and supervised work experience) - 3 cases for each use category for which AU status is requested
§ 35.392 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)	- 80 hours classroom and laboratory training - supervised work experience (including 3 cases involving administration of less than or equal to 33 millicuries)
§ 35.394 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)	- 80 hours of classroom and laboratory training - supervised work experience (including 3 cases involving administration of greater than 33 millicuries)
§ 35.490 - Training for use of manual brachytherapy sources (§ 35.400)	- 200 hours classroom and laboratory training - 500 hours supervised work experience - 3 years supervised clinical experience in radiation oncology**

§ 35.491 -	Training for ophthalmic use of strontium-90	- 24 hours classroom and laboratory training - supervised clinical training that includes treatment of 5 individuals
§ 35.590 -	Training for use of sealed sources for diagnosis (§ 35.500)	- 8 hours classroom and laboratory training
§ 35.690 -	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.600)	- 200 hours classroom and laboratory training - 500 hours supervised work experience - 3 years supervised clinical experience in radiation oncology**
§ 35.50 -	Training for Radiation Safety Officer	- 200 hours didactic training - 1 year supervised experience; similar types(s) of use(s)
§ 35.51 -	Training for an authorized medical physicist	- Master's or Doctor's degree - 1 year training - 1 year supervised experience
§ 35.55 -	Training for an authorized nuclear pharmacist	- 700 hours structured educational program

* An AU under §§ 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.690 must be a physician. An AU under § 35.590 may be a physician, dentist, or podiatrist. An AU, RSO, AMP, and ANP must also have a preceptor statement.

** May be obtained concurrently with supervised work experience.

Recommendations on Exposure to Embryo/Fetus/Nursing Child

- Threshold level is consistent with recommendations in
  - NCRP #54, Medical Radiation Exposure of Pregnant and Potentially Pregnant Women (1977)
  - AAPM TG #36, Fetal Dose from Radiotherapy with Photon Beams (1995)
  - NCRP Commentary #9, Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child (1994)
    - At a reporting threshold of 50 mSv (5 rem), there are no deterministic effects, and the risk of stochastic effects is less than 1%
    - Concluded that "setting requirements for action ... at some level below an effective dose of 100 mSv (10 rem) to allow for a margin of safety should enable all such incidents with the potential for harm to be dealt with appropriately

Projected Schedule

October 1999	Commission briefing on draft final rule
November 1999	SRM on preparation of final rule
February 2000	Submission of final rulemaking package for Commission approval
TBD	Commission approval of final rule
TBD + 90 days	OMB approval of publication of final rule in FR
6 mos after pub	Effective date of final rule