

1 UNITED STATES
2 NUCLEAR REGULATORY COMMISSION

3 ***

4 ADVISORY COMMITTEE ON THE
5 MEDICAL USES OF ISOTOPES

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7
8 U.S. Nuclear Regulatory Commission
9 Two White Flint North
10 11545 Rockville Pike
11 Room T-2-B3
12 Rockville, Maryland

13
14 Wednesday, November 8, 2000

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16 The above-entitled committee meeting commenced,
17 pursuant to notice, at 9:05 a.m.
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MEMBERS PRESENT:

MANUEL CERQUERIA, Chairman
LOUIS WAGNER, ACMUI Member
RICHARD A. VETTER, ACMUI Member
JEFFREY F. WILLIAMSON, ACMUI Member
SALLY WAGER SCHWARZ, ACMUI Member
RUTH MCBURNEY, ACMUI Member
NIKITA HOBSON, ACMUI Member
JOHN GRAHAM, ACMUI Member
DAVID A. DIAMOND, ACMUI Member
NEOMI ALAZRAKI, ACMUI Member
SUBIR NAG, ACMUI Member

ALSO PRESENT:

CATHERINE HANEY, Office of Nuclear Materials
Safety and Safeguards, NRC
DONALD COOL, Office of Nuclear Materials Safety
and Safeguards, NRC
THOMAS YOUNG, Office of Nuclear Materials Safety
and Safeguards, NRC
R.K. LEEDHAM, Food and Drug Administration
ROBERTO J. TORRES, Office of Nuclear Material
Safety and Safeguards, NRC
PAUL LOHAUS, Office of Nuclear Material Safety and
Safeguards, NRC
ROBERT AYRES, Office of Nuclear Material Safety

and Safeguards, NRC

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P R O C E E D I N G S

[9:05 a.m.]

DR. CERQUERIA: If everyone can take their seats, for the committee, and if visitors and guests could sign in, we'll get started.

We have quite a full agenda for the next day and a half and we're really going to try to stay on time.

My name is Manuel Cerqueria and I'm the Chairman of the ACMUI. What I'd like to do, formally, we have several new committee members and I'd like to sort of go around the table on the committee members and have people introduce themselves and their affiliations and the groups that they represent.

DR. ALAZRAKI: Neomi Alazraki. I'm a nuclear medicine physician at Emory University and the VA Medical Center in Atlanta. I represent nuclear medicine physicians.

DR. DIAMOND: I'm David Diamond. I'm a radiation oncology physician, new to the ACMUI, from Orlando, Florida. I represent the radiation oncology community.

MR. GRAHAM: John Graham, representing Health Care Management, from Beaumont Hospital, Royal Oak, Michigan.

MS. HOBSON: Niki Hobson, the National Association of Cancer Patients, and I am the patient advocate.

MR. LEEDHAM: I'm R.K. Leedham. I'm representing the FDA, work in the Center for Drug Evaluation and

1 Research. I'm the Associate Director of the Division of
2 Medical Imaging.

3 DR. CERQUERIA: I'm Manuel Cerqueria. I'm a
4 cardiologist and nuclear medicine physician at Georgetown
5 and I represent the cardiology community on the committee.

6 DR. WAGNER: I'm Lou Wagner. I'm from the
7 University of Texas, Houston Medical School. I'm
8 representing diagnostic nuclear medicine and I am a former
9 member of the ACMUI, and I'm now here as an invited guest.

10 DR. MCBURNEY: I'm Ruth McBurney, with the Bureau
11 of Radiation Control, Texas Department of Health. I'm on
12 the committee representing state radiation control.

13 MR. NAG: Subir Nag, Ohio State University,
14 Columbus, Ohio, representing brachytherapy and radiation
15 oncology.

16 MS. SCHWARZ: I'm Sally Schwarz, Washington
17 University, in St. Louis, Missouri, representing nuclear
18 pharmacy.

19 DR. WILLIAMSON: I'm Jeff Williamson, a radiation
20 oncology physicist from Washington University, and I guess I
21 represent radiation oncology physics.

22 DR. VETTER: Richard Vetter, Radiation Safety
23 Officer at Mayo Clinic, in Rochester, Minnesota. I
24 represent radiation safety officers.

25 MS. HANEY: I'm Cathy Haney. I'm the Designated

1 Federal Official for this meeting. I'm a section leader in
2 our Rulemaking and Guidance Branch of the Office of Nuclear
3 Material Safety and Safeguards.

4 DR. COOL: I'm Donald Cool. I'm the Director of
5 the Division of Industrial and Medical Nuclear Safety, here
6 in the Nuclear Regulatory Commission, and I'm very pleased
7 to have each of you here today, new and returning, to be
8 part of this group.

9 DR. CERQUERIA: Thank you very much. We are now
10 officially opened and I will turn it over to Cathy.

11 MS. HANEY: I'll make the official's opening
12 remarks.

13 DR. CERQUERIA: Yes. Cathy Haney.

14 MS. HANEY: Thank you. I'm very pleased to
15 welcome you all to Rockville today for a public meeting of
16 the Advisory Committee on the Medical Uses of Isotopes. As
17 I indicated, I will be the Designated Federal Official for
18 the Advisory Committee for this meeting.

19 This is an announced meeting of the committee.
20 It's being held in accordance with the rules and regulations
21 of the Federal Advisory Committee Act and the Nuclear
22 Regulatory Commission.

23 The meeting was announced in the Federal Register
24 on September 25, 2000.

25 The function of the Advisory Committee is to

1 advise staff on issues and questions that arise on the
2 medical use of byproduct material. This committee provides
3 counsel to the staff, but does not determine or direct the
4 actual decisions of the Commission. The NRC solicits the
5 opinions of the council and values the opinions of the
6 committee very much.

7 I do request that whenever possible, we try to
8 reach consensus on the various issues that we will discuss
9 today or at any other future ACMUI meetings. But I also do
10 value stated minority or dissenting opinions.

11 I do ask, if you have dissenting opinions, that
12 you state these for the record very clearly, so that we can
13 relay that information on to others.

14 As part of the preparation for this meeting, I
15 have reviewed the agenda for members and employment
16 interests based on the very general nature of the
17 discussions we're going to have today. I have not
18 identified any items that pose a conflict. Therefore, I
19 seen no reason for individual members of the committee to
20 reclude themselves from the discussion.

21 However, if, during the course of our business
22 today, you determine that you do have some conflicts, please
23 state it for the record and reclude yourself from that
24 particular discussion, or you can make me aware of it during
25 one of the breaks.

1 At this point, I would like to also introduce one
2 other person that I want you to know about today. Betty Ann
3 Torres, who is sitting off here to my left, is the Project
4 Manager for the ACMUI. So if you have any issues today or
5 tomorrow as far as just logistics or you're missing
6 documentation, anything we can help you with, please feel
7 free to ask Betty Ann or, also, come to me, or we have many
8 staff members available to assist you, also.

9 So with that, I'll turn it back to Dr. Cerqueria.

10 DR. CERQUERIA: Thank you very much, Cathy. I
11 guess the first item is going to be a presentation from
12 Donald Cool, to Lou Wagner.

13 DR. COOL: And maybe a couple of other things,
14 with the Chair's permission.

15 DR. CERQUERIA: Sure.

16 DR. COOL: I usually like to try and take a brief
17 opportunity when we get together just to give you a little
18 bit of overview of things that are going on within the
19 organization and agency that you should be aware of, and
20 I'll do that in just a moment.

21 But the first thing I'm going to do, and, Lou, I think maybe
22 you're going to get away without having the shutterbug
23 actually take a picture of this, we usually don't let people
24 get away without having their mug shot permanently enshrined
25 in the hall of -- I won't fill in the blank.

1 But I have here a Certificate of Appreciation,
2 signed by Richard Meserve, the Chairman of the Nuclear
3 Regulatory Commission, in recognition of your service over
4 the past fair number of years now on the ACMUI, which has
5 really helped us and significantly improved our
6 understanding in the regulation of byproduct material.

7 So I really want to congratulate you.

8 [Applause.]

9 DR. WAGNER: Would you believe it if I told you I
10 was speechless?

11 DR. COOL: No.

12 DR. WAGNER: Thanks, Don. I really appreciate
13 this. It's truly been an honor to serve on this committee.
14 I can't think of many things I've done on committees and
15 stuff that have been really enjoyable, but I have found
16 serving on this committee an extremely enjoyable task.

17 I think the real honor goes to the NRC for the
18 actions it has taken in trying to change the regulations
19 over these years. I've just been privileged to be part of
20 the procedure, but I think you've done a bang-up job and I
21 think you've got a wonderful staff.

22 So I think you guys deserve a pat on your back.
23 So thank you.

24 DR. COOL: Thank you very much.

25 [Applause.]

1 DR. COOL: I'd like to spend just a moment or two
2 to provide a little bit of an overview of some of the
3 activities here within the Nuclear Regulatory Commission to
4 set or reset, depending on whether this is your first time
5 within the committee or returning, a little bit of a
6 framework of what's going on here within the agency and some
7 of the things which set the stage and lay the groundrules
8 for our activities.

9 You may be aware of, or perhaps not, the formal
10 publication of the Nuclear Regulation Commission strategic
11 plan for physical year 2000 to 2005. If you haven't seen
12 copies of this, I expect that we can get copies for each of
13 the committee members. It's a document that has just
14 formally come out within the last couple of weeks, and
15 really sets the stage now in keeping with what the Federal
16 Government is doing all across the government in trying to
17 do more strategic planning, laying out our goals and our
18 mission, our performance metrics, how are we going to grade
19 ourselves, what is it that we're trying to do, how is it
20 that we're trying to do it, and how will we know whether or
21 not we've gotten there, which is an interesting sort of
22 challenge, particularly for regulatory agencies, where, in
23 the end, what you measure in terms of outcomes are not
24 necessarily always really neatly and clearly and concisely
25 tied to the outputs that you may produce.

1 But to very quickly go through, on a high order,
2 for you the Commission's mission, obviously, it's to
3 regulate the civilian use of the byproduct source and
4 special nuclear materials, and right there you immediately
5 see the first constraint, because that's only a slice of all
6 radioactive types of materials and radiation which is out
7 there; to ensure adequate protection of public health and
8 safety, promote the common defense and protect the
9 environment.

10 We have put together the strategic plan, which
11 looks at a variety of our activities, and, in particular,
12 this plan is outlined in accordance with several arenas.
13 And you're going, ah, now, what is the arena.
14 Well, over on the far left side of the arena, if we're under
15 the big top, you're going to see that this is more than a
16 three-ring circus, this is about a five-ring circus,
17 actually.

18 The fundamental arenas are, first, for the reactor
19 safety arena, which deals with the reactor program. That
20 includes the power and non-power reactor programs. In each
21 of these cases, you will see that the fundamental goal is to
22 provide protection for the public and the environment,
23 consistent with our overall mission, and, fundamentally, to
24 prevent radiation deaths and illnesses, promote security,
25 and those sorts of things.

1 So that's the reactors. We deal tangentially with
2 those. There have been some medical issues, such as boron
3 neutron capture and some others, which gets our interfaces
4 with some of the reactors a little more tangible than they
5 may have been previously.

6 Then you have the material safety arena. That's
7 where we spend the majority of our time. When we say
8 materials, you're going to find everything from the typical
9 byproduct uses that we will talk about in this committee in
10 medical, to the industrial uses, the academic uses, to the
11 fuel cycle facilities, all the folks who are in the chain to
12 make the fuel for the reactors.

13 Again, the fundamental goal being to prevent
14 deaths and illnesses, common defense, and security.

15 As would inevitably be the case, sooner or later,
16 we get to what happens after you're done with it. That's
17 the third fundamental arena, which is the waste safety
18 arena, looking at the issues of radioactive waste in
19 transport, high level, low level, spent fuel storage and
20 transportation issues all fall within that particular arena
21 of activities.

22 Our fourth arena is the international safety arena
23 and all of our interfaces external to this country, for
24 which there are actually a fair number of them, all across
25 the various sorts of categories, and then a fifth arena,

1 which I won't actually put up on a slide, which is our
2 management and organization arena, how we actually conduct
3 our business, the human resources attributes, paying people,
4 the information technology and all of those sorts of things
5 that are inevitably necessary in order to make any
6 organization go forward.

7 Fundamentally, across each of the arenas, there
8 are four performance goals and when we went through a rather
9 structured process, we ended up consistently boiling down to
10 saying what are our fundamental jobs, maintaining safety,
11 assuring that the activities conducted, no matter what
12 arena, are maintaining safety, protecting the environment,
13 providing the appropriate safety or safeguards for the
14 radioactive materials, no matter what their use.

15 The second one, and this is where it's gotten to
16 be more interesting, because some of these haven't really
17 been articulated previously in these ways.

18 One of the things that we felt a number of our
19 efforts came down to was increasing public or stakeholder
20 confidence. There's a number of things we do in order to
21 relay what it is that we do, why it is that we're doing it,
22 and attempting to get the buy-in, if you will, of different
23 organizations to both the understanding of our programs and
24 moving forward to helping us implement those programs.

25 Stakeholders range from our friends down on

1 Capitol Hill to the various state organizations, to all of
2 our licensees and you in the various professional societies
3 and individual groups who are effected with and work with
4 our regulations, to other environmental groups, citizens
5 groups, consumer groups, just a huge wide range.

6 And as you might imagine, they are not always
7 exactly aligned with each other when it comes to thinking
8 about what this agency ought to do.

9 So that makes for some rather interesting
10 discussions on occasions, because even within an overall
11 effort to increase understanding and confidence, there are
12 tradeoffs back and forth as you look at particular issues.

13 Our third is a continuing attempt to make
14 ourselves more efficient, effective and realistic. That is,
15 are we doing the right things, are we doing them the right
16 way, and are we doing them in a way which isn't either
17 overly precise or overly conservative in our processing,
18 calculations and activities. And a large part of our
19 research effort comes into trying to help us understand and
20 make sure that we understand the various issues and problems
21 that are going on in a way that we can make really informed
22 decisions.

23 That's another one of the places where this
24 committee really fits into the strategic plan. One of the
25 things we've asked all of our staff is to look at, because

1 we can find you in the plan, I can find you as a committee
2 in this plan and this is one of the places, helping us
3 assure that we are maintaining safety is clearly another one
4 of the places.

5 Helping us understand and assure that we're
6 looking at confidence is yet another place and our fourth
7 one, and I contend that you're also there, is reducing
8 unnecessary regulatory burden. And, oh, my goodness, what
9 do they mean by that.

10 Well, anything that this agency does imposes a
11 burden somehow. A license constitutes a burden or certain
12 things you have to do, and, of course, there's usually a fee
13 associated with it.

14 But there are all sorts of other burdens that go
15 along with, are we keeping the right records, are we
16 responding to the right things, are we reporting the right
17 activities, down to within the programs, what records you
18 have to keep, what kinds of documentations, just the whole
19 variety of issues.

20 Some of that is clearly necessary at any given
21 time and place. As you can also imagine, there is also a
22 continuing great debate about what is necessary or what
23 might be unnecessary at any given point in time.

24 The focus of our goal is to be looking at and
25 consistently evaluating whether there are things which are

1 not necessary in order for us to achieve our goals of
2 maintaining safety and increasing public confidence in
3 activities.

4 The last little slide that I have extracted from
5 some of the talks that we have given within the staff, what
6 are we asking our staff to do and, similarly, what are we
7 asking you to keep in mind as a committee helping the staff.

8 First, understanding how our work here in the
9 committee links up with those goals, assuring that we're
10 looking at the right things in safety. As new modalities
11 and activities come on line, are we focused on the right
12 kinds of issues.

13 As we begin to look at revisions to inspections
14 and licensing programs, are we looking at the right things,
15 are we using the right kinds of methods to look at them, are
16 we even using the right kind of paper is one of the
17 questions that's currently on the table, as this agency
18 moves for the first time towards a program of registration.

19 That doesn't happen to be in the medical
20 community, but involves a large segment of the industrial
21 community, in gauges and other activities which have
22 previously simply had a general license, and, quite frankly,
23 they probably never heard of the Nuclear Regulatory
24 Commission, unless they happen to read the little pile of
25 paper that came with the vendor when they got their gauge.

1 We're upping the gain on those a little bit to
2 understand it, because those keep showing up in the local
3 landfill and the steel folks, and every time an alarm goes
4 off, everybody starts to really have a lot of vibrational
5 energy.

6 Understanding the key messages and actually
7 thinking through each time as we go through the decisions
8 and focusing on the goals and assuring that we are, in fact,
9 accomplishing what we need to accomplish on those goals.

10 The other day, we came up with a short little
11 catch phrase, it was called Think-Think-Do. So many of us,
12 and it's very easy to fall into this, something happens and
13 what do we do? We react. And what we want to try and move
14 to a mode, and what I think you can help us do is when
15 something comes on the table, to actually think about it for
16 a moment before we actually do, where does it fit into the
17 system, what is the right way to accomplish this work before
18 we actually go out and take an action, and applying that
19 throughout all of our activities and all of the committee
20 activities.

21 And so as we start what is a very lively and
22 chockfull agenda that you have here today, I'd like to
23 suggest to you that that is really a framework from which I
24 would like you to look at all of the things that are going
25 on, how we're moving forward to implement Part 35 and, as

1 you will hear in a couple moments, the long awaited
2 conclusion by the Commission to promulgate Part 35 has taken
3 place.

4 We are now in the process of getting that through
5 the clearance system, so no, it's not published yet. I
6 won't steal anymore of Cathy's thunder from there. But then
7 you're going to hear about the efforts to risk-inform us,
8 which gets clearly to how do we maintain safety, but are we
9 looking at the right things in terms of burdens and issues.

10 Some new technologies that are going on that have
11 posed some rather interesting complications and a number of
12 events, and some issues associated with particular events
13 that have happened in pharmacies and in some of the
14 developmental production activities that produce the
15 radiopharmaceuticals that have been causing us to go back
16 and look very carefully at our program, because it's
17 uncovered some issues that perhaps we haven't exactly had
18 the right focus on, and I would encourage you to help us by
19 providing your advice on each one of those activities so
20 that we can move forward in the most appropriate manner to
21 maintain the safety throughout all of our activities, but do
22 that in a really efficient and effective manner.

23 Unfortunately, I am not going to be able to stay
24 with you for these two days. The scheduling is such that in
25 another couple of hours, I will go and do something very

1 similar for the folks in our Dallas office, in Texas this
2 afternoon and tomorrow morning, but I will be staying in
3 touch and I look forward to hearing a lot of good results
4 from the discussions of the committee over the next two
5 days.

6 I appreciate very much the opportunity to speak
7 with you. I look forward to hearing good work out of this.

8 Thank you.

9 DR. CERQUERIA: Thank you very much, Don. It's
10 always a pleasure to have you here and I think the strategic
11 plan is important. It would be good if we could get it
12 distributed to the committee members while we're here,
13 because I used to think that these were not important, but I
14 think they really are and it will give us some idea the
15 direction that you're going.

16 Any questions for Mr. Cool?

17 DR. ALAZRAKI: I would just like to say that I'm
18 really very, very thrilled to see this, and particularly two
19 things that I marked off on page number five, increase
20 public confidence. I really would like to see what the
21 Commission has in mind for increasing public confidence. I
22 think it's one of the most important things that you can do
23 in the next few years.

24 And although you described it, I'm sure there are
25 ramifications here to the public at large, which I think is

1 also an important component of that public confidence.

2 The public at large, in terms of educating about
3 radiation and risk and all of that, I think, has been sorely
4 lacking. And reduce unnecessary regulatory burden, we're
5 always glad to see that amongst your lists of top
6 priorities.

7 DR. CERQUERIA: Thank you very much for those
8 comments. Dr. Diamond, a quick comment.

9 DR. DIAMOND: Sure. Dr. Cool, just before you
10 leave, I just wanted to let you know that many of us on the
11 committee very much appreciate the fine job that you and
12 Cathy Haney and the rest of the staff have done in this
13 rulemaking process and it's important for you to know how
14 much we appreciate your work.

15 DR. COOL: I appreciate that. The job is only
16 half done, because it's one thing to write a rule, and this
17 was a rather interesting rule, which had a rather
18 interesting process, but, in fact, I am going to suggest to
19 you that the real challenge -- and Ms. Haney is going to get
20 to dodge this one, I think -- is going to be whether or not
21 we can now go through a process of implementing it in a way
22 that carries out our goals that we had when we wrote the
23 rule and not allow ourselves to slide back into a trap of
24 digging into all of the detail, when, in fact, we wrote the
25 rule to be more performance-based and less prescriptive.

1 DR. CERQUERIA: Well, with that as an
2 introduction, we'll move on to the next part of the agenda,
3 which is Cathy Haney, who has been through this process of
4 the Part 35 revisions since the beginning. Diane Flack is
5 not -- this is the first meeting --

6 MS. HANEY: Actually, Diane is sitting in the
7 back, but Diane has moved on. She's taken a new position
8 with Commission Diaz, as his technical assistant. So Diane
9 is here in spirit, just a different role.

10 And actually, since I didn't have Diane with me, I
11 asked Tom Young to come along. Tom Young is working in the
12 Rulemaking and Guidance Branch, also, and he's been helping
13 with getting Part 35 up and going for about the last --
14 almost, I guess, the last year, give or take.

15 So I asked him if he would do the beginning of the
16 presentation and then we'll both answer any questions that
17 you have. And you do have copies of the handouts, when we
18 took the quick break there, we handed them out at your desk.

19 DR. CERQUERIA: Tom?

20 MR. YOUNG: Good morning, Dr. Cerqueria. Let me
21 start with the medical policy statement, because we sent
22 that up with the medical rule. It was proposed in 1998 and
23 it went up with the SECY paper on the rule in May, and then
24 the Commission turned it around in just a few weeks, because
25 we had asked them to send it out before the rule. So it

1 came back down and was published in the Federal Register
2 then in August.

3 The information on this is in tab 5 of your
4 briefing book. You have the Federal Register Notice of last
5 August there for you. And then these are the four points
6 that you have in the handout that are the medical policy
7 statement for the year 2000, and this should be familiar to
8 you because you have looked at it for the past couple of
9 years.

10 Now, there were no changes from the proposed rule
11 as it went out in 1998. The comments that came in were very
12 similar to the comments that were discussed in the proposed
13 rule, Federal Register Notice.

14 So I will just move through this quickly, because
15 I want to try to help keep you on schedule today.

16 Again, it fits to our strategic plan and you will
17 have all four of those points there in tab 5 and also in my
18 slides for you to refer to later, if you need to.

19 As far as the rule portion of the rulemaking,
20 then, about a year ago, the rule went back to the
21 Commission. I think it was discussed at your last meeting,
22 October 1999, but the SRM came down then in February and we
23 worked it, there were changes, and submitted it back to the
24 Commission in May with the medical policy statement, and the
25 SRM just arrived a couple of weeks ago.

1 This is under tab 6 in your briefing book. We
2 have a copy of the SRM and the attachment, which indicates
3 changes to the Federal Register Notice and to the other
4 attachments to the SECY paper.

5 MS. HANEY: Tom, if I could interrupt you for one
6 second.

7 MR. YOUNG: Go ahead.

8 MS. HANEY: Because some of the newer members
9 aren't as familiar with some of the abbreviations you've
10 used.

11 MR. YOUNG: Sorry about that.

12 MS. HANEY: So if you give me two seconds. When
13 we refer to something as SECY-, that's a paper that staff
14 generates and sends to the Commission and we're either doing
15 it for information that we're providing to the Commission or
16 we're asking for the Commission to give us guidance.

17 There are various reasons that we're writing a
18 paper, but a SECY paper is something that is typically
19 staff-generated. The first two numbers, the 99, refers to
20 the year, if it's an 00, it's 2000, and then they just go in
21 numerical order from there.

22 So what happened, back I August, we did something
23 that was a little bit unusual with the rule. Again, Don
24 alluded to the fact that the Part 35 process was a little
25 bit unusual, I guess, challenging, where before we went to

1 the Commission with the final entire package, where you have
2 a reg analysis and an environmental assessment, we went to
3 the Commission with just the draft rule language and the
4 responses to public comments, and, basically, asked the
5 Commission if this is where -- are we on the right line, is
6 this where we want to be.

7 That was done in August. In February, they came
8 back with what we refer to as an SRM, which is a staff
9 requirements memorandum. That's the direction that the
10 Commission gives to the staff, and usually that says either
11 we agree with the recommendation in your paper or we don't
12 agree with your recommendation, we think you ought to do X,
13 Y and Z.

14 In the case of the Part 35 paper, this SRM said
15 basically the rule looks okay, response to public comment
16 looks okay, here are a couple of minor changes.

17 It also did introduce some language that had to do
18 with patient notification, because we had gone to the
19 Commission with two alternatives there. So we asked the
20 Commission to tell us which way they wanted to go.

21 But that particular February document said move
22 forward and actually come back to us with the official draft
23 final Federal Register Notice and that's what we did on May
24 31.

25 So that document, if you go on to our web site, I

1 think all totaled, it's probably close to about 1,000 pages.
2 It has the Federal Register Notice, it has the environment
3 assessment, it has a reg analysis with it, it has a package
4 that would -- a draft package that would go to Office of
5 Management and Budget for clearance for the record-keeping
6 and reporting requirements.

7 That was up at the Commission in May. As Tom
8 said, in October, we got an SRM, or a staff requirements
9 memorandum, from the Commission and that is what's in your
10 package.

11 It's fairly long. I will tell you that the
12 majority of the items in there are really clarifying text.
13 It's not really changing anything from what you've seen
14 already in one version or another, with the exception of two
15 different things. One, Tom is going to talk about in a few
16 minutes, which has to do with, again, patient notification
17 and record-keeping. The other item has to do with a request
18 for us to go forward and do another proposed rule and I'm
19 going to talk about that tomorrow.

20 But for the most part, when you look at all those
21 pages and you see a lot, realize most of them are just add a
22 word here or there or change this abbreviation or you forgot
23 to add a title, and that's the sort of thing that's in the
24 attachment.

25 So that kind of gives you the -- did I get all

1 your questions there?

2 DR. DIAMOND: Oh, I was just going to -- I
3 actually know the acronyms. I was going to suggest we say
4 them for the guests, in particular.

5 MS. HANEY: Okay.

6 MR. YOUNG: Okay. So where do we go from here?
7 Well, we're preparing the final rule for the Office of the
8 Federal Register and we're also preparing the clearance
9 package for the Office of Management and Budget.

10 DR. CERQUERIA: Tom, what is the clearance
11 package?

12 MR. YOUNG: Pardon?

13 DR. CERQUERIA: What is the clearance package? I
14 don't fully understand what that is.

15 MS. HANEY: We are required by the Office of Management and
16 Budget to have a clearance number for all of our
17 record-keeping and reporting requirements and we cannot
18 publish a final rule in the Federal Register until we have
19 that clearance number from OMB.

20 What we need to do is to go to OMB with
21 justification for all of the record and reporting
22 requirements, and it's a fair -- right now, I think the
23 package is up where it's around 60 pages of information that
24 we've had to give to -- or that we plan to give to OMB.

25 They do a very thorough review on the

1 documentation from the standpoint of making sure that it is
2 all justified, and really they're getting at the last bullet
3 Don was talking about, which is reducing unnecessary burden.

4 Once it goes to OMB, they have -- the agreement is
5 that they have up to 90 days to give us clearance. So we're
6 thinking that the package will -- we're incorporating the
7 changes that came down in that SRM and working with our
8 staff here, that is the liaison staff, with OMB to make sure
9 that they think that we've got most of their issues
10 addressed, so we don't get into a round of numerous
11 questions between the different Federal agencies.

12 But the hope is that that will go to OMB sometime
13 in December and then looking at roughly 90 days for OMB to
14 come back with a clearance.

15 Once it comes back, I think the rule will actually
16 be able to go into the Federal Register as a final rule
17 within, say, three weeks, give or take, because we'll just
18 have to insert all the numbers into the package and get it
19 down to the Office of the Federal Register, and at that
20 point is when the six-month clock starts as far as it
21 becoming effective.

22 DR. CERQUERIA: So we think December it will go to
23 the OMB. They have up to 90 days.

24 MS. HANEY: Right.

25 DR. CERQUERIA: So we're probably talking March,

1 April.

2 MS. HANEY: A March-ish publication, yes.

3 DR. CERQUERIA: So maybe April publication and
4 then six months to implementation, which will make it a year
5 from now from implementation.

6 MS. HANEY: Roughly, right.

7 MR. GRAHAM: Just one question. The SRM was to be
8 in the tab that was Part 35 status and implementation?

9 MR. YOUNG: Yes.

10 MR. GRAHAM: I don't have it. I don't know if I'm
11 the only -- I was looking for the SRM and I didn't have it.
12 Some of the books have it, some don't.

13 DR. CERQUERIA: Mine has it. But maybe if you
14 don't have it and you want to --

15 MS. HANEY: We can get some extra copies.

16 MR. GRAHAM: I think it was sort of random of it
17 made it in the book or not.

18 MS. HANEY: We'll get you copies.

19 DR. CERQUERIA: Okay. Tom?

20 MR. YOUNG: Okay. There is one significant change
21 that we wanted to show you today. It's in the notification
22 requirement and it's for -- it's subpart M for reporting for
23 these two situations, the medical event and a dose to an
24 embryo, fetus or a nursing child.

25 We're focusing on the notification paragraph for

1 each of these. I'm going to show it to you on the next
2 couple of slides. But these are -- if you look at the SRM,
3 the attachment, these are items one and two of the
4 attachment and we're incorporating these changes, and we
5 want to show them to you here.
6 But we're deleting this record-keeping requirement out of
7 35.2045 and 2047, the companion record-keeping requirement,
8 because we assume that if we get a report from the licensee,
9 then we're responsible for keeping that as a record.

10 With that, we should be able to go back to the
11 licensee.

12 Let me go to the next slide and show you the text
13 on the medical event. It's paragraph G. We're asking them
14 to annotate a copy of the report that they're required to
15 send to NRC within 15 days. They need to provide this then
16 to the referring physician.

17 They would take the report and just write in the
18 margin or some other fashion, however they want to do it,
19 the name of, the subject of the event, and an ID number that
20 goes along with that patient, so the referring physician
21 knows which case they're talking about.

22 Now, we wouldn't get a copy of the annotation.
23 The NRC would not get that information. We're not going to
24 get the patient information.

25 This is paragraph G. We're replacing it.

1 Paragraph G did refer to the record-keeping requirement,
2 2045, 35.2045.

3 DR. CERQUERIA: So this is going to replace what?

4 MS. HANEY: What happens is there's no longer a
5 record-keeping requirement to keep a copy of the report that
6 was kept to the patient, because we were concerned that,
7 from OMB's standpoint, that we could not justify keeping
8 that.

9 However, we still wanted the referring physician
10 to get a copy of the report that went to NRC and if a report
11 just showed up on the referring physician's desk that said
12 XYZ Hospital had a misadministration on this date and this
13 is what was involved and no patient's name, it would be
14 somewhat meaningless.

15 So the compromise there was to take a copy of the
16 report that you gave to NRC, to put -- just write somewhere
17 on it this is patient Cathy Haney, and then that goes to the
18 referring physician. So that takes care of that aspect.

19 There is not a requirement for the licensee to
20 keep a copy of this report, but common sense would mean that
21 if you're a licensee and you're sending a report to NRC
22 about something and a copy to the referring physician,
23 common sense is you're going to keep a copy in your files.

24 But we -- Part 35 does not have a requirement for
25 them to do that any longer. Then, also, one could start

1 arguing, and in this, you all know more than I do, that it's
2 actually a patient record and you come under whole other set
3 of requirements that is not NRC-directed. But NRC is out of
4 it from that standpoint.

5 So this is why it's a very -- it's almost a very
6 subtle change, because I don't think, in reality, it saves
7 you more than about ten minutes worth of work, because you
8 still have to send it to the referring physician.
9 But the bigger thing is that there is not this separate more
10 elaborate record-keeping requirement. All it is is just jot
11 the patient's name down and send it to the referring
12 physician.

13 DR. CERQUERIA: I think this is sort of in line
14 with what we had discussed. I guess the more contentious
15 area was the patient notification and that has basically --

16 MS. HANEY: That has not changed.

17 DR. CERQUERIA: Okay. Good. Sally, did you have
18 a comment?

19 MS. SCHWARZ: No.

20 DR. CERQUERIA: John?

21 MR. GRAHAM: Just one question. Has somebody
22 checked to make sure this is still going to comply with
23 HIPA? Health Insurance Portability Act. We had fairly
24 broad changes in patient confidentiality record distribution
25 as it related to that. It goes into effect the same time

1 this rule is going to go into effect.

2 MS. HANEY: We can check it, John. I can't say
3 that we did check it when this direction came down from the
4 Commission. So it's something that we can have our legal
5 staff look into.

6 In essence, it's very similar to what we had
7 before with the previous rule, the August version. So in
8 essence, it's not really changed anything. It's just that
9 there's one record now instead of two.

10 MR. GRAHAM: Also, Dr. Cerqueria, in this report
11 that's provided to the NRC by the licensee, they are
12 required to certify that they notified the patient.

13 DR. CERQUERIA: I'm sorry. What?

14 MR. GRAHAM: In this report here that is sent to
15 NRC by the licensee, they are required to certify that they
16 notified the patient.

17 MS. HANEY: Which, again, is not a change from
18 what the committee has seen before.

19 DR. CERQUERIA: Well, there was a lot of
20 discussion about it and --

21 MS. HANEY: And this is one of the areas where the
22 committee, on previous occasion, has recommended that there
23 not be a notification requirement, but this is one of the
24 things that the Commission has consistently felt strongly
25 that we do need this in the rule.

1 So there we were not able to go with the
2 committee's recommendation.

3 DR. CERQUERIA: So basically the committee did
4 make a -- we've had tons of discussion. I don't think we'll
5 discuss it further. It's going to be in there.

6 MR. YOUNG: Let me go to the next slide, because
7 in the case of the embryo/fetus/nursing child, the text, the
8 language is the same. We're just indicating that we have a
9 pregnant individual and a nursing child.

10 If there is a number, the referring physician is
11 going to get a copy. Same idea.

12 And then my last slide is -- Cathy is going to go
13 over this tomorrow morning, I believe, in the other
14 rulemaking session. This is a close-the-loop type of a
15 thing that was also in the SRM that just came down from the
16 Commission.

17 So I'll turn it back to you, Dr. Cerqueria.

18 DR. CERQUERIA: So additional rulemaking goes back

19 --

20 MS. HANEY: Let me give you -- so you're not
21 hanging there saying what are they doing with 3575, because
22 that's the catch one.

23 When we were developing the final package to go to
24 the Commission in May, there was an issue that was
25 identified that there was no requirement for a licensee to

1 come back and tell NRC when, for some reason or other, they
2 got information that a member of the public might have been
3 exposed to greater than 500 millirem and if you look at, in
4 Part 20, there are requirements that if a member of the
5 public gets greater than 100 millirem, that the patient gets
6 notified, NRC gets notified, things like that.

7 So this was raised to the Commission as possibly a
8 gap in the regulatory framework between Part 35 and Part 20
9 and we didn't want to flip back to Part 20.

10 Now, the Commission spent a lot of time thinking
11 about this and that's really why we had from the May to the
12 October date of getting that staff requirements memorandum.

13 And the decision was made that NRC would want to
14 hear about a problem, a situation where a member of the
15 public was exposed as a result of a release under 3575.
16 However, we've done a couple of things.

17 One is to make it risk-informed, is that the limit
18 -- we don't -- NRC -- the notification requirement, and this
19 is all -- you know, we're moving into proposed rule stage --
20 would be for a five rem limit. So you don't need to tell
21 NRC until you hit the five rem.

22 DR. MCBURNEY: Five rem?

23 MS. HANEY: Five rem, right, as compared to 500
24 millirem. So there is a big difference there, feeling that
25 the five rem limit makes the rule more risk-informed.

1 The other thing here is to realize that as NRC is
2 not changing any other of its guidance on what we expect a
3 licensee to do. We are not expecting a licensee to go out
4 and check up on the patients. This is merely an
5 after-the-fact of, say, you release a patient and you do it
6 case-specifically, assuming, say, ten percent occupancy, the
7 person says, oh, I'm going to my mountain retreat, they get
8 to the mountain retreat, they get a call from their daughter
9 that she's sick, so they jump on an airplane and fly to
10 Hawaii.

11 We're not looking for any requirement for the
12 patient to come back to the licensee and say, oh, I'm going
13 to change my plan, is that okay. The next time the patient
14 comes in for a checkup, the patient tells the physician, oh,
15 by the way, this happened, now we're in a situation where
16 the licensee goes back and recalculates and says, oh, I
17 could have gotten 5,001 millirem, that would require a
18 notification.

19 But we're not looking for anything proactive on
20 the licensee's standpoint. That is what is behind this, but
21 I would say -- I mean, this is a big topic and we all
22 believe that it's going to generate a lot of interest from
23 the stakeholders and I would say if we could defer
24 discussion on this particular aspect till tomorrow, because
25 we'll have more time on that.

1 DR. CERQUERIA: I think for the time, we should.
2 So basically Part 35, as revised, will come out. This is
3 something knew, which is sort of --

4 MS. HANEY: Actually, we're revising a rule even
5 before it's been issued in the Federal Register. So we're
6 really out there on this one.

7 DR. CERQUERIA: Ahead of the game.

8 DR. WILLIAMSON: But this will not affect the rule
9 as published in the Federal Register.

10 MS. HANEY: No.

11 DR. WILLIAMSON: This will be a subsequent --

12 MS. HANEY: Yes.

13 DR. CERQUERIA: Let's discuss it tomorrow, if we
14 have an agenda item. So we're at our break and we'll --
15 now, do you have any further comments or any questions about
16 Part 35 revision?

17 DR. NAG: There had been a number of different
18 versions and I'm not sure which is the latest version that
19 is going to be going out as the Part 35. Can you clarify
20 which is the version that will be finally --

21 DR. CERQUERIA: Was it published in the Federal
22 Register?

23 MS. HANEY: No, it's not been. What you need to
24 do now -- unfortunately, what's going into the Federal
25 Register does not exist right now today.

1 If you look at our web site, and there are a
2 couple of different ways you can get at it, but the easiest
3 thing is to go into Commission activities, and you look for
4 SECY-118, and then you look for SRM on 118, if you combine
5 the two of them, you have what is going to go into the
6 Federal Register.

7 But given that we didn't get the SRM until last
8 month, we haven't done that yet.

9 What we've left on your desks is so that you don't
10 have to go back and pull up the web site, and I think there
11 may be sometimes during today's discussion where we might
12 want to refer to the rule, is there's just -- there is a
13 document that looks like -- it's about a half-inch thick and
14 it says rule text taken from SECY-00-118.

15 DR. CERQUERIA: That's here.

16 MS. HANEY: So you have that. So if we have
17 discussions today about what's the most current version,
18 this is 99.9 percent of what is going to go in the Federal
19 Register. So it's close enough for discussion today and,
20 also, if you want to be looking at things for how you're
21 going to start changing your programs and improving, you're
22 pretty darn close with this version.

23 DR. NAG: But the amendment that was made, was
24 this something made only a few days ago or was this updated
25 six months ago?

1 MS. HANEY: No. This is the text as it appeared
2 in the SECY-118 in May of this year.

3 DR. CERQUERIA: So May 2000. Could we have the
4 lights up? This is important. We've spent three years
5 working on this. So I don't want to rush through the agenda
6 without dealing with this.

7 DR. DIAMOND: Excuse me. Cathy, in the document
8 that you're referring to, it says subpart J reserved. I'm
9 looking on page 625. What does that mean?

10 MS. HANEY: It just means that we've got a
11 placeholder in there. When we do our rules, every once in a
12 while, we like to leave some placeholders there so as in
13 five years from now, if we decide we need to do a new
14 regulation, we've got a place to fit it in here.

15 DR. DIAMOND: But isn't that a lot of the area for
16 discussion, that subpart J?

17 MS. HANEY: Subpart J, I think what you're -- the
18 current Part 35, and we'll put copies of that down for you,
19 in case we need to reference back to the current Part 35.
20 Subpart J is the current training and experience
21 requirements, but there's nothing really meant by this,
22 other than those -- all those requirements go away and once
23 this rule goes into effect and we're five years down the
24 line, we could put anything in subpart J.

25 We could put the training, the requirements, if

1 there was a new modality that came about, we'd just drop it
2 into subpart J.

3 DR. DIAMOND: So it's just a revised enumeration,
4 if you will.

5 MS. HANEY: Right. Yes.

6 DR. CERQUERIA: All right. John, quick question,
7 and quick answers, if possible.

8 MR. GRAHAM: So if we take the half-inch document
9 and add your slide notes from today, that's the closest
10 thing to what will be in the Federal Register, that has the
11 change for 35.3045 and 30 --

12 MS. HANEY: That's probably true.

13 MR. GRAHAM: Okay.

14 MS. HANEY: Because any of the things in -- the
15 majority of the items in that staff requirements memorandum
16 are changes to the statements of consideration and not the
17 rule. In fact, I don't think there are any that pertain --
18 no. There is one that does change to the rule and that is
19 anywhere where you refer to patient releases, in 35.75, you
20 will see, in the current structure, several things.

21 You will see in accordance with 35.75, under
22 35.75, governed, you'll see every -- we're going through
23 with a word search and making all of it under Part 35. So
24 it's a very subtle change, but from our Office of General
25 Counsel, it's a very important change, because that makes it

1 clear that anything that has to do with patient release is
2 in Part 35 and we're out of Part 20 space.

3 So I think with that caveat, John, you have a
4 correct statement.

5 DR. CERQUERIA: Okay. Are there other questions
6 or comments? If not, let's break and we will reconvene.

7 [Recess.]

8 DR. CERQUERIA: Mr. Torres?

9 MR. TORRES: My name is Roberto Torres. I work
10 for the Division of Industrial Medical and Nuclear Safety.
11 Today I will be talking about the implementation plan of
12 revised Part 35.

13 My presentation will be a brief one, and I will
14 broadly talk about this subject.

15 I will be focusing mainly on outreach, how are we
16 going to get the word out of the revised Part 35, how are we
17 going to conduct training and how are we going to revise our
18 procedures.

19 But first, I want the committee to have in mind
20 the following questions; what methods would be best suited
21 to communicate this revised Part 35 to your clientele, who
22 in your organizations that you represent, what persons can
23 we contact to establish coordination to arrange
24 presentations, discuss ideas, and to provide a mechanism of
25 how to answer questions from your members. Also, what

1 meetings you would suggest us to attend so we can make our
2 presentation.
3

4 DR. CERQUERIA: Mr. Torres, if I could just
5 interject. I think one of the things -- you know,
6 obviously, we need to contact the 20-some states that are
7 currently NRC-licensed, but one of the issues that we, as
8 sort of stakeholders in this, are going to have is the
9 agreement states in terms of this is going to be Federal
10 policy, but we're still going to have a lot of issues at the
11 state level, where there may be a variance.

12 So we kind of need to get this out to our
13 constituency, but we have to inform them that there may be
14 differences between what the final rule is going to have and
15 what may actually be done in their locale. So I see that as
16 a problem that is going to have to be addressed. I think
17 it's somewhat on the schedule tomorrow, but that is a
18 problem.

19 MR. TORRES: I will briefly mention that in the
20 few -- in the next slides. One of the first things that we
21 know is that we have to get coordination with agreement
22 states, stakeholders and licensees, and to do that, we are
23 going to -- the way we are going to get the word out is by
24 either written communication, like Federal Register notice,
25 which Tom Young already mentioned, information notices,

1 which are written by NMSS, NMSS licensee newsletters, and
2 personal presentations to medical societies and
3 organizations, like radiation therapy groups, cardiologists,
4 medical health physics societies, CRCPD and Organization of
5 Agreement States.

6 MS. HANEY: If I can interject for a second. One
7 of the things that we'd like to do, too, is we're really
8 just kicking off this whole aspect of implementing Part 35
9 and setting up a process for doing it, but what we do want
10 to do is involve the agreement states early on in how we're
11 implementing it.

12 So that when they do adopt similar regulations,
13 that they're not starting from ground zero. We routinely
14 have monthly conference calls with the representatives of
15 the board of the Organization of Agreement States and it's
16 usually about the third week of the month and what we plan
17 on doing during the November meeting is to give the OAS an
18 idea of where we are right now.

19 This is the first telephone conference we will have
20 had since the SRM came out, and sort of almost a similar
21 presentation to what Roberto is going to do today, is just
22 do the important points, talk to the board about that, and
23 then invite them to participate with us in this
24 implementation planning stages, so that if they're
25 interested in coming in, if they want a representative or

1 whatever, that they would be able to give us some ideas also
2 on what they think that we ought to be doing.

3 So we do see working -- a close relationship with
4 the agreement states on these implementation issues.

5 DR. CERQUERIA: And so far the overwhelming
6 indication is that they are going to be in complete
7 agreement and compliance.

8 MS. HANEY: Of course. Was that the right answer?
9 I will say that the -- well, actually, it's a Conference of
10 Radiation Control Program Directors has a committee, it's
11 called the SR-6 committee. We've talked about them
12 periodically on and off over the last couple of years. They
13 are working with our rule to come up with what they refer to
14 as a suggested state regulation that the states can look at,
15 and this is just one of the normal processes that CRCPD
16 does. It's not unique to Part 35.

17 So they're looking at that right now and working
18 on that and I would expect something in the near future on
19 that, also.

20 The other thing that the states will be looking at
21 is we assign what we refer to as a level of compatibility to
22 each one of the requirements in Part 35 and they range in
23 compatibility form where the states have to be virtually the
24 same to requirements where the state doesn't even need to
25 adopt something that we have, because it's unique to NRC.

1 The states had the opportunity to comment on those
2 compatibility levels during the developmental stages and so
3 there's been on -- basically, what I'm getting at, there's
4 been ongoing discussion.

5 So to a certain extent, there isn't anything
6 that's surprising in these particular requirements. The one
7 thing where it was a Commission-directed issue about
8 compatibility had to do with training and experience
9 requirements, and that came out as a compatibility level B.
10 It was directed by the Commission and that issue came --
11 meaning that the states have to adopt essentially verbatim
12 what we've done.

13 But I would say if we could wait to talk about
14 maybe the training and experience issue and compatibility to
15 our next session on the boards, that -- because I think that
16 that's an issue that probably is kind of where you're going.

17 DR. CERQUERIA: Certainly the training and
18 experience is going to be an issue, but I think all the
19 reporting indications and everything, we're going to create
20 chaos if we don't have some degree of uniformity on this.

21 MS. HANEY: I think from the standpoint of the
22 states, and, Ruth, maybe if you want to comment on if you've
23 heard anything recently from the states, they are aware of
24 the levels of compatibility and when it comes to the
25 reporting requirements, the states can be more restrictive,

1 if they want to, but they are at least at the level where
2 NRC is and then on the training and experience, when the new
3 Part 35 does go into effect, they will have to be
4 essentially the same.

5 DR. McBURNEY: I agree that I think the states are
6 fully aware of that level of compatibility.

7 DR. CERQUERIA: And the sense of compliance is
8 overwhelmingly positive?

9 DR. McBURNEY: I'm sure they will.

10 DR. NAG: I have a question in terms of the
11 timing. The NRC will publish sometime in April and maybe
12 with implementation by October of 2001. Would this be the
13 same time schedule for the states or each state will do
14 whatever they want?

15 MS. HANEY: No. The states have up to three years
16 from the date of our rule going -- our rule becoming
17 effective to implement or to promulgate similar
18 requirements. So there will be that three-year time period
19 when some states will essentially be operating under their
20 current --

21 DR. NAG: The old.

22 MS. HANEY: The old, their version of the old Part
23 35.

24 DR. CERQUERIA: Jeff?

25 DR. WILLIAMSON: What document outlines the levels

1 of compatibility requirement by requirement?

2 MS. HANEY: In the Federal Register Notice, there
3 is a very brief summary, but that's not what you want to
4 look at. There's basically just the -- generally speaking,
5 what the different levels are.

6 There is a matrix that we developed to support,
7 just from staff level, the different requirements. If it's
8 not available on the web site, we can put it on the web site
9 or make available to different -- you know, whoever wants
10 it, we can make it available to them.

11 DR. WILLIAMSON: I think it would be helpful if
12 we, at least on the committee, could have access to that
13 document.

14 DR. CERQUERIA: It would be useful to have it out.
15 Again, I don't want to dwell on this, but I think that we've
16 done a great job, the staff and the committee, of revising
17 this, but we need to go the next step, which is to basically
18 get everybody to be in line. Otherwise, it's going to be
19 worse than it was before we had a uniform rule.

20 So, Mr. Torres, I apologize for the diversion
21 there.

22 MR. TORRES: I want to expand on something that
23 Cathy Haney mentioned before. The main purpose of this
24 presentation is not showing that the very structure of the
25 implementation plan and then had it to the agreement state

1 or stakeholders to make comments.

2 What we are presenting here is in the first stages
3 of the development, we will have their inputs, how are we
4 going to have their input and comments, it's by information
5 technology. We are going to create a Part 35 web site in
6 our home page. The Office of State Programs also has a web
7 page which will be linked to that, so we will have comment
8 from agreement states coming through the agreement state
9 home page and it will be linked to our main home page.

10 One of the tools that we are going to use and that
11 I, when I was a licensee, found very effective, it's having
12 a very simple table explaining what was the old Part 35
13 versus the revised Part 35, what are the changes. So one
14 can quickly forward through the table and find out if a
15 change will affect your radiation safety program.

16 Also, like many web pages have today, there will
17 be a question of frequently answered questions, and we
18 agreement state people, licensees, stakeholders, will
19 provide -- will make questions or comments on to this web
20 page and NRC/NMSS, Nuclear Materials Safety and Safeguards
21 Office, will provide a monthly answer to these questions.

22 We can also in that web page and we will have a
23 scheduled videoconference. We are going to explore this
24 technology at the most and this is nothing new, but we in
25 NRC, we have computerized self-study for -- to train our

1 personnel. We can also train other personnel outside the
2 agency, and this can be developed with different topics in
3 mind and we have found this a very useful tool.

4 Our proposed training schedule is the headquarters
5 staff, cognizant staff will be trained in January, sometime
6 during January, and the agreement state personnel and the
7 NRC regions will be trained something late February, early
8 March 2001.

9 MS. HANEY: And realize, with what Roberto is
10 saying, with some of these training, this is our initial
11 thinking, as he had said. We really have not gotten the
12 opportunity to discuss with the agreement states and OAS
13 about how does this fit.

14 And if we did the training, kind of what we're
15 using as a baseline model, which is what we did with Part 20
16 when it was revised back in early '90, is we did training
17 for all of the NRC offices and then if there was -- we
18 usually had them in large conference rooms. If the states
19 wanted to come, they could, they were welcome to come.

20 But a lot of this is just early thinking and
21 before any of this would become finalized, we would spend
22 considerable time talking to OAS and CRCPD about how do they
23 want to get involved and what works for them, because this
24 type of formal training may not be what's most advantageous.

25 DR. CERQUERIA: Is there an OAS contact person who

1 is sort of doing this?

2 MS. HANEY: What we have, and anybody from State
3 Programs that's behind me wants to chime in, we do have --
4 there is a board of directors for the Organization of
5 Agreement States and we have Paul Lohaus, which is the
6 Office Director from the Office of State and Tribal
7 Programs, is the lead NRC individual responsible for
8 coordinating with OAS.

9 So usually what we do is we have these weekly
10 conference calls, where you have the board on the telephone
11 and then you have Paul definitely, but then the other
12 cognizant staff.

13 So there's a lot of exchange during this and then
14 the information filters out from those different
15 organizations.

16 Also, there is an annual meeting with the
17 Organization of Agreement States, where -- similar to this,
18 where you have all the states, but we make formal
19 presentations to them. So we are working very closely
20 with agreement states.

21 DR. CERQUERIA: Yes. I think it would be very
22 important to get them involved. The last thing they will
23 accept is something which we have put together, the NRC
24 staff, and then sent to them. I know there's a lot of
25 issues in here, but, again, I think it's important to get it

1 straightened out.

2 MR. TORRES: As Cathy mentioned, this is an
3 initial training. We envision that once we get the input
4 from the licensees and the stakeholders and agreement
5 states, we will retrain our personnel before the final rule
6 goes out.

7 The regions will be in charge of coordinating a
8 workshop with the stakeholders, agreement states, licensees,
9 and we foresee that they will have to do that in the window
10 period that Tommy was talking about before, sometime between
11 February 2001 and August-September 2001.

12 Also, Cathy mentioned that agreement states will
13 have a three-year period for implementing this rule, so we
14 foresee that we will have to train them, give additional
15 training to them after 2001.

16 Internally, NMSS will have to revise our
17 inspection procedures, management directives. Our technical
18 training center in Chattanooga will have to review the
19 manuals and we have a nuclear material safety, nuclear
20 material event database, known as NMED. NMED will have to
21 be reviewed, because we have to change the event type, the
22 classification and reporting criteria according to the
23 revised Part 35.

24 And the NUREG-1556 series was issued this year,
25 the series, consolidated guidance about material license.

1 And this is the --

2 DR. WILLIAMSON: Excuse me. Could I ask a
3 question? What is the status of the regulatory guide that
4 accompanies the revised Part 35?

5 DR. CERQUERIA: Cathy?

6 MS. HANEY: It will come out at the same time as
7 the rule does. There are certain corresponding changes,
8 like minor word tweaks that we need to make in the NUREG
9 document. It actually -- and if you want to see the last
10 version of that NUREG, it's attached to that SECY-00-118.
11 So that's about 90 percent there, also.

12 But that's the last one. We just need to make
13 some changes, put it through the editors and all of that
14 sort of stuff, and then it will be set to go at the same
15 time that the rule is published in the Federal Register.

16 So what we're really -- and that is what we're
17 really striving for, so that when the rule hits, the
18 guidance is there, also.

19 I'll do my pitch here, but realize that is
20 guidance and there are no requirements in the -- there are
21 no de facto requirements in that guidance document.

22 DR. WILLIAMSON: But I think it's an essential
23 element for people --

24 MS. HANEY: Oh, definitely.

25 DR. WILLIAMSON: -- to do a detailed

1 implementation of the program. They will look to that for a
2 lot of suggestions and further --

3 MS. HANEY: Exactly.

4 DR. WILLIAMSON: -- explanation about what the
5 regulations mean.

6 MS. HANEY: Right. And that's why at the same
7 time, we're trying to get them issued at the same time.

8 MR. TORRES: And this is the last slide of my
9 presentation and I want to leave the committee with this
10 idea, with this question, how can we -- how can you best
11 communicate -- how can we best communicate our message to
12 your clientele, what input comments can you provide us, so
13 we can start to incorporate those in our implementation plan
14 of revised Part 35.

15 Thank you very much.

16 DR. CERQUERIA: Thank you very much for a really
17 focused -- if we could get the lights up and let's try to
18 answer that last question. Neomi, what, in terms of the
19 nuclear medicine community?

20 DR. ALAZRAKI: I think at the annual meeting,
21 there should be one of your presentations. I think it
22 should go out in the Newline, which is part of the Journal
23 of Nuclear Medicine, as an important article. I think that
24 the leadership of the nuclear medicine ought to be informed
25 of the details and then they can further implement other

1 ways of disseminating the information and maybe make some
2 other recommendations directly to the NRC, to you.

3 But I think it has to be a very multimedia type of
4 approach in terms of reaching, because everyone has to be
5 reached by this. Everyone must know about it and I think
6 you have to do everything available, use all modalities of
7 media available to let everyone know.

8 DR. CERQUERIA: So some practical things, getting
9 information to the professional societies so they can get
10 them into their journals, either as news items, and it
11 probably would be worthwhile to just contact them and let
12 them know and then provide a contact person here who could
13 provide that information.

14 DR. ALAZRAKI: And the same to the diagnostic
15 radiology community and, of course, to all of these
16 communities and at all of their major meetings.

17 DR. CERQUERIA: So certainly all of the
18 professional medical societies that have sent letters and
19 comments to Part 35 revisions should be contacted. The
20 boards that are applying for recertification should be
21 contacted. And the ability to provide written information
22 that could be incorporated into newsletters would be
23 important, and attending the national meetings would be very
24 worthwhile.

25 The radiation oncology community?

1 DR. DIAMOND: Yes. I think we can do it rather
2 efficiently. We, in ASTRO, have an electronic notification
3 system, ASTROgrams, which go out periodically, reach a large
4 number of individuals. We could publish the relevant
5 information in brief form in our official journal, which is
6 read by a very large proportion of our practitioners.

7 We could have inserts in the American College of
8 Radiation Oncology bulletin that is put out periodically.
9 We can certainly invite members of the staff to address our
10 societies at our meetings. We have a large meeting held
11 each fall and a smaller meeting held each spring.

12 So I believe we can do it rather efficiently. I
13 think many questions from the membership will revolve about
14 the issues that you raise in regard to the agreement states,
15 as we're trying to get a sense of how the agreement states
16 are moving, to what level of compatibility and what
17 timeframe, I think that will generate, by far, the largest
18 number of inquiries.

19 DR. CERQUERIA: Good. John, how do we contact
20 administrators at hospitals?

21 MR. GRAHAM: I think, stepping back a little bit,
22 the communication plan, in general, in most of the
23 discussion we've had so far, is presentations at national
24 meetings. The difficulty of that is in like any mandatory
25 communication plan, the people that come to the meetings are

1 the people that are most engaged, they're the people that
2 probably know it's underway already.

3 So the key is you've got to be able to identify
4 what your communication plan is to get it out to the guy who
5 is in Podunk that still has responsibility for this, that he
6 hasn't attended an annual meeting of his group in years, and
7 yet he has to be aware of the change that's occurring.

8 But even before that, I think that -- I assume
9 that you have, in your staff discussions, had some review of
10 the opportunity that this represents to communicate the
11 direction that the NRC is trying to go in, or I would
12 encourage that how you spin this will be as important as any
13 of the content in here.

14 So to the extent that you introduce this and link
15 it to the goals of the NRC and focus on increasing public
16 confidence, so that there is less confusion about who is
17 going to die from what we do with any nuclear substance
18 tomorrow, and reducing the unnecessary regulatory burden, if
19 you put it in context, and, frankly, without getting
20 adversarial, I'd go so far as to tie it to the review that
21 occurred with the advisory committee and even identify the
22 areas where the balance of public safety was outweighed in
23 the eyes of the Commission compared to the advisory
24 committee's recommendation.

25 The credibility of this group long-term and the

1 ease with which its implemented will be affected by whether
2 they think they had a voice at the table. This group
3 represents the primary voice at the table, but the
4 credibility of these people into the future is that they're
5 not simply saying, oh, well, you approved this thing, which
6 is really why are you having us go back and tell the
7 patient, when we all know the patient is just going to get
8 jacked out of shape and you should have deleted that.

9 So I think there is, again, an opportunity, if you
10 spin this, that there was a group that had broad
11 representation that recommended certain changes that, in the
12 opinion of the Commission, simply didn't cover the public
13 patient safety, and yet it does represent the best balance
14 that could be achieved.

15 I would come back and hammer the spin that this is
16 an intent to reduce regulation, to reduce the amount of
17 documentation, to make it more performance-based, to make it
18 less prescriptive, and then you're going to have to use
19 every -- I assume you're going to have a written document at
20 the end of the day that goes to every licensee.

21 That's the only way you're going to assure that,
22 again, the person out in Podunk who never attends a
23 professional meeting, who has ignored all of this, will --

24 MS. HANEY: We'll do a mass mailing of the Federal
25 Register notice and the guidance document.

1 DR. CERQUERIA: But I think John's point about the spin and,
2 also, the way it's presented, when you get something this
3 thick, people aren't going to go through it. So you almost
4 need an executive summary that really hits some of these
5 high points, the risk-based performance.

6 MR. GRAHAM: Otherwise, it just looks like, oh,
7 great, here's a new set of Federal regs.

8 DR. CERQUERIA: This isn't dealing with the
9 problem. It's basically trying to reduce the amount of
10 bureaucracy that exists. I think those are important
11 things.

12 Niki, from the perspective of the consumer?

13 MS. HOBSON: Obviously, the consumer is not going
14 to be part of the implementation. That's really the medical
15 community and the regulatory community. It might be
16 worthwhile just to put out some general information to, for
17 instance, cancer support groups, like the American Cancer
18 Society, that some revisions have been made that will affect
19 patients' rights.

20 I don't know that I would go into a lot of great
21 detail on that, but at least let them know, if they're
22 interested, that there have been some changes.

23 DR. CERQUERIA: But actually go to these
24 organizations of patient support groups.

25 MS. HOBSON: I think the support organizations,

1 cancer patients, obviously, are beneficiaries of the
2 services covered by Part 35, but there are probably other
3 patient groups, maybe to a lesser extent, that would benefit
4 from at least knowing it's been done. The deed has been
5 done.

6 DR. ALAZRAKI: Every patient group is affected by
7 this, because almost every segment of the patient population
8 at one time or another during his or her health care
9 encounters radiation, almost all.

10 DR. MCBURNEY: Is there an organization of patient
11 rights advocates from the hospitals? Are they organized in
12 any way, do you know, John?

13 MR. GRAHAM: Not that I'm aware of.

14 DR. CERQUERIA: I mean, each hospital has one, but
15 I'm not aware of any kind of --

16 MR. GRAHAM: I don't think there is any
17 interconnectivity, no.

18 DR. CERQUERIA: Any input to the FDA that is
19 necessary on this?

20 MR. LEEDHAM: I know that when we have major
21 changes in our regulations, we have workshops on a local
22 basis. Also, at the different centers, when we have a new
23 initiative that goes on, usually on a regional basis, we
24 have points of contact, versus everything coming here to
25 Rockville.

1 So that might be one way of doing it, where you
2 had outreach teams in each one of the regions.

3 DR. CERQUERIA: Let me get from Niki -- from Ruth,
4 any -- again, the agreement state implementation I think is
5 still going to be a major hurdle, and anything that you
6 could contribute would be important.

7 DR. McBURNEY: The work of getting information to
8 the agreement states, and the agreement states are all fully
9 aware of what is going on with Part 35 and actually
10 participated on the working group and the steering committee
11 for its development.

12 But I think that the point of the joint-regional
13 training workshops and having the states join in with the
14 NRC at the regions when that goes on will be beneficial.

15 Also, something Dr. Diamond said, brought up,
16 touched on trying to find out how soon the agreement states
17 plan to implement the provisions of Part 35. We can
18 probably work through the Organization of Agreement States
19 and do a survey of what the states plan to do and how soon
20 they plan to implement that.

21 DR. CERQUERIA: Something like that, certainly for our
22 members, the organizations we represent, would be very, very
23 helpful to at least get them some idea of where there is
24 going to be complete compliance and what timeline. That
25 would be important.

1 DR. McBURNEY: And the agreement states also have
2 an e-mail service, we call RADRAP, where we can exchange
3 information and even though frequently asked questions may
4 be put on the web site, some of the more infrequently asked
5 questions, we can go back and forth with this e-mail
6 service.

7 DR. CERQUERIA: That definitely would be
8 worthwhile.

9 DR. NAG: A couple of points. First of all, I
10 think many of the points made here we all good. I want to
11 know how much staff the NRC has, because if you are going to
12 go to every sub-specialty, that is going to require a lot of
13 staffing.

14 One thing you may want to think about, and this is
15 something worth discussing, let's say for each
16 sub-specialty, you don't need to explain everything. You
17 want to tell them the part that is relevant to them. Can
18 some of that be delegated or you have training from
19 individuals from that sub-specialty who can then go back and
20 explain to their sub-specialty specifically about that part.
21 That is one maybe that will help you out.

22 The other, if you are going put it in journals,
23 there are two definition kinds. You have the newsletters,
24 where you do not have peer review, and basically this is so
25 important, you can have those go out immediately.

1 You also have the peer review journals, which if
2 you are putting an article, it has to go through peer review
3 and that takes a longer time. You may want to directly
4 contact the editor of that journal and see if instead of
5 going through peer review, it can bypass that and go like an
6 editorial.

7 And if you were to have four or five different
8 versions, one for the radiation oncology, one for the
9 diagnostic journal and so forth, that can go in a lot faster
10 than trying to go to a peer review publication.

11 DR. CERQUERIA: I think that definitely would --
12 let's sort of go around the table and then we'll come back.
13 Sally, any comments from the radiopharmacy?

14 MS. SCHWARZ: I think probably the groups that are
15 interested would be the American Pharmaceutical Association
16 and the American Society of Hospital Pharmacists, as well.
17 They have web site availability. There's a lot of
18 individuals in education and certainly I think that there
19 would be an annual meeting, also web site information.

20 DR. CERQUERIA: So it seems like all of our
21 organizations have the same sort of capability and I think,
22 Roberto, what you and the NRC staff are going to need to do
23 is identify the right contact people and then sort of
24 initiate it.

25 Jeffrey?

1 DR. WILLIAMSON: I think all of what has been said
2 is very good and useful, the idea of sort of promoting
3 general knowledge in the community of the new regulations.
4 But I think the major point seems to have been missed here.

5 It's that the people who are responsible for
6 implementing this are the radiation safety officers and the
7 radiation safety committees in each institution, and I think
8 the success of the program, of implementation, is going to
9 depend on the interactive communication you set up with that
10 very select targeted audience.

11 So I would suggest that you put more effort into
12 working with those individuals. I think -- you know, I can
13 assure you, Washington University, with its radiation safety
14 staff, will be on top of it and I think maybe the licensees
15 of concern are those that are smaller and may not have a
16 professional health physicist as their RSO.

17 So you might want to figure out some sort of a
18 prioritization scheme based upon the probability that an
19 institution might not implement the new regulation or be
20 aware of all of the provisions.

21 So I would suggest approaching it, to some extent,
22 from that direction. That's one general comment, for all
23 specialties.

24 I think something that could be done to be very
25 helpful would be to put all this stuff together in a nice

1 packet, the statements of consideration, the Part 35 text
2 itself, the regulatory guide, in a nice, big binder, and I
3 think all of the societies, I know the AAPM would be willing
4 to sort of send a member-wide notice out and create a system
5 whereby this could easily be ordered by any individual who
6 wanted all of the documents assembled in an orderly fashion.

7 So I think that's one thing that would help.

8 DR. CERQUERIA: That would take care of filling
9 the landfills, but I think perhaps some summaries would
10 definitely -- that could be easily extracted and sent out to
11 people would be appropriate.

12 DR. WILLIAMSON: I wasn't suggesting send it to
13 everybody, but creating a mechanism where those who wanted
14 it and who would be responsible for implementation, which
15 usually physicists are, would be able to get the information
16 in a --

17 DR. CERQUERIA: Good point.

18 DR. WILLIAMSON: -- in an orderly form. I don't
19 think it would be a good idea to send a big binder out to
20 everybody. That wasn't the intent.

21 The other thing I would suggest with respect to
22 the agreement states is to the extent that this can be sold
23 as an improvement, a regulatory relief over the existing
24 suggested state regulations, the local AAPM chapters and
25 other professional groups could perhaps turn the heat up on

1 their sort of state legislative organizations and maybe be
2 advocates in trying to get some of this accomplished,
3 because I think it's going to be very highly variable, I
4 think, at the state, individual state levels, how rapidly or
5 quickly this can be passed or how much --

6 DR. CERQUERIA: Those are very good points.

7 DR. WILLIAMSON: -- there's going to be by
8 different regulatory agencies, state regulatory agencies.

9 DR. MCBURNEY: The suggested state regulations are
10 being developed along in parallel with this. So they should
11 be coming out in the same --

12 DR. CERQUERIA: Let's hear from --

13 DR. WILLIAMSON: But I think every state does not

14 --

15 DR. CERQUERIA: Let's hear from the radiation
16 safety committee aspect.

17 DR. VETTER: Yes. What will radiation safety
18 officers read? I would like to underscore something John
19 Graham said. I think you need to start with development of
20 a very strong communications plan, and you've got experts in
21 the agency that can help you with that. And then relative
22 to -- and in that plan, you will incorporate, of course, all
23 these things that were mentioned.

24 One of the primary routes of communication will be
25 the link to your web site, to the Part 35 web site that

1 Roberto was talking about, that would contain all this
2 information. So most of us don't have to receive it in the
3 mail. We can go get what we want.

4 I would recommend that you very specifically
5 identify that, though. There's a lot of good stuff at the
6 NRC web site that's just hard to find. So just make sure
7 it's highlighted.

8 Then relative to reaching the RSOs, there are
9 several organizations that they communicate through or with,
10 and I can get you a list of those, like Health Physics
11 Society, AAPM, the American College of Medical Physics,
12 American Academy of Health Physics, those kinds of things,
13 and we can get you those web sites, where they could
14 actually simply communicate to their people and put the link
15 right on their page, and that makes your job easy.

16 DR. CERQUERIA: Plus, they could even download
17 some of this material, so you don't need the hard copy.

18 DR. VETTER: They can download the portion they
19 want. They don't have to have the whole thing.

20 MS. HANEY: One other thing, too, that I have seen
21 happening over the last couple of years is that as different
22 individuals in the professional societies become aware of
23 Part 35, they go out and do presentations at their local
24 chapters.

25 So now I'm feeding it back to you guys, you all

1 are familiar with Part 35, and I'm sure you're all involved
2 with the local chapters or national chapters of your
3 professional societies, going out and you making the
4 presentations, because Dr. Nag is right. We do have limited
5 resources here.

6 There will be some devoted staff at headquarters
7 that are working on implementation and we do plan to use our
8 regional staff and they will be out there and they also are
9 involved like with health physics, I can speak from that.

10 A lot of inspectors hold positions in the HP, the
11 local HPS chapters, and they have done presentations.

12 And with that in line, as you have your associates
13 going out to make the presentations, we're happy to supply
14 material. I've done that in the past, a lot with, I think,
15 HPS and Society of Nuclear Medicine, where I've had one of
16 the physicists contact me and say I'm making a presentation,
17 can you help me.

18 So I think it's -- you know, we'd be looking to
19 you also helping.

20 DR. VETTER: Could you put together a PowerPoint
21 presentation that we can download?

22 MS. HANEY: I'm sure that we could do something
23 like that.

24 DR. VETTER: That would be great.

25 DR. CERQUERIA: That would be good. Lou, I didn't

1 mean to skip over you as we went around here.

2 DR. WAGNER: Not a problem. I think the things
3 that I've seen here are that one of the most important
4 things you need is a user-friendly web site referring to the
5 regulations, so that you have a search engine that can look
6 at the Part 35 and say, okay, I want to see what you say
7 about brachytherapy or I want to see what you're saying
8 about wipe tests, I want to see what you're saying about
9 this.

10 So that those things can be referenced easily for
11 a very user-friendly aspect to see how things have changed
12 relative to the interests of specific users.

13 And the web site, to me, is the absolute ideal
14 place to have all the information and the ideal means of
15 communication now, bulk storage almost everybody has it and
16 everybody is getting used to using it. If it's
17 user-friendly, it's really important.

18 I guess that's about all I have to say.

19 DR. CERQUERIA: This has all -- I think, you know,
20 we've given you a lot of input, but I would like to go on to
21 the next topic. I know people want to make other comments,
22 but perhaps you could talk to Roberto afterwards.

23 But there's a lot of stuff that was thrown out and
24 you're going to have to select what you grab onto, but I
25 think you've got enough ideas.

1 Thank you very much.

2 Then we'll move on to the next agenda item, which
3 is the status update on NRC's new process to recognizes
4 certification boards, and Sam Jones and Bob Ayres.

5 MR. GRAHAM: While they are getting set up, just
6 to come back on a comment Cathy made, that states have the
7 opportunity to establish regulations that are more
8 restrictive than what is in this guideline. The whole
9 intent was to reduce unnecessary regulatory burden.

10 I know this is almost a shift in paradigm. Can't
11 the directive go out that it is the same or less onerous?

12 DR. CERQUERIA: A tough issue.

13 MR. GRAHAM: I understand that. I will just go on
14 record saying that was kind of the goal we were trying to
15 get to here.

16 DR. MCBURNEY: There are different levels of
17 compatibility for each of the rules and for the ones that
18 cross state lines, the training issues and so forth, it's
19 got to be essentially the same.

20 In some of the areas where it's more of a local
21 site by site thing, then the states, the NRC assigns a level
22 of compatibility in which the states can be more restrictive
23 or have something a little different, because it's not all
24 the same level of compatibility.

25 DR. CERQUERIA: Right. Basically, it has to be at

1 least as restrictive as the NRC, but it can be more.
2 They've got up to three years to make the decision and if
3 they don't, there really is no enforcement mechanism from
4 the NRC on the states to make them comply.

5 DR. MCBURNEY: Yes, there is. Paul?

6 DR. CERQUERIA: Paul, if you could introduce
7 yourself.

8 MR. LOHAUS: I'm Paul Lohaus. I'm Director for
9 the Office of State and Tribal Programs.

10 Ruth is correct in terms of talking what our
11 policy provides. What we did about three years ago is
12 developed a new policy which defines adequacy and
13 compatibility, which are the two areas that we use in
14 judging the state programs under our Atomic Energy Act
15 authority, and, at the same time, we developed a set of
16 implementing procedures.

17 And what those procedures provide is, as Ruth
18 talked through, are varying levels of compatibility and in
19 some cases, where there are trans-boundary implications or
20 where the activities of one state or NRC have a big impact
21 on the activities in another state or at NRC, those areas
22 need to be -- we use the term -- essentially identical.

23 They basically have to be identical. There may be
24 some minor differences in wording due to state preferences
25 in their administrative laws, but the context and the

1 wording of the regulation need to be identical.

2 Transportation, for example, is one, sealed source
3 and devices, the training and experience requirements in
4 Part 35 is another that had been identified as a category B.
5 This is one that it has to be essentially identical.

6 But as Ruth noted, there are other categories.
7 Category C means that a state has to adopt the essential
8 objectives of the NRC regulation. It may be worded
9 differently, but the intent of the regulation and the
10 actions that would be required by a licensee, the same
11 action would need to be taken in the agreement state as in
12 NRC's jurisdiction under that requirement.

13 That's really sort of the test, if you will, for
14 Category C. That does allow, though, the states to be more
15 restrictive for some of the standards. So they could have a
16 requirement that's more restrictive, but the standard is
17 really that the actions are going to be basically
18 equivalent. That's what we use as our standard in that.

19 Now, in terms of implementation, under the policy,
20 the states have three years to adopt a compatible rule.
21 Some will do it sooner than that, but that's what we use as
22 guidance.

23 We do review each draft in final state regulation.
24 We provide comments to the states relative to whether
25 they're in line with the policy and the implementing

1 procedures, and we also have a program for reviewing state
2 programs. It's called the integrated materials performance
3 evaluation program.

4 And through that program, we look at the statutes
5 and the regulations, along with the licensing inspection
6 process, and do make judgments relative to compatibility and
7 adequacy of the program. So there is a review process that
8 we use, as well.

9 DR. CERQUERIA: From the user community, what
10 unfortunately may sometimes happen is if someone is
11 practicing in Virginia, which is NRC-regulated, and then
12 they decide they're going to practice in Maryland, right
13 across the line, they can be licensed in one state,
14 potentially, the NRC state, but not in the agreement state,
15 and that's going to create quite a bit of controversy for
16 training programs.

17 Now, do these people have an appeal process? I
18 mean, can they appeal to, say, the NRC or to this committee
19 if they're basically -- if the agreement state requirement
20 -- if they're allowed to practice in one state and the meet
21 the NRC requirements, but then they don't meet the agreement
22 state requirements, do they have an appeal process?

23 MR. LOHAUS: I'm not certain I fully understand
24 the context of the question.

25 DR. CERQUERIA: Training and experience for an

1 authorized physician user can be gotten in several ways and
2 what can be held in an NRC state and what can be required
3 and is currently required in some agreement state is
4 different.

5 So that somebody qualifies for an NRC license, but
6 may not be allowed to operate as an authorized user in an
7 agreement state.

8 MR. LOHAUS: Under the current set of rules and
9 during the three-year period, there will be differences.
10 The states have existing requirements and until they amend
11 their requirements and adopt a compatible rule, there may be
12 some differences.

13 But the goal would be, under the levels of
14 compatibility, is that when the states complete their rule
15 adoption process, the states should have rules that are
16 compatible with NRC's rules.

17 Now, that's not to say, however, that a state or a
18 few states may adopt regulations or rules in this area that
19 may be different than NRC's and if that occurs, there's
20 really two parts in the process.

21 There is no appeal process, that I'm aware of, but
22 there are two steps in the process. One is we would review
23 the regulations and we would provide comments to the state
24 that the rules are not compatible and we would identify the
25 changes that would be necessary to make those rules

1 compatible.

2 If the state chooses to adopt a rule that is not
3 compatible, there is a second step in the process, which is
4 our review program and as a part of the review program, that
5 would be identified as a rule that is out of line, if you
6 will, with the compatibility policy.

7 Now, whether that individual rule would be a
8 sufficient basis to affect the entire program is a different
9 question and that question, the process -- just very
10 quickly, there's a senior level board of NRC managers, which
11 also includes an agreement state liaison manager, which
12 actually makes the determination for each state program
13 review under IMPEP, and that would be a question and an
14 issue that that board would address as a part of the overall
15 finding coming out of the review program for that particular
16 state program.

17 So there is a process and there is a review
18 process and there's a board that would make that
19 determination, but I'm not aware that there would be any
20 appeal process, let's say, for an individual licensee within
21 an agreement state.

22 And the reason I'm saying that is if you look at
23 our program, our program is different than a Federal
24 delegation program under the legislation. Actually, NRC
25 gives up regulatory authority and the state assumes

1 regulatory authority under state statutes and regulations
2 and they operate their own program. They do their licensing
3 under state statutes and it's not a delegation.

4 So from that standpoint, what rules the state has
5 and what legislation they have, that's the basis for the
6 program. One of our jobs, though, is to ensure that if you
7 look at this nationally, there is harmony, there is
8 consistency, there is not wide variation, there's not --

9 DR. CERQUERIA: But if you can't enforce it, then
10 you've got 21 NRC states and 29 agreement states, so you
11 basically can have 30 different policies.

12 So we should probably go on with the agenda,
13 unless anybody has a burning question.

14 MR. LOHAUS: I guess I'd like to say that we can
15 enforce it, but there are going to be degrees and a single
16 regulation or a single rule section may not be of sufficient
17 significance and compatibility, in the compatibility area to
18 rise to a point where we would find a program not
19 compatible.

20 And if we found a program not compatible, then
21 there are certain actions that we take, which could lead all
22 the way up to reasserting authority, if you will.

23 DR. WAGNER: I'm a little confused. When you talk
24 about compatibility, you're talking about being less
25 restrictive, not more restrictive. Is that correct? Or are

1 you talking about more restrictive, also.
2 DR. McBURNEY: It depends on the level.
3 MR. LOHAUS: It depends on the level of
4 compatibility.
5 DR. WILLIAMSON: The level.
6 MR. LOHAUS: Yes.
7 DR. WILLIAMSON: If it's A or B, it can't be more
8 restrictive, isn't that correct?
9 DR. McBURNEY: That's correct.
10 MR. LOHAUS: That's correct, yes.
11 DR. WILLIAMSON: And just so everyone understands,
12 the training and experience requirements are level B.
13 MR. LOHAUS: That's correct. They could not be
14 more restrictive, under the designation that's been
15 assigned.
16 DR. CERQUERIA: Is that true?
17 MS. HANEY: Under the -- yes, that's true.
18 DR. CERQUERIA: It cannot be more restrictive.
19 MS. HANEY: In training.
20 MR. LOHAUS: That's correct.
21 MS. HANEY: But realize there is that three-year
22 gap where we could have differences.
23 MR. LOHAUS: I apologize. I talked about the
24 category C, which is a different level, but some of the
25 requirements are category C, but training and experience is

1 a category B, which has to be essentially identical. They
2 cannot be more restrictive.

3 DR. NAG: Now, that brings up a second question.
4 You say category B can't be more restrictive, it can't be
5 less restrictive.

6 So if --

7 MR. LOHAUS: Neither. It can be neither.

8 DR. CERQUERIA: Well, thank you very much. It's
9 very useful. We should go on.

10 MR. AYRES: I would make a quick comment. Some of
11 you may have missed it, but I passed out the definitions of
12 compatibility levels in the earlier package this morning,
13 off of the state program web site. They're in that earlier
14 package this morning.

15 DR. CERQUERIA: Great. Mr. Jones, Mr. Ayres, if
16 we could hear about the board process.

17 MR. JONES: I'm going to give you an overview of
18 NRC's new process regarding recognizing boards.

19 I'll be going over the first four bullets up here
20 and Dr. Ayres will go over the last bullet. The last bullet
21 will get into actual implementation questions that's come in
22 from the boards.

23 I know, Dr. Nag, you have a question and will
24 address it now regarding the T&E. So we really want to get
25 the ACMUI input on these questions that's come in from the

1 boards. So I will go rather quickly through the first four
2 to allow Dr. Ayres time.

3 The NRC sent letters out to the boards on June 22,
4 2000, to these boards here. All of these boards are
5 currently listed in Part 35.

6 The letters informed the existing boards that are
7 listed in the regulations that NRC intended to change its
8 process -- first of all, that the regulations in the revised
9 rule would no longer list specific boards.

10 Therefore, if they wanted to be listed, they would
11 have to specifically come in to NRC and request for
12 recognition. And we say that we intended to start this
13 process immediately and we laid out what they needed to do
14 to be recognized.

15 In this letter, we sent the draft final rule language to the
16 boards, so they could review it and determine which areas of
17 the regulations they wanted to be recognized.

18 In addition to the letters to the boards, we also
19 have a Federal Register notice that was published November
20 the 2nd, which essentially says the same thing the boards'
21 letters say.

22 And once we determine that we're going to
23 recognize a board, we're going to set up a web site, the NRC
24 web site, and it will have all the boards that NRC
25 recognizes on that web site.

1 The responses that we received from the letters
2 that we sent to the boards, two boards have come in and said
3 that they would like to be recognized by the NRC as meeting
4 the training and experience requirements in the draft final
5 rule, and they were the American Board of Nuclear Medicine
6 and the Board of Pharmaceutical Specialties.

7 The American Board of Nuclear Medicine is
8 requesting recognition for essentially 35.190, 290, 390, 392
9 and 394, essentially all of the unsealed categories. And we
10 would like to know basically if the ACMUI has any comments
11 on this request for recognition.

12 DR. CERQUERIA: So are you asking for approval of

13 --

14 MR. JONES: No, we're not asking for approval.
15 We're just asking if you have any comments regarding this
16 board and NRC recognizing all these training and experience
17 requirements.

18 MS. HANEY: Let me back up with just a little bit
19 of information. How we're handling the board recognition is
20 almost a self-certification sort of process. Over the last
21 three years, we've talked a lot about what we're going to
22 look at and what we need and what level NRC should get
23 involved, and the decision was made that we would really go
24 with just the boards giving a self-certification that in
25 order to sit for that board, that you would have at least

1 had the training equivalence of what we call the alternative
2 pathway.

3 So just to use the American Board of Nuclear
4 Medicine as an example, in this case, by them coming in with
5 this letter and asking for recognition under these
6 particular items and with it being signed by a
7 representative of the organization, what they are telling us
8 is that if they had an individual that sat for one of their
9 boards and was certified, that that individual would have
10 had the training in each one of these categories.

11 So for example, under 290, the individual would
12 have at least had 700 hours of training of clinical or
13 experience and didactic training and that they were
14 obviously a physician and that there was a preceptorship
15 involved and the preceptor is saying when they nominate the
16 -- when they get to the point of taking the board, that from
17 the preceptor's opinion, that this individual is capable of
18 functioning as an authorized user for use of unsealed
19 materials for diagnostic.

20 And you can use a similar example in whether it's
21 392 or 394, when we get into the therapy areas, which we
22 won't get today.

23 But that's what's behind this. That's what that
24 means. One of the things that we did put in the statements
25 of consideration for the rule is that as these boards came

1 up, we would discuss it with the ACMUI. So we are not
2 asking for a formal recommendation from the committee. This
3 is merely part of our exchange of information between NRC
4 staff and the ACMUI and if -- and we're working through
5 this.

6 I mean, this is a kickoff for us, also, that if
7 there are things that you need to -- we should be thinking
8 about, that's what we're looking for by this presentation.

9 DR. CERQUERIA: So do they provide a list of the
10 eligibility requirements for the people?

11 MS. HANEY: No. We did not ask for that. We are
12 going -- it's strictly the self-certification and we are
13 assuming that Dr. van Heerdom, when he sent that letter in,
14 that the organization has done that and in good faith, they
15 believe that their requirements, eligibility requirements
16 meet the alternative pathway.

17 MR. JONES: It is pretty much a
18 self-certification. I mean, the Federal Register notice has
19 the regulations in there, they read the regulations,
20 determine which section of the regulations that they want
21 their board to be recognized in, and essentially send us a
22 letter back stating that and have it dated and signed.

23 DR. NAG: There are two components to the therapy
24 part. One is administration of the radionuclide, which you
25 have training of X hours and you can administer the

1 radionuclides.

2 The second component is the training of the
3 disease process and I'm wondering when we made this
4 regulation or drafted the regulation, do you take into
5 account that a person can take different conditions, a
6 radiation oncologist can prescribe, that yet this person
7 needs this therapy and then a nuclear -- someone who has had
8 training in the delivery of the unsealed sources can deliver
9 that, whereas you can take it another way, that the same
10 person who had been certified can also diagnose, as well as
11 deliver the isotope.

12 I mean, are these two processes taken separately
13 or how do you implement? It's mainly a clarification. How
14 do you implement this?

15 MS. HANEY: From NRC's standpoint, we are only
16 focusing on the safe handling of the material. We are not
17 -- we do not want to cross into the bounds of is this the
18 right treatment for this patient. We're staying apart from
19 that. It was fairly easy over the last three years to focus
20 on radiation safety for the unsealed uses and that's why the
21 requirements are -- if you look at the diagnostic versus
22 therapeutic.

23 You see a different approach and a way to handling
24 them. When we ran into the oncology area, it became very
25 hard to separate clinical competency and radiation safety.

1 So there is -- you know, one could argue that
2 maybe we're right in the gray zone there when you look at
3 the requirements for an oncologist, but it would seem that
4 you just couldn't separate them in this area. In the
5 diagnostic area, it was a little bit easier to do that.
6 So the questions that you're asking are really -- the
7 answers are inherent in the rule text right now, how we've
8 decided what the appropriate requirements are for the user.

9 DR. CERQUERIA: We basically tried to take the
10 radiation safety, which is what this committee and the NRC
11 is dealing with from the practice of medicine, which is some
12 of the decisions about which test is appropriate for --
13 although some of that is implicit in the training, but it's
14 certainly medical practices.

15 Dr. Alazraki, did you have a comment?

16 DR. ALAZRAKI: Yes. Well, I think it's pretty
17 obvious. If you look at the ABNM requirements, to sit for
18 their exam, they exceed by something like 30 times the
19 requirements that the NRC has. So there's no discussion
20 here, I don't think, on this.

21 DR. CERQUERIA: Good. Lou?

22 DR. WAGNER: The only comment I would make is that
23 you could have a circumstance where boards sometimes change
24 their requirements. They're not exactly fixed one day and
25 then in perpetuity. They can change.

1 Do you have any ideas on how often they should
2 renew these statements? Are we going to renew them every
3 five years, every ten years or every year or every month or
4 what?

5 MS. HANEY: I guess I hadn't really though -- I
6 can't the use we haven't thought, but I haven't really
7 thought about that.

8 I would say, I mean, it's a good point and we
9 probably, as part of this implementation plan, come up with
10 some type of idea of how frequently. I would think at no
11 more frequently than two years, but I think that's where you
12 all who are dealing more with the boards and how they change
13 their eligibility requirements more than I am, is two years
14 good, is five years.

15 DR. WAGNER: That would be fine with me. I don't
16 think it's a big deal, but it's a matter that -- of course,
17 the major boards, they're not going to have any problem, but
18 some of the -- we don't know exactly how this process is
19 going to go, but you may come up with some minor boards who
20 don't meet these criteria or might change their criteria
21 over time and you've got to be careful about that.

22 MS. HANEY: I think that's a great point.

23 MR. AYRES: I recently got tasked with the
24 implementation. My suggestion would be, in the letter back
25 to the board, recognizing them, that we indicate in that

1 letter that we wish to be notified anytime their board
2 training and experience requirements change. So we could
3 review those changes. That would seem to be a reasonable
4 mechanism.

5 MR. GRAHAM: Only as it relates to radiation,
6 safety, though.

7 DR. WILLIAMSON: Well, that's not true. There's
8 also requirements for experience with a certain number of
9 cases, which are included in there, and --

10 MR. GRAHAM: As is germane to radiation safety.

11 MS. HANEY: I think probably the better thing to
12 do is if it would -- if -- focus it more back to our
13 regulations. If you would -- if any change in your
14 eligibility requirements would affect the fact that you have
15 this as a bare minimum, then you need to tell us.

16 MR. AYRES: Or if they have a question.

17 DR. CERQUERIA: John?

18 MR. GRAHAM: Just one process question.
19 Rhetorically speaking, if they had put 35.490 in there, how
20 do you go through and review whether it's uses that have any
21 relationship to a sub-specialty or a specialty board? I
22 mean, if you had a group that tosses in brachytherapy, but
23 there doesn't appear to be any reason to -- test of
24 reasonableness that would indicate that they have much
25 experience in that, how do you review that?

1 MS. HANEY: We could go back and ask additional
2 questions, if we had to. I mean, with the larger boards, I
3 think it's a non-issue. I think when we get into some of
4 the smaller boards --

5 MR. GRAHAM: The smaller boards I'm worried about.

6 MS. HANEY: That we might have more questions and
7 things like that. And one of the reasons for coming to the
8 ACMUI and just discussing this is if there is something that
9 we missed -- I mean, if ABNM stuck up there 490 or 690, we
10 would have questioned that right off the bat. But there may
11 be some other subtleties with other boards where we need
12 more input from you.

13 In other words, this is an easy one. Wait till
14 six months from now when we're back.

15 DR. CERQUERIA: I would suggest that in the
16 future, if you want us to comment specifically on a board,
17 it would be useful to have a listing of their eligibility
18 requirements, as well as the hours that we've put into the
19 guidelines. That certainly would help us to give very
20 specific information.

21 DR. ALAZRAKI: And the NRC doesn't have to request
22 that from the board. It's published material.

23 MS. HANEY: That's a good point. We can get it
24 probably off web sites and things.

25 DR. CERQUERIA: Dr. Diamond?

1 DR. DIAMOND: I'd just like to state that
2 according to the regulations, as they are now proposed, I
3 have no problem. I think it's wholly appropriate for the
4 American Board of Nuclear Medicine to be recognized by NRC.

5 I also think that it's a smart idea, as you point
6 out, to separate this differential in handling safety and
7 competency, because for NRC to get into that is a difficult
8 task.

9 However, there are occasions where that
10 differential blurs and I will hope that the respective
11 societies do go and recognize scope of practices that the
12 individual physicians should recognizes. For example, there
13 is a big difference between being able to safely handle 250
14 millicurie of I-131, which is actually a fairly easy task,
15 and then being able to safely deliver that, for example, to
16 a child with widespread thyroid carcinoma.

17 And what you may have is, in certain
18 circumstances, individuals with very, very limited training
19 administering this. Now, again, you're trying to get out of
20 the clinical competency issue, but what you may end up doing
21 is developing a public safety issue or a patient safety
22 issue, whereby patients get hurt or killed.

23 So I would like to very strongly stress that there
24 are circumstances where that dichotomy or that construct
25 where you separate competency in the clinic versus safe

1 handling can be blurred and one of the most important areas
2 that I can think of offhand is the administration of very
3 high administered activities of I-131 by people who don't
4 have a lot of experience doing it.

5 DR. CERQUERIA: We had a lot of discussions about
6 this during the committee's sessions and we identified that
7 the fact that eligibility requirements for credentialing at
8 hospitals have some of that, professional medical societies
9 have some role, so that there are other bodies out there
10 that deal with that.

11 DR. DIAMOND: I agree, and that's why I can sleep
12 well at night because I hope that the hospital privilege
13 committees and the respective societies do recognize that
14 just because you have the authorized ability to do something
15 does not necessarily mean that you should be doing it.

16 DR. CERQUERIA: Good point. Other comments?

17 MR. JONES: And the other board that came in was
18 the Board of Pharmaceutical Specialties, and they were
19 looking for recognition for 35.50 and 35.55.

20 DR. CERQUERIA: Now, I'm sort of struck by
21 pharmaceutical specialists, not radiopharmaceutical
22 specialists. Do they have some specific training
23 requirements for --

24 MS. SCHWARZ: Yes, they do. The Board of
25 Pharmaceutical Specialties essentially licenses many

1 different specialties and one of them is nuclear pharmacy.

2 DR. CERQUERIA: Okay.

3 MS. SCHWARZ: So that is just one of the sub-specialties
4 that's licensed.

5 DR. CERQUERIA: But, again, sort of getting back
6 to the point, if somebody is board-certified by the
7 pharmaceutical specialist, does that mean that they will
8 necessarily have had training in radiation?

9 MS. SCHWARZ: Yes. There are specific
10 requirements for training, both didactic and experience, as
11 far as regulation for board certification.

12 MR. JONES: In addition to the requests we got for
13 recognition, we had several letters here that are asking for
14 clarification of different parts of the training and
15 experience requirements, and I'll turn it over to Dr. Bob
16 Ayres to go through those.

17 DR. AYRES: We'll swap places. I'd like to start
18 off by qualifying my remarks in a couple ways. One, I
19 recently took on this task and Sam Jones did a lot of the
20 background work. So if I get in trouble, hopefully he'll
21 help me out here a little bit.

22 The other is I listed as NRC staff response.
23 That's just what it is. It's staff like myself and Sam's
24 view of this from the plain English reading of the
25 regulations. It has not went through a concurrence process,

1 nor through our General Counsel's office.

2 So it is not our -- the response I'm giving on
3 these slides are not an official NRC response. These are --
4 I'm going to be discussing issues where boards and/or
5 members of boards have raised potential problems with the
6 boards complying with our requirements.

7 So what we -- we're going to address specifically
8 those raised in those five letters up there. The reason I
9 put ADR after Wisconsin, it's an individual from the Medical
10 College of Wisconsin, the letter actually raising issues
11 relation to ABR board certification.

12 DR. CERQUERIA: Just to point out, he is Vice
13 President of the American Board of Radiology.

14 DR. AYRES: Yes. He didn't write it in an
15 official capacity of the board. So we qualified that a
16 little bit.

17 The first letter was from the American Board of
18 Medical Physicists, and they simply asked about any
19 deadlines or timeframe for submitting their certification.
20 And there really is none. When they have supplied the
21 necessary information, it will then be listed on the NRC web
22 site, before, after or during the implementation of the
23 rule.

24 DR. CERQUERIA: Bob, just a point of
25 clarification. In the old days, we had all those written

1 regs and everything. Now, the web site will suffice if
2 there's questions for individuals in terms of board
3 recognition. They could just go to the web site and that
4 will be --

5 DR. AYRES: That's the intent, yes. If it's
6 listed on the web site and the board and for what
7 recognitions will be listed on the web site.

8 DR. CERQUERIA: Now, that's the intent. Do we
9 have any precedent for that within the NRC?

10 DR. AYRES: No, this is brand new. Cathy can jump
11 in if there -- I know of no comparable thing that we do.
12 The closest that we get to that sort of thing under our
13 current process is our sealed source and device registry,
14 which carries a regulatory check-off impact which is
15 maintained in paper and on a web site.

16 That's the closest analogy I can come up with.

17 DR. CERQUERIA: I'd like to find out from Ruth.
18 Do you think the agreement states would basically be willing
19 to take sort of web site listing of boards and if somebody
20 provides a board certification as being adequate?

21 DR. MCBURNEY: Yes.

22 DR. CERQUERIA: Okay. Good.

23 DR. AYRES: It was done, going way back in
24 history, to get out of locking ourselves into rulemaking to
25 --

1 DR. CERQUERIA: I think it's totally appropriate
2 and there's a lot of organizations that are doing that, but
3 I just -- for our users.

4 DR. AYRES: The next letter, like I said, come
5 from the American Board of Health Physics and their reading
6 of the regulations, if not always the letter, whether or not
7 that's sufficient for NRC to recognize the American Board of
8 Health Physics. I said medical physics and I misstated,
9 it's Health Physics.

10 There really is a problem there with the board
11 meeting the letter of the intent or letter of the
12 requirements, NRC regulation, and the next one, slide, goes
13 into some detail on that, as I recall.
14 We set forth the requirements, you have asked for this, so
15 this is the requirements that are in question, which is one
16 year of full-time radiation safety experience under the
17 supervision of an individual identified as an RSO on a
18 Commission or agreement state license.

19 And by the way, that was discussed a little
20 earlier and generally reciprocity is given between
21 authorized user and authorized medical physicist between
22 agreement states and NRC.

23 One grants it, the others recognize it when they
24 move. Anyway, they have to go through all those tasks and
25 the first issue was that the American Board of Health

1 Physics does not require one year of full-time radiation
2 safety experience under the supervision of an individual
3 identified as a radiation safety officer, that is authorized
4 to do work with similar types of material and uses.

5 The Health Physics Board's position was that they
6 don't require this. They have an alternative requirement of
7 full-time practice of health physics for a minimum of six
8 years. So they don't have the one year full-time use with
9 the similar use and with under the supervision. So they
10 don't meet the exact, the precise requirements of the
11 regulation.

12 DR. CERQUERIA: We have a question.

13 DR. WAGNER: But it seems to me that if they have
14 six years of practice, they have to be working under
15 somebody who has a license.

16 MS. HANEY: Then the problem is you've got -- I'll
17 give you a real -- you've got a health physicist that has
18 spent six years in a nuclear power plant, decides to leave
19 the nuclear power plant and I want to be an RSO at a
20 hospital now. That's the issue here.

21 DR. VETTER: It doesn't demonstrate any experience
22 in medical.

23 DR. AYRES: Or it could be the RSO for a very
24 small licensee that has -- that did not work under any
25 supervision. So I missed on my editing. The NRC staff

1 position, which, as I said, is not an official NRC position,
2 but they don't meet the requirements of the regulation.

3 The supporting statements for the final rule
4 states that the final rule requires that an RSO must have
5 one year of full time radiation safety and experience with
6 similar types of uses and material and the signed preceptor
7 statement, which the board does not require.

8 DR. CERQUERIA: But we have a question from Ruth.

9 DR. MCBURNEY: Under those circumstances, I don't
10 think that any board certification for a radiation safety
11 officer would qualify.

12 DR. AYRES: I think you're correct.

13 DR. WILLIAMSON: I'm not sure, but I think the
14 American Board of Medical Physics, medical radiation safety
15 would satisfy it.

16 DR. AYRES: There is those pathways, too. Yes,
17 you may be right. We have a problem here with a currently
18 recognized board that under the new Part 35 looks like they
19 don't meet the requirements for recognition.

20 DR. ALAZRAKI: One thing you might consider is if
21 you want to recognize a board and then qualify what
22 additional documentation would need to accompany that board
23 --

24 DR. AYRES: I think that requirement would need to
25 be satisfied prior to recognition, in the implementation

1 process.

2 MS. HANEY: Also, something to keep in mind, just
3 because we don't recognize the American Board of Health
4 Physics doesn't mean someone can't be a radiation safety
5 officer. What this -- there are two ways you can become an
6 RSO or an authorized whatever.

7 One of them is to come in under the board route,
8 which is the easier way to do it, saves some paperwork on
9 both sides, because -- and you can begin work immediately
10 and all you do is notify NRC that this person has started to
11 work for you.

12 The other way is to come under the alternative
13 pathway, which means you submit a license amendment. So in
14 the case of -- if there is a board of something that we
15 don't -- we decide not to recognize, it doesn't mean
16 everybody is out and all bets are off. Then they would just
17 come in with the amendment. It's really where you were
18 going, is the recognition was something extra.

19 It would just be we would tell our license
20 reviewers that when you see someone coming in that's by the
21 American Board of Health Physics, just look to see that they
22 have provided extra documentation on this one year.

23 So we're not asking people to jump through hoops
24 or saying people aren't qualified. It's just this short
25 easy -- the easy method might not work in this case.

1 The other thing with the radiation safety officer
2 to keep in mind is that the RSO always requires an amendment
3 to the license, except there's a little exception there with
4 what we've created as the temporary RSO.

5 So the fact that maybe the short sweet method
6 doesn't work for the RSO is not a big problem because you've
7 got to submit all your paperwork anyway.

8 DR. AYRES: And assuming this plays out this way,
9 that this board does not meet the requirements and is not
10 listed as qualified, it's not an immediate problem because
11 current RSOs are grandfathered under the new rule and there
12 are alternative pathways. And as you mentioned, it's
13 probably a lot easier for a board to change its requirements
14 than it is for a change in the rulemaking. So that option
15 exists for these boards.

16 DR. CERQUERIA: Let me make one comment. Cathy
17 has informed me that our 11 to 12 presentations are
18 relatively brief, so we're going over knowingly. But, Dick,
19 I would like to hear your comments on this, since you're --

20 DR. VETTER: Sure. Thank you. I think the
21 problem here is that there is a philosophical shift on the
22 part of the NRC as to what they expect from boards.

23 If you look at the mission of the boards, their
24 mission is to certify, not to credential. So they certify
25 minimum competency and they have never intended to get into

1 the regulatory business of telling the regulator whether or
2 not someone is qualified to be an RSO.

3 Their position is they want to certify that a
4 person has the minimum competency to be a good health
5 physicist or medical health physicist or whatever it is.

6 Consequently, they are not set up to do what
7 you've asked them to do and they are struggling, both health
8 physics and medical physics, the boards are struggling with
9 this, determining what direction they want to go.

10 DR. AYRES: IN many cases, they satisfy that
11 requirement and we're showing some cases now where boards do
12 not.

13 DR. CERQUERIA: So we've got two fixes here. One
14 is that people do have an alternative way to become
15 authorized radiation safety officers and also the boards
16 themselves may consider. I mean, the intent of the
17 requirements was to make certain that at least that one year
18 of training was done by somebody who had all their
19 prerequisite knowledge rather being all on the job
20 experience.

21 DR. AYRES: And the types of uses for which
22 they're going to exercise.

23 DR. CERQUERIA: Exactly. Yes.

24 DR. AYRES: And that's true of all of our training
25 and experience or all of our certification processes or

1 credentialing has alternative pathways. The board
2 certification is simply one of them.

3 DR. WAGNER: So I presume what could happen is,
4 say, the American Board of Health Physics could make maybe a
5 specialty under their boards and say, okay, you're certified
6 in American Board of Health Physics, with special
7 application in medical physics or something of that nature,
8 and then they would say that sub-specialty would require
9 that these requirements and, therefore, would meet it.

10 I mean, they could do that, right?

11 DR. AYRES: Or we could say that that board meets
12 all the requirements except the one year of supervised
13 experience and they simply provide the preceptor
14 certification that that's done and together with board
15 certification, establishes all the requirements.

16 DR. CERQUERIA: We will have to be careful how we
17 do that. In theory, you could, but we have to make certain
18 it really meets the law.

19 Dick, do you have a comment?

20 DR. AYRES: It's very early in the process.

21 DR. VETTER: Just two real quick things. I don't
22 think we want to be telling boards what they should do.
23 That's number one.

24 DR. AYRES: We're not.

25 DR. VETTER: Well, I think -- well, if you tell

1 the American Board of Health Physics that they should
2 certify in medical health physics, you're telling them what
3 to do.

4 DR. AYRES: No, we wouldn't tell them that. I'm
5 just saying that they have the voluntary option on their own
6 to try to do something. That's all my point is.

7 DR. VETTER: Okay. I see. All right. Now, the
8 second thing is, I think the business Cathy mentioned and
9 Bob mentioned about, okay, someone is board certified in
10 health physics, but they don't have the one year experience
11 or the board didn't require that they signify they have one
12 year, certify they have one year.

13 If that could be put in the guidance, that someone who is
14 certified by American Board of Health Physics or American
15 Board of Medical Physics, and then they have to provide, in
16 the license application or whatever, provide that --

17 DR. AYRES: Missing component.

18 DR. VETTER: -- missing component, that takes care
19 of it.

20 DR. CERQUERIA: That does. John?

21 MR. GRAHAM: My question is a direct follow-up to
22 that. Reading paragraph A of 35.50, as it reads, it's is
23 certified by a specialty board whose certification process
24 includes all of the requirements in paragraph B. And I
25 agree with Richard's point. I don't think we want to get

1 into where we're trying to direct boards that they need to
2 modify the requirements.

3 Then it goes on to say "and whose certification
4 has been recognized by the Commission or," and then it's
5 everything down below.

6 Does this language have to be changed to create a
7 third option, which is they are certified by a specialty
8 board whose certification process includes all of the
9 requirements in paragraph B or they are certified by a
10 specialty board and they have documented meeting the
11 requirements that are not covered under section B?

12 MS. HANEY: No, I don't think we would need to do
13 that. I think you could handle it through the structure
14 that's set up there, through the license amendment.

15 DR. AYRES: I think it's something willing to try
16 to do. I don't -- I am not saying it's going to be
17 successful and trying to change the language I think is not
18 an option.

19 DR. CERQUERIA: Certainly we're not going to
20 change Part 35 revision. So I think at least for this
21 particular board, we really feel that it doesn't meet the
22 requirements.

23 We can go on to the next one.

24 DR. AYRES: This is a continuation of the letter
25 from the American Board of Health Physics. The second issue

1 was that the American Board of Health Physics certification
2 does not require the written certification. The first one
3 really addressed the year of specific experience, and I
4 think we've already talked about this pretty well, unless
5 there's additional comments on this part.

6 DR. CERQUERIA: No.

7 DR. AYRES: I'll try to step through this.

8 DR. CERQUERIA: Let's try to finish this at 11:30.

9 DR. AYRES: The next one comes from the individual
10 from the University of Wisconsin, more or less expressing
11 concerns relating to the American Board of Radiology
12 certification process.

13 Again, with the radiation safety officer
14 regulation in 35.50, which the one year of radiation safety
15 and experience under supervision, including the list of the
16 items A through G, which you can certainly read for
17 yourself. And the first issue was the American Board of
18 Radiology wishes to know whether the educational and
19 clinical experience of a physicist eligible for
20 certification in the medical nuclear physics will be
21 interpreted by NRC as satisfying the requirement for one
22 year of full-time radiation experience.

23 Their position was, in the letter, in this letter
24 from the representative, I guess you could say from the
25 board, that the educational requirements for certification

1 include all of the items in B.1.I, and the three years
2 clinical experience include all of the items in B.1.2.A and
3 A through G.

4 So the three years clinical experience are
5 obtained under the supervision of an RSO. However, the
6 experience is usually embedded with the clinical
7 responsibilities and extend beyond the specific RSO duties
8 and talk about the strict interpretation of 35.50 would
9 imply that they would not satisfy the requirement for one
10 year.

11 On our plain English reading of the rule, the
12 supporting -- and the supporting statements from the final
13 rule, that the final rule requires that an RSO must have one
14 year of full-time radiation safety experience and similar
15 uses of materials and the signed preceptor statement that --
16 and this really isn't a change, that was the retained from
17 the previous rule, and that the three years of clinical
18 experience usually is embedded within the set of clinical
19 responsibilities and so forth, do not really meet the plain
20 English reading of that requirement.

21 DR. ALAZRAKI: But wouldn't the question be do
22 they meet the intent?

23 DR. AYRES: No, they've got to meet the
24 requirement.

25 DR. ALAZRAKI: Does it have to be one year non-stop

1 full-time or why couldn't it be three years of part-time?

2 DR. AYRES: I think they could meet the
3 requirement if the RSO who was overseeing this work as a
4 preceptor provided the certification. Now, there is nothing
5 in the requirement that says that they have to be one
6 continuous year, that I'm aware of. It could be three
7 months in '97 and six months in '98 and three months in '99.

8 DR. ALAZRAKI: Okay.

9 DR. AYRES: Or something like that.

10 DR. CERQUERIA: Dr. Nag?

11 DR. NAG: First of all, that letter that was sent
12 to you, it did say that he is the Vice President of the ABR.
13 So he is giving it to you as an officer of ABR, the
14 statement. But more important than that, I think, is the
15 fact that we have to recognize the overlap of the training.

16 For example, when I'm doing one thing, I'd say
17 that I had three months rotation in brachytherapy and three
18 months in external beam. It's really hard to differentiate
19 that.

20 Similarly, it's very hard to differentiate knowing
21 what my apprentice does that I cannot say that this portion
22 of his training was supervising all this old stuff and this
23 portion was in calculation of the -- so it's really hard to
24 define that differentiation, to differentiate that.

25 I think if someone had three years of training as

1 a medical physicist, that training encompasses all the
2 things you are required to know in radiation safety and that
3 itself should qualify.

4 DR. CERQUERIA: It should meet the intent, if not
5 the specific one year sort of continuous requirement. Jeff?

6 DR. WILLIAMSON: I have a big concern with the way
7 you're interpreting this. As I understand your
8 interpretation, you are basically saying that to qualify,
9 the board, any board, has to basically require that the
10 individual be directly supervised for the equivalent of one
11 year by the safety officer doing only these things.

12 You're going to create a manpower crisis that
13 you've never seen before. Basically, nobody will satisfy
14 this, except those individuals who have worked directly
15 under the supervision of a radiation safety officer.

16 DR. AYRES: Unfortunately, the rule says --

17 DR. WILLIAMSON: Can I finish?

18 DR. AYRES: -- what the rule says.

19 DR. CERQUERIA: But it says one year and if you do
20 that over the -- if you have the one year content over the
21 course of three years, then you really meet the intent.

22 DR. WILLIAMSON: That's not the issue. Let me
23 finish.

24 DR. AYRES: Jeff is raising a definition variance.

25 DR. WILLIAMSON: I think this hinges on the

1 interpretation of the word supervised, under the supervision
2 of a radiation safety officer licensed by such and such and
3 involving, the word is involving.

4 So I think the intent -- I know, because we
5 discussed it many times here, was we fully recognized this
6 was embedded in a matrix of larger clinical duties within a
7 medical center and that's why the word involving didn't mean
8 that 100 percent of the one year experience would be
9 exhausted by receiving packages.

10 I think you could make the case that almost nobody
11 would satisfy that requirement. That's my interpretation of
12 the word involving.

13 It means that that's an integral part of that one
14 year of experience. And I think supervision may mean -- has
15 to be interpreted to allow for different levels of
16 supervised experience. In some sense, the RSO directly
17 supervises everybody that is involved in the handling of
18 sources, but, in fact, the trainee may be reporting to the
19 chief medical physicist and not directly to the RSO.

20 DR. AYRES: Well, I think there's two issues here.
21 One, you're talking a little bit about meeting the training
22 and experience requirements, not the board certification
23 process.

24 DR. WILLIAMSON: No. I'm trying to defend the --

25 DR. AYRES: In other words, the board does not

1 require this.

2 DR. WILLIAMSON: Let me step backwards. I guess
3 what I am trying to defend is that the training and
4 experience requirements of, for example, the American Board
5 of Radiology for therapeutic radiological physicists and the
6 requirements for American Board of Medical Physics for
7 medical radiation safety and radiation oncology physicists
8 do, in fact, meet the intent of this regulation.

9 DR. AYRES: Well, basically, we're asking the
10 board to certify that they meet the regulation. Now, I
11 grant you, there's training and experience alternative and
12 you can certainly conceive of radiation or medical physics
13 training programs where the medical physicist would never be
14 involved in shipping, receiving and the necessary arcania
15 that go with that.

16 I think the bottom line is the radiation safety
17 officer, as a preceptor, is making a certification. If
18 that's done -- but I don't think that -- what ABR is saying
19 is they don't have that as part of their board certification
20 requirements, and I can completely understand why, and
21 therefore, they do not meet a requirement set forth in
22 35.50.

23 That's where we're at.

24 DR. CERQUERIA: Dick?

25 DR. VETTER: I agree with Jeff. I don't think

1 anybody is going to meet this requirement.

2 DR. AYRES: I don't disagree with that.

3 DR. WILLIAMSON: But I think this goes against the
4 intent that --

5 DR. NAG: I think what we have to do, one of the
6 intents of the NRC to make things simpler and not make
7 things more difficult, and, therefore, the intent is
8 something we have to look for. We want to help preserve the
9 safety of the public. That's the foremost. If someone had
10 the training without saying that one year with direct
11 supervision, but had received all that knowledge, that is
12 what we want.

13 So if they can say that the intent was fulfilled,
14 that should be enough.

15 DR. AYRES: And unfortunately, that position is
16 not even dealt with in where intent is often addressed in
17 the statements of consideration.

18 DR. CERQUERIA: Niki?

19 MS. HOBSON: I understand what he's saying, that
20 the board certification doesn't specifically require these
21 things and -- but that doesn't preclude these people from
22 still qualifying as radiation safety officers.

23 DR. AYRES: No, not at all, but it does preclude
24 them from qualifying as radiation safety officers purely on
25 the basis of the board certification.

1 DR. CERQUERIA: John?

2 MR. GRAHAM: I guess I just want to clarify what
3 Cathy -- my understanding is that if somebody had the ABR
4 and then someone is willing to sign the certification, they
5 could -- they would meet all the requirements for RSO.
6 That's how it's going to be written in the guidance. So the
7 intent of what we hammered on for two years is still in
8 here.

9 MS. HANEY: Yes.

10 MR. GRAHAM: It's just takes those two things
11 together.

12 MS. HANEY: It's just how you get there.

13 DR. AYRES: The simple board certification, in and
14 of itself, doesn't appear to work and the board is
15 recognizing that and raising the issue.

16 Continuing on with the ABR letter --

17 DR. CERQUERIA: Bob, we're going to have to wrap
18 up in about four or five minutes.

19 DR. AYRES: Okay. I will make it real simple.
20 The issue, if a physicist certification for all the
21 specialties and it applies across the board to authorized
22 users, too, you can conceive -- I think it's fairly
23 reasonable to recognize that if you sum together Parts 400
24 and 600, that not all medical physicists nor authorized
25 users are going to get training in all of it, in manual

1 brachytherapy, remote afterloaders, teletherapy, and, in
2 particular, gamma knife. The gamma knife is probably the
3 real -- the Lixel stereotactic radiosurgery unit, otherwise
4 known as a gamma knife, is probably a place where a lot of
5 medical physicists and/or authorized users would have no
6 experience and it's not incorporated in the board
7 certification process.

8 The way I would envision this playing out, on a
9 first look, is that board certification such as by medical
10 physics and the ABR and those sort of things, would be
11 qualified. A board certification would establish
12 credentialing for a medical physicist and authorized users
13 in 35.400 and 35.600, teletherapy and remote afterloading
14 brachytherapy, but not, because it's not part of the
15 certification process or training and experience,
16 stereotactic radiosurgery and they could come back in with
17 the training and experience and proctoring statement and add
18 that as appropriate.

19 What I'm saying is the board certification process
20 doesn't encompass all of the specialties contained in 600 in
21 particular, bottom line.

22 DR. CERQUERIA: Jeff, any comments?

23 DR. WILLIAMSON: I think this really is 180
24 degrees away from the intent of recognizing board
25 certification as a basic credential for being an authorized

1 user and authorized medical physicist or an RSO.

2 The idea was to establish a sort of core
3 competency that would allow the person to competently
4 practice whatever modality comes along.

5 So for example, a radiation oncologist would not
6 be disqualified from practicing intervascular brachytherapy
7 automatically because that was not included in his residency
8 training. I think that would be wrong.

9 Let me finish, before you interrupt.

10 DR. AYRES: No, I was thinking.

11 DR. WILLIAMSON: So I think the idea is that board
12 certification provides the sort of intellectual framework
13 and matrix of experience that allows the professional to
14 learn as new modalities become available and practice them
15 safely. That's the idea of being a physician or a
16 physicist, is that it's a sort of a portable expandable set
17 of skills.

18 And now you're sort of making this very nitpicky.
19 I think this goes against completely the philosophy that was
20 articulated first thing this morning.

21 DR. AYRES: Well, I don't want to argue with you
22 on intervascular brachytherapy, or brachytherapy is
23 brachytherapy, I'll say. But unfortunately, the regulation
24 calls out training and experience in each one of those
25 specific areas, and what I'm saying, it's looking like the

1 boards are going to have problems certifying that they
2 provide training and experience in each one of those
3 specified areas, which is brachytherapy, teletherapy and, in
4 particular, stereotactic radiosurgery.

5 DR. NAG: I think I need to take the floor here.
6 It is very, very important to recognize that there is an
7 overflow of knowledge from one section to the other. For
8 example, for the radiation oncology, there are five sections
9 that they are involved in. That is 390, unsealed isotopes;
10 392, sodium iodide less than 33 millicuries; 394, sodium
11 iodide more than 33 millicurie; 490, manual brachytherapy;
12 491, strontium; and 690, remote afterloader teletherapy, et
13 cetera.

14 What we have to recognize is each of those
15 sections, I think the rule as it is written makes sense.
16 However, if you are to say that each of those sections have
17 to be done separately, you have to add up all those hours,
18 that is not enough hours in any training program to ever
19 qualify that.

20 But it is not needed because once you learn the
21 physics of one section, that overflows into the other
22 section. This can be eliminated simply by saying that it's
23 the total number of hours, not number of hours in each
24 section.

25 If you have 700 hours of training and that 700

1 hours encompassed each of these sections, that should be
2 able to qualify. That's one problem that I think we have to
3 clarify or we have to write it in or modify it so that it is
4 clear to everybody that we are not asking 700 hours on each
5 of those sections.

6 And the second thing is you can have people who
7 have had all the training, but not separate -- who are not
8 practicing all day. They may not be board certified, but
9 they -- they will not now qualify.

10 DR. CERQUERIA: They could be by the hourly
11 experience, couldn't they?

12 DR. AYRES: That's the current slide, that's the
13 next question up.

14 DR. NAG: And the other thing is for the use of
15 Cobalt-60 teletherapy, many institutions are now not having
16 Cobalt-60. However, the operation of Cobalt-60, you need to
17 have the knowledge of teletherapy and most institutions are
18 now having teletherapy with linear accelerator, which is not
19 covered by the NRC.

20 So you can have a fully trained radiation
21 oncologist, trained on the linear accelerator, who can use
22 that Cobalt-60, but did not have Cobalt-60 in that training
23 program, and they finish that training, they are now board
24 certified, they go out to a smaller community hospital and
25 now they cannot practice medicine at all because they did

1 not have 500 hours of Cobalt-60.

2 So I think before this regulation goes out, we
3 have to --

4 DR. CERQUERIA: Well we can't change the
5 regulation.

6 DR. NAG: No, we are not changing. We have --

7 DR. CERQUERIA: The interpretation.

8 DR. NAG: The interpretation of that.

9 DR. CERQUERIA: Of how we deal with the boards.

10 DR. WILLIAMSON: I think something has to be done.
11 This is very serious. I think this will all grind to a halt
12 if something is not done about these interpretations.

13 MS. HANEY: Well, I think there are some things
14 that we can still modify in the statements of consideration.
15 I think what we need to do is make sure we keep a common
16 sense approach to this and, as you said, not make it more
17 difficult than what it needs to be.

18 But I think the issue that Dr. Nag is bringing up
19 about it doesn't have to be 700 hours in everything, there
20 is some overlap between the training, just as there is
21 overlap between the training for a brachytherapy user, as
22 well as one that's using an HDR.

23 So I think that common sense needs to be applied.
24 The decay formula is the same decay formula whether you're
25 in 100 or whether you're in 600. So you don't need to hear

1 that six different times.

2 So that's the common sense aspect that I think
3 needs to be sure that it's applied.

4 To go to your linear accelerator example, where
5 you're learning how to treat, if you go to a teletherapy
6 unit, that one is a little bit harder, because probably 90
7 percent of the information they have, and it would be
8 adequate, but there is that ten percent knowledge about
9 knowing how to handle a sealed source that they're not going
10 to have.

11 DR. NAG: But you don't need 500 separate hours.

12 MS. HANEY: Exactly. That's the common sense
13 aspect that needs to be used here.

14 DR. AYRES: Both of those are issues we had the
15 earlier slide on, the additive hours, and Cathy was talking
16 about she really was dealing with the 200 hour training and
17 experience. If the user wanted to do 390, 490 and 690 -- or
18 300, 400 and 600, it looks like the 500 hours are additive
19 and come up to the total of 1,500, because the training and
20 experience requirements are completely different for those
21 three.

22 And we talked preliminarily with our general
23 counsel, who was in general agreement. I'm not saying it's
24 right, but from a plain English reading of the rule, it
25 looks like that works out that way.

1 Now, how it will shake it out in the end, I don't
2 know.

3 MS. HANEY: Well, for the sake of time, I think
4 it's probably something that maybe this is ongoing
5 discussion.

6 DR. DIAMOND: Cathy, I think this could be
7 addressed very easily in a guidance document, if we just
8 insert the word concurrent. That's the very simple phrase.

9 MS. HANEY: I'll tell you, the problem is, and we
10 can insert words as we need, it's not -- I don't want to say
11 totally concurrent, because there is not 100 percent overlap
12 between all the trainings. There are some things when you
13 talk about handling unsealed material versus sealed.

14 It's not as important that an -- take this with a
15 grain of salt. It's not as important that an oncologist
16 know how to clean up a spill of I-131, if they're only
17 dealing with HDR units. So you may not have had that
18 training.

19 So if you all of a sudden wanted to become a user
20 of 35.300 material, you might need an extra hour of
21 training. I mean, you don't need an extra 700 hours, but
22 you might need an extra hour.

23 DR. DIAMOND: I understand that. I understand
24 that, but what I'm saying is now that these rules have been
25 promulgated, how can we go and address these very important

1 concerns in an efficient manner and perhaps some type of
2 guidance along these lines would be sufficient.

3 MS. HANEY: And that can be done through the
4 statements of consideration.

5 DR. AYRES: What we're doing here is pointing out
6 the areas of concern that have been identified by the boards
7 already and they are legitimate areas of concern.

8 DR. CERQUERIA: One final comment from John, and I
9 guess Niki.

10 MS. HOBSON: I'm listening to this and I really am
11 getting concerned that if there is a literal interpretation,
12 very stringent interpretation such as Mr. Ayres is giving
13 us, that cancer patients, other kinds of patients are going
14 to go without needed medical procedures because there's not
15 going to be enough people out there to do them.

16 And the patient is the most important person, in
17 my opinion, in this whole thing. So I don't know how to
18 resolve this technically, but I'm saying make it work so
19 that the patient gets the needed treatment.

20 DR. AYRES: And, again, it's not an immediate
21 problem because of the grandfathering.

22 DR. CERQUERIA: And, again, a lot of this deals
23 with the radiation safety, but institutions are going to
24 have some requirements in place in terms of what people can
25 do relative to all these treatments.

1 I think, John, one last comment and then we'll go
2 on.

3 MR. GRAHAM: And I think it's following up on
4 Jeff's. I think as we've discussed it for a couple years,
5 whether you've met the intent of the training requirement,
6 if I were the risk manager for any of these boards, I would
7 probably send you a letter saying I don't know if we comply,
8 because I don't want the exposure that I've become a
9 quasi-regulatory body.

10 I'm amazed that anybody has been willing to go in
11 writing saying we comply and we want to be identified that
12 way.

13 So as a general rule, I think you're going to have
14 to deal with boards that come back and say we provide all
15 this training, we're not sure if we're in complete
16 compliance with your rules, and that's the safest risk
17 management approach to take.

18 So you're going to have to have guidance that
19 dovetails that in and identifies discretely that if there
20 appear to be missing elements, there is a simple way to get
21 that documented, so you're not going redundantly back
22 through hundreds of hours of training.

23 DR. CERQUERIA: Exactly. I think the intent of
24 the committee was basically to not necessarily a literal
25 interpretation, but looking at the intent and certainly some

1 of the guidance documents could deal with some of these
2 specificities.

3 DR. AYRES: I think this was addressed much better
4 in 100, 200 and 300, where training was recognized on down
5 and there's "or" and that sort of thing were put in. That
6 language seems fairly clear and crediting experience on one
7 level at other level.

8 That same language was not incorporated in the
9 400, 500 and 600 portions of the rule.

10 DR. WILLIAMSON: To summarize, that this
11 conversation or discussion we've had indicates that board
12 certification is now completely discredited as a method of
13 qualifying for any of these things.

14 DR. CERQUERIA: Dr. Nag, last comment, and then we
15 need to move on.

16 DR. NAG: One comment. That is, these rules are
17 going to be in force forever or for a long time and we may
18 not be here. And the problem is that if we do not write it
19 in a way that it's not open to misinterpretation, tomorrow
20 it can be misinterpreted.

21 Today we are saying, well, you can have
22 concurrent, you only need a few extra hours, if you already
23 know all about brachytherapy, sealed source, you need a few
24 extra hours to learn about unsealed sources, if you need to
25 know about the linear accelerator, you need a few hours to

1 learn about handling of Cobalt-60.

2 This is not clearly written out. Tomorrow,
3 someone else will be here and they can interpret this to
4 have a separate 500 hours on each of these things.

5 So I want this to be clearly written so that there
6 is no ambiguity at all.

7 DR. AYRES: The writing, as far as the rule has
8 gone, is finished. As Cathy said, there may be something in
9 the interpretation and the statements of consideration.

10 MS. HANEY: Rule text is fixed, but there are
11 still things we can put -- or at least let me say I believe
12 there are things we can still --

13 DR. NAG: I want that to be written in, so that
14 it's not --

15 DR. CERQUERIA: I'm not sure you're going to be
16 able to get it written into the document and the
17 professional societies had ample opportunities for the last
18 two and a half years to comment and so obviously, some of
19 this is the wording may not have been as specific now when
20 we get down into the actual interpretation.

21 DR. AYRES: And one of the more important
22 components, a final reading on this from our general
23 counsel, it's not part of what I presented to you, and that
24 would be very important on exactly how these requirements
25 get -- are applied.

1 DR. CERQUERIA: I didn't --

2 DR. AYRES: Well, our general counsel has an awful
3 lot to say about what the rule means exactly and it's only
4 been discussed in a general way with them and exactly how to
5 apply these requirements. There's no final -- I'm not
6 presenting any NRC final position on this whatsoever, just
7 some preliminary thinking.

8 DR. CERQUERIA: That's sort of -- maybe we should
9 have had the counsel involved in all these meetings for the
10 last three years, because we've spent time and come up with
11 --

12 DR. AYRES: They have been.

13 DR. CERQUERIA: Well, not making direct comments
14 and supplying direct information.

15 DR. MCBURNEY: The guidance document still is to
16 be written and although that doesn't carry the force of law
17 the way the rule does, still, if those who are inspecting or
18 interpreting what goes on in the real world use the guidance
19 document, if that clarifies the intent --

20 MS. HANEY: We can always put out guidance that
21 clarifies the intent and whether it goes into the statements
22 of consideration or goes into the questions and answers that
23 Roberto talked about maintaining on the web site, we can put
24 the things in documentation.

25 The only issue right now is where it would exist

1 and I can't give you an answer to that right now, and some
2 of these things we're able to correct. I think some of the
3 issues of concurrent training will be easy to address at
4 this point.

5 I'm not sure some of the ones with the health
6 physics and the radiation safety officer, because I see the
7 one year of experience as a totally different issue.

8 So some things we can fix, some things we won't,
9 but I think we're in a unique situation with this rule where
10 we're, to a certain extent, implementing it before it's even
11 been in the Federal Register.

12 And with anything you write, you see that there
13 are issues that come up that you need to work on. So we can
14 fix most of these, I think, or at least work through them,
15 but we're just bringing you in on the ground floor to let
16 you know that there are some of these issues.

17 DR. AYRES: Exactly, the very early thinking, and
18 I think we'll probably be back here regularly and the next
19 step would be an official response to the board on the
20 position, which it will become the NRC response, which has
21 been approved and run through our general counsel.

22 DR. CERQUERIA: I think it would be important to
23 have counsel at the table in the future if these discussions
24 do come up, to at least, if they have issues, it would be
25 better to identify these issues before the committee rather

1 than at the time of implementation.

2 We really did promise, I believe, Dr. Van Decker,
3 from the ACC and the American Society of Nuclear Cardiology,
4 to make a comment relative to board certification, and we
5 should do that and then go on to the next topic.

6 DR. VAN DECKER: Thank you for the opportunity to make a
7 brief comment. I'm Bill Van Decker. I'm part of the
8 faculty at MCP Honomon University in Philadelphia, and long
9 involved in a nuclear cardiology training program, a member
10 of the Society of Nuclear Cardiology. I actually speak for
11 a couple of moments just on behalf of the certification
12 board for nuclear cardiology.

13 I just wanted to say I thought the discussion in
14 the last 45 minutes was actually excellent and I was very
15 impressed by taking a new look at old things. Sometimes
16 some of the issues that come up, and I think there was a lot
17 of good and well meaning here.

18 We just wanted -- on behalf of the CBNC, we just
19 wanted to say thank you for the November the 2nd, 2000
20 notice in the Federal Register opening up solicitation for
21 other medical specialty boards for consideration.

22 The CBNC's requirements to sit for that exam do
23 meet the imaging and localization requirements, as outlined
24 in 10 CFR 35, and we will be submitting such a application,
25 and we thank you for that opportunity.

1 We want to bring up the point that this highlights
2 the issue of the three year interlude between NRC states and
3 agreement states. If you don't force the level B right
4 across the board early, you will then have physicians board
5 certified, potentially, that are a mix and match across
6 different states, which really confuses the issue quite a
7 bit.

8 So some thought in that regard would be helpful.
9 And the last kind of tangential comment I will make is that
10 if this body, which did such a great job of discussion a
11 moment ago, is going to be the forethought for most of the
12 boards that come through that have not been deemed boards in
13 the past, then we need to make sure that representation of
14 everybody involved in the use of isotopes in medical
15 practice is involved for the furtherment of patient good
16 down the line.

17 And I just wanted to thank all of you this morning
18 for the discussion and thank you for the opportunity to make
19 a short comment.

20 Thanks.

21 DR. CERQUERIA: Any questions for Dr. Van Decker.
22 If not, then we'll move on to the next topic, which really
23 relates to the NRC initiatives for risk-informed and
24 performance-based. I apologize for having cut the time, but
25 I couldn't exactly cut off the last discussion that we had.

1 So it will just cut into our lunch break.

2 MR. KOKAJKO: I think it's still morning, right?
3 My name is Lawrence KOKAJKO. I'm the Section Chief for the
4 Risk Task Group, reporting directly to the Office Director
5 in the Office of Nuclear Material Safety and Safeguards.

6 I would like to give you just a brief background
7 on who we are and where we're going with all this, and I
8 need to perhaps give you just a little more background.

9 First of all, the risk task group itself is an
10 interdisciplinary group composed of members from all four
11 major divisions within the Office of Nuclear Materials
12 Safety and Safeguards. We have representatives from Fuel
13 Cycle Safety and Safeguards, Division of Waste Management,
14 Industrial, Medical and Nuclear Safety, as well as the Spent
15 Fuel Project Office.

16 The primary reason why we are here is that
17 SECY-99-100 proposed a framework for risk-informing the
18 regulations within the materials and waste arena activities.
19 And in the SRM that the Commission provided to the staff,
20 they said we want you to try to develop appropriate
21 materials and waste safety goals and use it an enhanced
22 participatory process and, in fact, we had a two day
23 workshop in April in Bethesda and out of that workshop came
24 an approach that we're going to talk about a little later on
25 this morning.

1 We also rolled out our approach on September 21 to
2 our stakeholders and they were pretty much in agreement with
3 what we were trying to do.

4 Just to refresh you, in SECY-99-100, it identified
5 five major steps to risk-inform materials and waste arena
6 activities. One was that we should identify those
7 applications and who is responsible, decide on how to modify
8 the approaches, change them as appropriate, implement them
9 and develop or adapt risk-informed tools.

10 And the tools that I'm talking about primarily are
11 integrated safety assessments, probabilistic risk
12 assessments, hazard operations barrier analysis, and those
13 types of approaches.

14 And I have to tell you, if it looks like this
15 doesn't quite flow, that would be true, and the primary
16 reason is that the NMSS programs start from different levels
17 of risk information. The data and the tools are sometimes
18 lacking, in other places, they are much more advanced.

19 For example, radioactive material transportation,
20 there's been a lot of risk assessment techniques that have
21 been employed in the past. In other areas, such as uranium
22 recovery, there's been much less.

23 The risk task group has developed an operating
24 plan and although we primarily view ourselves as supporting
25 the third performance goal, which is making our activities

1 more efficient, effective and realistic, implicit in that is
2 that we will always maintain safety and you will see that in
3 our screening criteria that I will talk about a little bit
4 later.

5 Our activities and how we meet these performance
6 goal are in three major areas. One is we're performing case
7 studies which came out of our workshop in April. We're also
8 doing training of NMSS staff and regional staff and we're
9 providing assistance to divisions.

10 The first thing I would like to talk about more
11 full is our case studies. In order to develop this
12 framework, we've had to take a look at how we could go about
13 reviewing past decisions in a systematic manner, and hence
14 we came up with this case study approach.

15 And as I said, this did not come from the staff
16 itself. It came from the stakeholder workshop in April. In
17 fact, it was an external person that came up with this
18 approach, and this was seconded by a number of members of
19 the NMSS staff who were in attendance.

20 We're also following other activities, as well,
21 such as activities going on in Research, the International
22 Council of Radiation Protection, as well as the National
23 Council, the National Academy of Sciences, and the EPA. We
24 recently are aware of some efforts that DOE and DOD are also
25 doing and we're following them, as well.

1 The case studies have two primary purposes, what
2 could be done to materials and waste arenas to make it more
3 risk-informed and to establish this framework by testing the
4 draft screening criteria.

5 The case studies themselves will cover a broad
6 spectrum of applications and material in the waste arenas.
7 This case study plan has been approved by the NMSS risk
8 steering group, and I have to tell you, this has got some
9 challenges.

10 For instance, although we believe that safety
11 goals are feasible and we are taking a very positive
12 approach to that, we're not quite sure how they would tie to
13 a given particular application, and it's complicated by who
14 is our target population that we're trying -- is it the
15 public or a subset of the public, is it the worker, is it
16 under accident or non-accident conditions.

17 And this is very different than the reactor safety
18 goal program, which was primarily focused on low
19 probability, but high consequence reactor accident
20 conditions, and materials area has a much different focus.

21 The case study plan was presented to stakeholders
22 on September 21 and based on stakeholder comments, we
23 finalized the plan and it was issued on October 27, just
24 recently, and we have now started working on our case
25 studies this month.

1 We will be providing results to the Commission, as
2 well as interim status reports, over the next year or maybe
3 two years. One thing that I would like to point is we are
4 also seeking early stakeholder involvement on each case
5 study that we're going to do.

6 Another aspect of the case studies that I would
7 like to point out is that we have developed screening
8 criteria to figure out which approaches might be suitable
9 for risk-informing. The first four questions that we would
10 have to ask and we would have to get a yes answer to any of
11 the above, would it resolve a question of safety, would it
12 improve our efficiency or effectiveness, would it reduce
13 unnecessary regulatory burden, and would it help us to
14 communicate a regulatory decision or situation more
15 effectively.

16 This does look a lot like our performance goals in
17 our strategic plan.

18 The fifth one, do we have information or data that
19 suggest -- or analytical models that suggest that we could
20 make a risk-informed regulatory activity, are they of
21 sufficient quality. This is something that we are
22 struggling with now, is trying to determine what is out
23 there for the given programs in the materials and waste
24 arena activities.

25 The sixth one, can startup and implementation

1 costs be reasonable. WE recognize that if we have to start
2 from scratch in developing new models, new techniques, go
3 out and seek out data that has not been pulled together
4 before, it's going to create costs that we may not want to
5 incur.

6 And costs, by the way, may be to the NRC, the
7 applicant or licensee, the public, and we would have to show
8 a net benefit. The final criteria came from the NMSS risk
9 steering group in discussions with the -- also concerning
10 the risk-informed regulation implementation plan, which was
11 just released to the Commission, I believe that's
12 SECY-00-213.

13 Do other factors exist which would preclude
14 changing the regulatory approach? It could be legislative,
15 judicial or other adverse stakeholder reaction that would
16 say this may not be appropriate to consider further.

17 We recognize that we have to do a balance that is
18 attendant to change. We have to recognize that we may not
19 be able to always want to go forward with something for a
20 variety of reasons and if so, we have to take that into
21 consideration.

22 Our eight selected areas right now that we're
23 going to start exploring whether or not we can test the
24 draft screening criteria and perhaps develop some draft
25 safety goals are in gas chromatographs, fixed gauges, site

1 decommissioning, uranium recovery, radioactive material
2 transportation, Part 76, which is primarily the GDPs,
3 gaseous diffusion plants, spent fuel interim storage, and
4 the static eliminators.

5 These are not in any particular order and we are
6 taking a retrospective look at our past decisions to try to
7 test the criteria, as well as see if there was an inherent
8 safety goal that was used to make the regulatory decision.

9 I might point out that I believe we're going to
10 start with gas chromatographs and fixed gauges and static
11 eliminators will be on the early ones done. We will also do
12 transportation in-house and I believe we're going to start
13 with a contractor with the site decommissioning, probably
14 either later this month or early in December.

15 DR. CERQUERIA: So no planned forays into medical
16 applications. You don't feel that that's high risk enough?

17 MR. KOKAJKO: Medical is an area that we did not
18 -- first of all, there was the SECY paper that was out and
19 the SRM was, I think, being drafted at the time we started
20 up a lot of this project and we felt that there was -- it
21 probably would not be prudent or reasonable to expect that
22 we could make a major impact in the medical area at this
23 time.

24 We thought long and hard about it. Cathy may have
25 provided a different perspective, I think she was in the

1 Commission office during some of the Part 35 deliberations.

2 MS. HANEY: I think where Lawrence's group will
3 come into play, though, is they will be looking at changes
4 in inspection procedures and one of the things that we will
5 hear about tomorrow is some ongoing efforts to revise the
6 inspection procedures for all material licensees and a large
7 component of that is material licensees.

8 And those revisions to the inspections procedures
9 will be to make them more risk-informed and
10 performance-based. So with that in mind, Lawrence's group
11 will be coming into play in helping with that.

12 So while superficially right now it doesn't look
13 like Lawrence's effort is touching medical, it will
14 ultimately get into that area.

15 MR. KOKAJKO: The case studies that we have here,
16 we're talking roughly a year, maybe a year and a half of
17 effort, for the most part, and if we began to look at
18 medical, it would be probably after that point.

19 And by the way, I want to get to a third topic, I
20 said we were doing three things, case studies, training and
21 assistance to divisions.

22 As things do come up from INMS on the medical area
23 that they would like us to explore, we will take a look at
24 that.

25 I'd like to briefly mention training. We are

1 developing a class now with our contractor, which is Idaho
2 National Engineering and Environmental Laboratory, as well
3 as our technical training center, to train staff on risk
4 activities in the materials and waste arenas.

5 We held the pilot in September and we hope to
6 implement the final version in December 2000. We had a
7 major review in October and we think the material is almost
8 there.

9 This is -- we're trying to establish a culture
10 change within NMSS that risk-informing and risk assessment
11 techniques should be utilized more fully in our risk
12 management decision processes, and once again, we're looking
13 at across the spectrum of materials and waste programs.

14 The final thing I would like to note is the
15 assistance that we're providing to other divisions, and this
16 list is growing. In fact, it grew just a little bit before
17 I came in this morning. We have reviewed and commented on
18 the Yucca Mountain review plan. We're looking at a petition
19 on irradiators right now. We are also looking at the study
20 that relates to the Mallinckrodt lessons learned. It was an
21 inspection issue, that Mallinckrodt had an over-exposure, I
22 believe. We also have a team member on that lessons learned
23 task force.

24 We are assisting fuel cycle in the integrated
25 safety assessment summary review of their -- at BWXT, which

1 is a fuel cycle facility, fuel fabrication for Naval
2 reactors.

3 We are also monitoring the spent fuel interim
4 storage probabilistic seismic hazards analysis for
5 independent spent fuel storage installation designs. Also,
6 we're monitoring the dry cask storage probabilistic risk
7 assessment that Research and Spent Fuel Project Office is
8 doing.

9 Monitoring the fuel cycle oversight program, which
10 is primarily inspection focused, which is similar to the
11 reactor program. Recently, fuel cycle ahs come up with an
12 integrated safety assessment approach related to design
13 basis threat and adversary characteristics, we're looking at
14 that, as well, to assist them to modify their technique.

15 Recently, the center has done a study on uranium
16 recovery in situ leaching, we're looking at that, and we're
17 considering -- and we're following a bunch of other areas,
18 as well.

19 A couple of them, recently, Yucca Mountain
20 project, DOE has suggested that they may do a graded
21 approach for structures, systems and components, and we will
22 review that, as well as a couple of other things.
23 The final thing I would mention is we are visiting a number
24 of regulated entities to -- since we come from a variety of
25 backgrounds, sort of inform our own group about some of the

1 other activities and one area we did visit just recently was
2 NIH, the radiopharmacy there and some of the other locales.
3 It was very interesting and I tried to make this as quick as
4 possible.

5 DR. CERQUERIA: You did a great job. Thank you
6 very much. I think that the intent of this committee,
7 certainly in the time I've been on it, is looking at the
8 risk and performance-based and I think it's been our feeling
9 that medical was relatively low risk and certainly the
10 revisions have tried to incorporate that, and I think some
11 of your case studies would probably help to reinforce that
12 in the future.

13 DR. DIAMOND: Can someone here give me a one
14 sentence definition of what risk-informed means, when I'm
15 asked this by my constituents? Because I haven't heard it
16 yet. What does it mean?

17 DR. CERQUERIA: Cathy?

18 MR. KOKAJKO: It is program to -- I probably
19 wouldn't do much better with writing this down first, but
20 it's a program to try to use risk assessment techniques to
21 identify vulnerabilities, such that we can apply our
22 resources in the best manner possible. It doesn't mean that
23 it is -- it does not substitute for risk management.

24 Risk management is another outgrowth entirely.

25 DR. CERQUERIA: I hope that answers your question,

1 Dr. Diamond. Should we go on to the next presentation? Any
2 other questions? I don't want to cut off discussion, but I
3 think people's stomachs are putting pressure.

4 MR. SMITH: I'm Jim Smith, from the Office of
5 Nuclear Materials Safety and Safeguards. I'm currently
6 attached to the risk task group, hopefully for a long, long
7 time.

8 The topic that I wanted to talk about was the high
9 level guidelines for performance-based activities. The
10 Commission white paper on risk-informed and
11 performance-based regulations asked that the staff develop
12 approaches that could focus a regulatory framework on
13 performance-based activities rather than always using
14 prescriptive models.

15 The staff provided a paper to the Commission in
16 99-176 on pursuing performance-based initiatives. The
17 Commission said, well, gee, why don't you come up with some
18 high level guidelines, so we have a consistent approach to
19 choosing these candidates for performance-based activities.

20 So the staff developed a working group, which is
21 comprised of members of Office of Research, NMSS, NRR, and
22 we had a staff member from Region III on that task group,
23 too.

24 We provided our draft guidelines that the working
25 group developed in the Federal Register notice and we held

1 one facilitative workshop, where we invited members of the
2 public.

3 We had a second workshop that was online, which
4 was a fairly new approach for us. We announced it in the
5 Federal Register and then we had folks sitting here manning
6 telephones, as well as computer monitors, while people sent
7 in comments.

8 One of the things that has confused folks at times
9 is when we talk about risk-informed and performance-based,
10 does one have to be one or the other or can it be a mixture
11 of both.

12 And we've come up with a flow chart that we use
13 and I will try my best to explain it to you. We have a
14 number of inputs to our decisions to pursue any type of
15 regulatory activity. One could be operating experience. We
16 could have seen things in the field that tell us that we
17 need to do something to prevent some activity from
18 occurring.

19 We could get Commission direction, if someone
20 upstairs feels it's important we cover an issue. WE could
21 have stakeholder suggestions through the PRN process, or it
22 could be something one of our staff members initiates.

23 At that point, we've got to decide on whether or
24 not we are going to modify our regulatory framework and, if
25 so, how. I can't really read that one.

1 DR. WILLIAMSON: Prioritization using NRC
2 performance goals.

3 MR. SMITH: At this point, we go through a
4 decision process, determining whether or not it, A, falls
5 through the screening criteria to make it risk-informed.
6 Also, we check what we call our high level guidelines, which
7 are more or less considerations rather than screening
8 criteria.

9 I believe the example of the screening criteria,
10 you have a yes/no answer and if you hit a no anywhere along
11 the line, you boot yourself out.

12 The considerations for our guidelines were more or
13 less just that, considerations. You would look at them as
14 guidance, but just because you answered no to any one
15 particular question, you don't automatically throw ourselves
16 out of the loop.

17 We are assuming that folks with a fairly high
18 degree of experience in the area and good common sense will
19 be looking at the guidelines and applying them in that
20 sense.

21 After you come through that, you make an option,
22 you decide how you want to do it. It could be a
23 risk-informed, performance-based, risk-informed traditional
24 approach, performance-based solely, or it could be any
25 number in the continuum in between those. We may have

1 certain parts of the regulation that would still be
2 prescriptive, certain parts that will be risk-informed, some
3 risk-informed and performance-based, and some just
4 performance-based.

5 DR. CERQUERIA: We have a question.

6 DR. WILLIAMSON: I think it would be helpful if
7 you gave a one-sentence description for all of us what
8 performance-based means, before you go on.

9 MR. SMITH: Performance-based is in lieu of a --
10 and this will be my description, my definition, not legally
11 binding on the NRC. A performance-based initiative is one
12 where you're looking at the outcomes rather than the method
13 of getting there. I think in the medical regulations, an
14 example would be of a decay in storage requirements, where,
15 in the past, we had a requirement that you hold the material
16 for ten half-lives and then measure it with a survey
17 instrument.

18 It's my understanding that's changed, so that now
19 there's no time limit, it's just the requirement that you
20 check it to make sure the material is not above background.
21 That's a performance goal. We're not stating how you get
22 there, we're just stating that we don't want it to be above
23 background.

24 At that point, we go back into our little loop of
25 decision-making, but I think that gets beyond where we need

1 to be in this discussion.

2 We have a set of guidelines, there are four issues
3 that you have to look at. First, we look at it and see
4 whether it's a viable option. Is there measurable
5 parameters out there currently or can we develop those? Are
6 there objective performance criteria? Can you look at a
7 survey meter, can you look at the number of times an
8 incident happens, or is it something that's always going to
9 be subjective?

10 Also, we didn't want a failure, a performance
11 parameter or something that would result in an immediate
12 safety concern; i.e., we don't want to be counting dead
13 bodies as the performance successes. If it fails, you want
14 it to fail in an area that gives us an indication there's a
15 problem, but not result in somebody being injured or going
16 beyond our regulatory requirements.

17 Also, once you've checked through the viability
18 assessment, if you determine that, yes, you can and, yes, no
19 one will get hurt if you do not meet these performance
20 criteria, you have to look and see whether or not it really
21 makes a difference. Is it feasible, but also does it make
22 sense? Are you actually going to give a net benefit to
23 anyone along the line?

24 If we change the regulation, are we actually going
25 to cost people more money? Also, if you look at our

1 performance goals, which are along the line of maintain
2 safety, we want to ensure that there is an adequate level of
3 safety for everyone. We want to increase public confidence,
4 increase effectiveness, which, in a way, that's a way of
5 reducing the amount of money that - I'm sorry?

6 DR. NAG: With the feedback, I'm having a problem
7 hearing you. We need to do something about the feedback.

8 MS. HANEY: Try the other microphone, try the one
9 next to you.

10 DR. NAG: You have to turn one of them off.

11 MR. SMITH: There are other issues that we look at
12 as far as --

13 MS. HANEY: You could come sit in my chair or come
14 sit here.

15 MR. SMITH: That's okay. I need to be close to my
16 notes. We have additional guidelines in the group,
17 including the net benefit test, as I mentioned earlier, and,
18 also, can we feasibly incorporate in our current regulation
19 process, is it something that we can do and inspect and
20 license.

21 And the third is are the -- is there going to be
22 consistency with our other regulation principles. There are
23 other issues that we look at besides whether or not it can
24 be performed. There may be some outside activities that are
25 being forced on us. So we may decide at that point that,

1 yes, it can, it is viable, yes, there is a benefit, and
2 there could be some change, but there are other issues that
3 come into play that won't allow us to proceed with it.

4 Last, but not least, is what we're planning to do
5 in the future. This was provided to the Commission recently
6 as an information paper, but we're planning to apply the
7 guidelines in ongoing and future approved rulemaking.

8 Now, what that means is we're not going to
9 retrospectively go out and out and seek candidates for
10 performance-based activities. As they come along, as things
11 are provided to us through that initiation process, either
12 Commission, stakeholder input, staff input, events, we're
13 going to look at them, and the way we will do that is to
14 implement our guidelines into our normal regulatory
15 processes in the form of management directives, staff policy
16 and guidance directives, et cetera.

17 Also, we're going to continue to report back to
18 the Commission on the results of our activities in the next
19 year. We're going to continue to look at the guidelines to
20 see whether or not they need to be modified, if they're
21 effective or not.

22 That's about it.

23 DR. CERQUERIA: Any questions for Jim? I think
24 they're worried about lunch. If there are no further
25 questions, I think we will adjourn until 1:10.

1 [Whereupon, at 12:20 p.m., the meeting was
2 recessed, to reconvene at 1:16 p.m., this same day.]
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A F T E R N O O N S E S S I O N

[1:16 p.m.]

DR. CERQUEIRA: If everyone could take their
seats, we'll get started momentarily.

[Pause.]

I think we should start without Kathy.

DR. AYRES: That's all right. What I'm planning
to talk about now is licensing for intravascular
brachytherapy, and I've broken it down into three
presentations, which means I've got to pause and reload.

The first two are informational. I'm going to try
to step through them fairly quickly. If anybody has any
questions, stop me.

There will be a little pause for bringing up the
next one. What I'm going to do first is describe to you,
how we presently license for participation in trials.

Then I'm going to present your experiences in
terms of misadministrations and events that we've observed
during the course of these trials, which provides, I think,
maybe some of the background with some of the problem areas
with these -- potential problem areas with these systems
that we've seen in practice, if you will.

And then we'll move on to how we're really going
to license the routine use of this technology.

DR. CERQUEIRA: Bob, just to sort of know how to

1 schedule my time, how long do you think your presentation is
2 going to take?

3 DR. AYRES: I'm going to try and speed through the
4 first two. They're usually, I'd say, about five or ten
5 minutes for the first one, and 15 for the second one, and
6 god only knows for the third one.

7 DR. CERQUEIRA: For the discussion, okay. Well,
8 that's good, because we do need to have discussion on this,
9 and okay, great.

10 We do need to have discussion on this. Okay,
11 great.

12 DR. AYRES: I envision most of the discussion
13 occurring in the third, and that's where I've prepared, but
14 I'm willing for anybody to interject into the first two and
15 to have a question or something.

16 DR. CERQUEIRA: Sure. And then we have
17 presentations from outside people as well, too.

18 DR. AYRES: Okay.

19 DR. CERQUEIRA: Good.

20 DR. AYRES: All right, I'll go ahead and get
21 moving on this, then. Like I said, this first one is on
22 what we're presently doing in license for the participation
23 in trials.

24 We actually published our guidance in an FDA
25 document which is now really outdated. I'll just note that.

1 It was also a later update to that that was done in a
2 intravascular conference presentation abstract, which is not
3 very well available.

4 As I said, it's become outdated, and if you have
5 access to Advances in Radiation Therapy, that's where that
6 was published in 1998.

7 Really, licensing is important on what class of
8 licensee we have. And the two major classifications are, of
9 course, Type A, broad scope licensees, medical licensees.

10 And they really, in most cases, don't even have to
11 come into us to participate in these trials, because as
12 standard license conditions, they have the necessary
13 exemptions to our normal regulatory requirements to
14 participate, that being the sealed source and device review
15 that exempts them from 35.49(a), and they're exempted from
16 the use requirements set forth in 35.400.

17 So, broad scopes can pretty well move on ahead,
18 although we've had problems, and that was addressed with an
19 IN awhile back, about we're delegating the responsibility
20 for radiation safety to them by these exemptions, and
21 they're not picking up the gauntlet and ensuring that these
22 are using these in a safe manner.

23 For limited specific licensees, which are, of
24 course, the larger number of ours and Agreement State
25 licensees themselves -- and I should say that what I'm

1 talking about is the way that NRC does it.

2 The Agreement States, many of them follow very
3 closely what they do; some are more restrictive; some are
4 less.

5 So, you have to talk to your local friendly
6 Agreement State to find out what differences there are.

7 Basically, we require all requests for
8 authorization to participate in these trials that come into
9 the Regions, that they be submitted to headquarters for
10 review, and basically I looked at these with six criteria:

11 First, that it had undergone a sealed source and
12 device evaluation and been registered in our registry. If
13 it hadn't, we would not authorize it; we would not grant
14 exemptions to this requirement.

15 The second one is that it had and FDA-approved
16 protocol. FDA has classified this as a high-risk human
17 trial, and therefore mandated the IDE process.

18 And so that was a regulatory checkoff that -- and
19 that also satisfied our requirement in 35.6 for the conduct
20 of human research, informed consent, IRB approval, all of
21 those components.

22 And then the appropriately-qualified user
23 physician: Essentially that boiled down to 35.400, a
24 radiation oncologist qualified in manual brachytherapy, or
25 remote afterloading brachytherapy. I'll mention one place

1 where we differed from that a little bit.

2 Then we also, in these IDE processes, which the
3 FDA had reviewed quite thoroughly -- there was embedded in
4 those, a number of radiation safety commitment. And so we
5 asked our licensees to extract those and submit those to us
6 in a separate document, because we could not incorporate by
7 reference, radiation safety commitments that were contained
8 within a confidential document, which an IDE is.

9 In some cases, these documents restricted access
10 to confidential information, which we had the right for
11 access to under the Atomic Energy Act, and just save a lot
12 of wrangling. We made sure that we were included in the
13 list of agencies that had access to that information, if we
14 needed it.

15 And then the last one is not really a requirement,
16 but a requirement on our part to issue an exemption to 10
17 CFR 35.400 for the use of whatever source or system was
18 being used for intravascular brachytherapy, because all of
19 our 35.400 uses are for the treatment cancer and none for
20 benign disease.

21 With regard to the new Part 35, that will change
22 it some, and that's been talked about quite a bit here. I'm
23 not going to go into that in any detail.

24 The main thing is that it gives us a new way to
25 write these authorizations, 35.1000, the emerging

1 technologies, and as intravascular brachytherapy is not
2 addressed within the new Part 35, it will be viewed in most
3 cases, if not all, as an emerging technology and handled
4 under that section. We'll talk about that later, because
5 that's certainly important to the routine use
6 authorizations.

7 Under existing Part 35, the training and
8 experience requirements for authorized users were pretty
9 much established by 940, which is, under the new Part 35, is
10 35.400. It's training and experience for manual
11 brachytherapy.

12 Under the new Part 35, clearly some of these
13 systems will be classified as remote afterloaders, and so
14 those that are manual afterloading devices would -- the
15 training and experience would most likely come under 35.490,
16 or be similar to those. Using 35.1000, we're no longer
17 bound to those training and experience requirements, but if
18 they're appropriate, then they're likely to be used, or if
19 it's a remote afterloading device, 35.690.

20 One problem that comes up -- and I've got one on
21 my desk now -- and we have not yet addressed this issue or
22 made any decisions. Some of these new devices use unsealed
23 sources or what I like to call contained. Generally, they
24 are gas or liquid-filled balloons.

25 They neither meet our definition of a

1 radiopharmaceutical, nor do they meet our definition of a
2 sealed source. They kind of fall in a space we didn't
3 anticipate.

4 And, again, there, what is the most relevant
5 training and experience? Is it 930? Radiopharmaceutical
6 therapy, or 940, brachytherapy?

7 Handling the material is kind of the training and
8 experience you would expect from handling
9 radiopharmaceuticals; on the other hand, the dosimetry and
10 the other issues are no different from traditional
11 brachytherapy, so it's kind of a mixture of the two, and it
12 could be a problem.

13 What we have authorized, to date, for
14 participation in these trials is the Best/Cordis System,
15 which is Radium 192 seeds and nylon ribbons, and nucletron
16 Paris study, which is the traditional high-dose rate remote
17 afterloader for treating re-stenosis and peripheral
18 arteries, primarily the femoral and the popliteal arteries
19 in the leg.

20 And early on, IN-implanted P-32 stents, it looks
21 like the have -- well, they went away, and I think they're
22 going to stay that way. It looks like there are some real
23 technology problems there that to the best of my knowledge,
24 are not solvable at this point.

25 Except for the stent systems, we used all the

1 presently authorized trials that we've authorized. There
2 are plenty of other trials that FDA has authorized that we
3 haven't, that use traditional photo emitters in the form of
4 sealed sources.

5 The stents were authorized under 35.300, and have
6 concerns related to leaching of the material and so forth.
7 I think that was inappropriate and it's been discussed, and
8 if they ever reappeared -- which seems unlikely -- we might
9 revisit how we would authorize stents.

10 Clearly, the one thing you can say about stents is
11 that it's unfortunate, I guess, that maybe the technology is
12 not working out, because they probably have the least
13 radiation safety hazard issues associated with them of any
14 of these systems.

15 And that is all I had on how we're presently doing
16 things for authorizing for trials. I'll bring up the other
17 file, and if anybody has any questions about this, I'll be
18 glad to answer them.

19 DR. CERQUEIRA: Does anybody have any questions
20 for Bob at this point? This is mostly sort of historical in
21 terms of what we've done to date.

22 DR. NAG: This may be historical, but the question
23 I have is, the NRC is in the business of radiation safety
24 aspect.

25 There are two aspects: One is the safety aspect

1 of intravascular brachytherapy, and the other is the
2 efficacy and technique of doing intravascular.

3 Now, in terms of an emerging modality, in terms of
4 -- a vessel, other than going into the issue, it is
5 different. But in terms of the safety issue, why is this
6 any different from the use of sealed sources or any other
7 therapy that means under 35.490?

8 There are no issues that are any different from
9 any of the manual brachytherapy sources. In terms of the
10 use of the remote afterloader, the -- system, the radiation
11 safety aspect is no different from 35.69 within the remote
12 afterloader.

13 So why are we now trying to differentiate
14 intravascular brachytherapy from any other brachy therapy?

15 DR. AYRES: Well, you take something like
16 Best/Cordis system, the radium seeds and nylon ribbon, and I
17 agree. There is very little difference.

18 But if you take something like the Nova system
19 with the beta emitter, there is all kind of requirements
20 that are inappropriate.

21 And there are additional considerations that maybe
22 should be in, and we'll get to those when we start talking
23 about what we should be doing.

24 DR. CERQUEIRA: Right.

25 DR. AYRES: So, like I say, they vary all over the

1 lot, particularly the liquid-contained systems.

2 DR. NAG: Yes, but that difference, we are saying
3 about the sealed sources -- I mean, the liquid is entirely
4 different, and that can come under the same category. But
5 when we are talking about the high dose rates that we use
6 for any other brachy therapy and the high dose rate you use
7 in the vessel, the safety considerations, they are no
8 different.

9 DR. AYRES: We get into some peculiar situations.
10 For example, our definitions of new Part 35, all of the
11 intravascular brachytherapy systems are high dose rates, so
12 we'll have high dose rate manual afterloading systems, which
13 we don't have now, for example.

14 And so there are a whole lot of new issues that
15 pop up.

16 Well, let me go on and talk about the problems --

17 DR. CERQUEIRA: We'll come back to this during the
18 discussion.

19 DR. AYRES: We'll talk about misadministration or
20 event. Misadministration is just something that met our
21 definition of plus or minus 20 percent or in the wrong site,
22 and an event was something of a lower significance, but it
23 was reported and of interest because it indicated some sort
24 of problem with the delivery or the system.

25 To date, we've had 16 misadministrations or events

1 reported, and counting. The trials are still ongoing, and
2 they will be ongoing for quite some time.

3 And I'll --

4 DR. CERQUEIRA: Bob, let me just ask one point of
5 clarification: We're talking about intravascular
6 brachytherapy?

7 DR. AYRES: This is purely intravascular
8 brachytherapy.

9 DR. CERQUEIRA: If those trials that are currently
10 being done -- I mean, are we still talking almost
11 exclusively about the heart, or are we doing a lot of other
12 organ systems? You did mention peripheral.

13 DR. AYRES: There's one trial that I'm aware of
14 with the peripheral arteries. And there is also some work
15 with the shunts for dialysis patients that also stenose or
16 occlude.

17 But compared to the intravascular, it's very small
18 amount.

19 DR. CERQUEIRA: To the intracoronary?

20 DR. WILLIAMSON: Yes, the cardiac intravascular.

21 DR. CERQUEIRA: Yes.

22 DR. AYRES: Yes, coronary, cardiac intravascular,
23 yes.

24 DR. CERQUEIRA: In terms of the FDA, do you have
25 any specific information in terms of the number of ongoing

1 trials and the different types of agents that are being used
2 and the targets?

3 MR. LEEDHAM: We can't specifically comment on any
4 applications that we have before us, however, I know for
5 information that's been in public venues, that there are in
6 heart, the renal system, and --

7 And a point of clarification just if I may: FDA
8 has -- we have drugs, we have devices, medical devices, and
9 we have drug/device combinations. Your example of the
10 catheter with the radioactive material in a balloon, that's
11 considered a device, however, it does have a
12 radiopharmaceutical inside, but since it's intended use is
13 not to be outside --

14 DR. AYRES: Exactly.

15 MR. LEEDHAM: It's considered fully a device.

16 DR. AYRES: I believe drugs does participate
17 sometimes, jointly in these evaluations, particularly on the
18 potential hazards, should a balloon rupture, on the
19 materials.

20 MR. LEEDHAM: Very infrequently.

21 DR. AYRES: But it is classified as a device, and
22 I'll talk some more about that issue later.

23 DR. CERQUEIRA: Okay.

24 DR. AYRES: We've had 16 misadministration events.
25 There are several dozen of these trials underway, and not

1 only vendor-sponsored, but at larger research institutions.

2 There were seven misadministrations in one; four
3 misadministration events in a second; three in a third; and
4 I'll talk about those, and then we have one each in three
5 additional ones, for a total of problems in five separate
6 trials. Some were device-related; some were not.

7 We used this information. I go around to the
8 various intravascular meetings and talk about this to alert
9 other users of the potential problems and we published an
10 information notice on a couple of these.

11 It is also why I am here, why I am presenting it
12 now. It's good guidance on what is the appropriate level of
13 regulation perhaps to govern these device approvals to
14 prevent those that would be easily preventable and to
15 provide feedback on ways to improve the device designs or
16 study protocols.

17 I think there are some interesting lessons learned
18 and I will try to point some of them out. The trials were
19 the Novoste Beta-Cath trial. I got BERT but there are
20 several trials there. There were seven there, three with
21 the guidant. The guidant is a -- well, the Novoste
22 Beta-Cath is a Strontium-90 hydraulically moved pellets,
23 sealed sources. The guidant is a P-32, HDR-driven wire.
24 The Angiorad was a hand-cracked radium wire. The Radiant is
25 one of the Rhenium-188 filled balloons, the Nucletron pair

1 study I already mentioned and the Sabre trial was a chelated
2 Rhenium-188 liquid filled balloon.

3 The first one that was reported to us was a
4 patient receiving an unintended dose to the wrong treatment
5 site by one of our licensee and in a very similar event less
6 than a month later it was reported by the State of
7 Washington with the same device.

8 This one was looked at quite extensively and
9 determined a root cause and the possible source transport
10 failure modes and this one was also one that was covered in
11 considerable detail by an information notice.

12 We looked at the factors that contributed to the
13 reported misadministration and the licensee prepared some
14 quite reasonable corrective actions to prevent this sort of
15 thing in the future.

16 DR. CERQUEIRA: So the device went out there but
17 didn't get to where it was supposed to go?

18 DR. AYRES: That's what I am getting to right now,
19 okay?

20 What the root cause was determined to be was
21 over-tightening of the Touhy-Bourst valve, which is the
22 valve that provides access to the femoral artery for doing
23 the catheterization. If you tighten this anywhere near
24 where an intravascular cardiologist would normally tighten
25 this to prevent blood leakage, you crimp the transport

1 catheter for the sources and block the source path.

2 In fact, you can put a crimp in there that remains
3 after you loosen the valve and it takes some time for it to
4 expand -- for the elasticity to return back to normal. I
5 suppose if you way overdid it, it never would.

6 Anyway, this blocked return of the sources to the
7 storage position, left them in the patient and it did allow
8 the saline flow. This system depends on two-way flow.
9 That's been changed. It is no longer saline. It is now
10 water.

11 A reversible flow in a triple lumen catheter to
12 move the sources in and out of position from the storage
13 safe, which is a hand-held device.

14 The second event more than likely had the same
15 root cause but it wasn't investigated to the extent that the
16 first one was, so we can't say with any certainty.

17 Like I said, there were identified and our
18 licensee did an excellent job of analyzing the system after
19 the event, and we pointed out that this is exactly the sort
20 of thing we would prefer to have happen before they started
21 using these new technologies -- in another information
22 notice, and identified three modes of failure, one being the
23 Touhy-Bourst valve over-tightening.

24 You can also -- the source movement and holding
25 the sources in place depend on the physician, generally the

1 radiation oncologist, holding a constant amount of pressure
2 on a device or there is an indicator to show that that is
3 being done, but any inattention in it, it seems to not
4 happen.

5 If you for example apply too much pressure you can
6 deplete the transport fluid prematurely and then the sources
7 float again, so that is another failure mode.

8 It was possible in our earlier design -- I think
9 that has been corrected -- to over-tighten the syringe to
10 the lure which supplied the transport fluid.

11 Like I said, we talked about the Touhy-Bourst.
12 There was also issued related to the training and so on. It
13 was felt that there was an excessive time interval between
14 training and start of the clinical procedures.

15 The training itself was less than optimal for the
16 didactic and practical training. There were limited and
17 very limited opportunities for self-practice and rehearsal,
18 which I think was certainly adverse and a contributing
19 effect.

20 There was lack of detailed operational and
21 emergency checklists, which is something we normally require
22 for remote afterloaders. There may be some debate. I think
23 this qualifies as a remote afterloader. I know not everyone
24 agrees with me.

25 The proposed corrective actions was to improve the

1 radiation oncology training, and particularly a review of
2 relevant interventional cardiology procedures. What you run
3 into in these collaborative efforts between in this case an
4 interventional cardiologist and radiation oncologist, they
5 are not familiar with each other's procedures, equipment,
6 and operations, and it is that lack of familiarity on the
7 parts of a team that can cause problems.

8 That could be considerably aided by providing
9 realistic training exercises in the Cath Lab environment,
10 also be conscious of possible treatment catheter damage
11 before and during treatment, develop a checklist of
12 essential steps, checks, and there also should be emergency
13 procedures checklist, and precautions to be followed in
14 executing the treatment and develop an appropriately
15 modified version of AAPM's device, called the assurance
16 protocol.

17 There is a subcommittee of AAPM now expressly
18 working on intravascular brachytherapy and I think there
19 will be some useful guidance coming out of them, and a new
20 Part 35 reference to industry standard documents and so
21 forth. Hopefully more and better information will be coming
22 in this kind of area -- daily testing of all the treatment
23 units, testing of the treatment catheter before positioning,
24 testing of the position catheter with dummy source train for
25 unobstructed passage, verification of source strength and/or

1 prescription dose rate.

2 This latter one of one issue I'll talk about later
3 is testing the catheter for unobstructed passage. That is
4 now done laying out on a table, not in the torturous
5 pathways into the coronary arteries. Maybe it might be
6 better that the dummy source train be run in and out with
7 the catheter in the treatment position rather than laying on
8 a bench.

9 Verification of the source strength and/or
10 prescription dose rate -- one of the things that one needs
11 to keep in mind and we did this and didn't put much emphasis
12 on dosimetry that we usually should, the important thing in
13 clinical trials is that everything be done consistently even
14 if the dosimetry is not optimal, because you invalidate the
15 data if you decide that you know how to do something better
16 than the trial protocol says.

17 FDA is acutely aware and reminds me of this and so
18 you don't want to do better. Everybody wants to do the
19 same, but once you go into normal use then the best
20 dosimetry should be applied. We are out of the trial and
21 into preparing data.

22 DR. CERQUEIRA: So in all three of these
23 situations then basically the device is just pulled out
24 inside the catheter, is that correct?

25 DR. AYRES: Well, this one, what happened --

1 DR. CERQUEIRA: I don't want, for the sake of
2 time, so the problem was that the source was in the wrong
3 position?

4 DR. AYRES: Yes, it was free-floating in an
5 unknown position because these are hydraulic -- so you only
6 know where the sources are at when it is in the safe or in
7 the treatment position where it is in the fluoro field.

8 Anywhere else you have no idea where the source
9 is.

10 Okay, continuing, to develop a mechanism for
11 facilitating self-initiated practice procedure review,
12 redesign a treatment to guide catheter interface to
13 eliminate the possibility of catheter damage and there's
14 been some of that done, and I will mention that when I go on
15 to the routine licensing.

16 The issues are going to be there's been corrective
17 actions. They are not now mandatory. Should they be? --
18 and this is some of the reason why I am presenting this
19 information.

20 Comments from our licensee on the corrective
21 action is that they could take care of the first three but
22 the latter three required approval and support of the trial
23 sponsor and was not in the hands of our license. For
24 routine use I think everything important related to
25 radiation safety needs to be in the hands of the licensee.

1 We wrote these up in the IN.

2 The AngioRAD ARTISTIC trial event, that one was a
3 hand-cranked iridium source on a wire, so it was like your
4 Nucletron HDR only it was a hand-crank, simpler. One of the
5 problems is with all of the current HDR systems they drive
6 the source with a pinch roller, not with the take-up drum.
7 This hand-crank device used a take-up drum.

8 You got what you might expect. They encountered a
9 blockage which was caused by over-tightening the connector
10 to the catheter to the exit so when the wire hit that
11 obstruction it acted just like a stiff rod and you got just
12 what you would get with a fishing reel, a snarl, and not
13 only snarls were bad, they couldn't move the source forward
14 or backward. It bird-caged the wire so that it was jammed
15 in the transport system, and this was a case that they
16 didn't have the equipment readily available. They had to go
17 to their HDR and get their wire cutters because this time
18 they needed them.

19 Fortunately, this occurred on the exit from the
20 machine and the patient got no real dose and they reacted
21 fairly quickly and there was no real significant dose to the
22 users either.

23 I got ahead of myself. It did have a clutch
24 mechanism but again this one depended on you turning the
25 crank at the right rate. If you turned it too rapidly the

1 clutch mechanism couldn't react in time to prevent the
2 backlash.

3 There were a number of exactly similar failures.
4 This is one that prompted the IN, including one identical to
5 it during the demonstration to this licensee which the
6 licensee never in turn reported to the Radiation Safety
7 Committee when they applied for authorization to participate
8 in the trials, which upset, rightfully so, the Radiation
9 Safety Committee and prompted our IN to say, hey, you need
10 to review the radiation safety issues before approving
11 participation in these trials.

12 Since then we have learned of two more failures
13 very similar to this, only with dummy sources. It didn't
14 feel right when they kept trying to move it back and forth
15 and finally gave up, and they couldn't verify the position
16 with fluoroscopy.

17 Unlike electronically driven systems, really with
18 most of these system you only know where the source is when
19 it is in the safe or when it is in the treatment position.

20 I have pretty well covered most of this. One
21 other thing they did, they had the wrong kind of survey
22 meter. They had a GM survey meter anywhere in the room it
23 was pegged so it didn't help them a bit in finding out where
24 the source was jammed at, so they used scissors to cut the
25 catheter until they found the source.

1 They went then with their HDR emergency
2 procedures.

3 Like I said, there was fairly minimal exposures
4 because they did react quickly to it, and it didn't, even
5 though they fumbled around a bit, it didn't take them too
6 long to isolate it and it was partially shielded because
7 they hadn't fully exited from the machine.

8 This was a U.S. Surgical Corporation, which is now
9 out of this business, sponsored device, and they did root
10 cause analysis which found out they over-tightened the lure
11 lock that connected the catheter to the device and that
12 shaved off some plastic and blocked the source pathway.

13 The Rhenium-188 balloon, it was originally
14 reported as broken and actually in further analysis it
15 looked like it leaked, but anyway it dumped Rhenium-188 into
16 the coronary arteries and it's been determined if the
17 balloon ruptures, which has an order of a 10 percent
18 probability on most balloons, angioplasty balloons, that the
19 dosimetry has been calculated to show that there shouldn't
20 be any real patient harm.

21 In both of these cases, whether it is the chelated
22 version or the oxide or the perinate itself rather, most of
23 the dose goes to the bladder, and it has a very short
24 biological half-life.

25 The radiation dose here was 50 centigrade to the

1 bladder and like I said, it is an expected event with these
2 liquid filled systems. They do take some extra precautions,
3 sometimes double balloon, over-inflating the balloon with
4 excessive pressure before actually using it and some tests
5 for burst pressure.

6 That was what they proposed a corrective action, a
7 pressure test before using the balloon.

8 The MAG, SABER trial was when they disconnected
9 from the system they flopped the catheter around,
10 contaminated the Cath Lab. Well, it there was a little
11 message there that says if you are going to use a liquid
12 contained system be prepared to give up the Cath Lab for the
13 decay of the contamination. That is what they had to do.
14 Poor Bill Bass worked till past 2:00 in the morning and
15 could not get it cleaned up and they had to close the Cath
16 Lab until it was decayed, so if you have only got one Cath
17 Lab you might want to think about using such systems.

18 Like I said, contamination events can readily
19 occur. If you can't tolerate the loss of lab, better not do
20 it and although they can occur with sealed sources the
21 probability is infinitely lower that they will happen with
22 sealed sources.

23 The nuclear trials was mostly -- were not really
24 device-related. They were mostly lack of thinking I guess
25 you would say.

1 Originally the afterloader came with a 34
2 centimeter elbow, which made the transition from the
3 non-sterile afterloader to the sterile field with the
4 catheter connected. The vendor changed that and got rid of
5 the elbow and went directly to the catheter connecting to
6 the device, and they actually had the vendor's
7 representative there and put the elbow in anyway on the new
8 catheter which meant they treated 34 centimeters from the
9 intended target position for the full course of it because
10 they thought they saw the source when they didn't. They saw
11 the guide wire.

12 One of the corrective actions when they got a dose
13 of 70 to 108 gray to the wall there, they introduced with
14 this new type of catheter, one of the problems was, one of
15 the corrective actions is they made the radiographic markers
16 on the source more visible. They were not particularly
17 sharp.

18 So it was a new procedure and they used the
19 old techniques and treated 34 centimeters away and they
20 didn't confirm properly with fluoro and again it was a
21 training issue and direction.

22 The two others were really kind of silly. Well,
23 one was just an event. The source stuck out of the safe
24 during a source exchange. It was just a failure during the
25 source exchange. There was no real exposure to anybody.

1 The other one, the radiation oncologist or the
2 medical physicist, I've forgotten which one, I think it was
3 the radiation oncologist -- on these clinical trials they
4 are double blind trials and he opened a randomization
5 envelope to find out whether they get radiation or they
6 don't, which he did, and then when he went into the
7 treatment room he forgot which arm it was supposed to be and
8 it was supposed to be receive radiation and he gave them the
9 dummy source instead, so it was 100 percent radiation
10 delivery error.

11 What is our perspective? Are they of unusually
12 high frequency? Yes. I would say these are close to an
13 order of magnitude higher misadministration rates in
14 brachytherapy in these trials, which you might expect with
15 new techniques and new technologies to a certain degree than
16 they are in the traditional cancer therapies with ionizing
17 radiation sources.

18 Can the frequency be reduced? Sure. Better
19 review of the protocols and appropriate implementation and
20 improved training, emergency procedures and checklists.

21 What else could we do? We already mentioned the
22 IN, reminding our broad scope radiation safety folks of
23 their responsibilities. That was IN-9924.

24 We expected them to do a better job and that
25 covers the issue relating to the problems we have seen over

1 a couple of years of clinical trials, with a limited number
2 of our licensees participating.

3 DR. NAG: Let me just say, we went 20 or 30 years
4 back, all right? We had most of the radiation implants that
5 were done with cesium in the cervix. Now, if you went and
6 did interstitial implants, are you going to see that as an
7 entirely new category, and therefore we have an entirely new
8 mechanism of licensing?

9 Then we have an iodine implant, which is lower
10 entity, and again you have a separate section. You know,
11 that didn't make sense to me to categorize each of these
12 like a section, because, you know, there is the broad
13 category of high dose rate afterloader, or broad category of
14 sealed source. Yes, that makes sense, because if you use
15 the same reasoning, by now we should be having at least 20
16 different categories of sealed isotopes, because I can tell
17 you the implication of iodine implant is entirely different
18 from the implantation of iridium.

19 DR. CERQUEIRA: I think part of the thing that has
20 come into this is the fact that obviously there are other
21 people that could be using these devices and some of the
22 discussions have been related to sort of more limited
23 training which is specific for a particular type of
24 treatment.

25 Similar to what you were discussing with the other

1 protocols this morning, there are some things to generalize
2 and you don't need training on every specific device, but
3 perhaps we have presentations from people. We have had
4 discussions on this. I would also like to point out that a
5 lot of the things that were misadministrations were sort of
6 really mechanical failures of the system to some extent.

7 DR. AYRES: Right.

8 DR. CERQUEIRA: Resulting in radiation problems.

9 DR. AYRES: That was one objective. I said to
10 catalogue them and determine what we could feed back to
11 improve the system, whether it is the protocol or the
12 training or the design of the device.

13 DR. CERQUEIRA: Right.

14 DR. AYRES: Or in some cases you compensate --

15 DR. CERQUEIRA: We will come back to your point
16 but --

17 DR. NAG: The second point also is important. You
18 said you would like to get and limit that application but as
19 Bob has pointed out, the safety implications are just the
20 same problem so even though it may be a low entity the
21 safety issues are exactly the same. Therefore, I feel --

22 DR. CERQUEIRA: Well, again, we can discuss this
23 when we get to it, but we have other presentations from the
24 other people.

25 DR. AYRES: And there are some different safety

1 issues which are coming up.

2 DR. CERQUEIRA: Okay.

3 DR. AYRES: First off -- again we have the same
4 situation. We have the broad scope and limited specific
5 scope and the broad scope for routine use again don't have
6 much of a problem, although some of the issues we want to
7 talk about we probably want to provide some guidance to
8 them, and I am looking for that guidance and then we will
9 flow it on.

10 Darn. I think I modified a slide set and I think
11 I goofed. I think I got the wrong one.

12 DR. CERQUEIRA: Maybe you could summarize it?

13 DR. AYRES: Yes. The main thing is I wanted to
14 point out to you that we are really going to be -- and this
15 is the second slide in your handout -- that we are going to
16 be talking about two licensing issues, old Part 35 and new
17 Part 35.

18 Really the relevant information I need at this
19 time is for the old Part 35 because we are going to have to
20 do licensing now.

21 The FDA has approved this technology and we have
22 no choice. We are going to have to license it under old
23 Part 35, which is far less flexible in many senses than new
24 Part 35, and at the end I'll talk a little about new Part
25 35, but the important issue before us right now is licensing

1 this technology under old Part 35.

2 DR. CERQUEIRA: Bob, maybe perhaps we could -- you
3 know, the FDA has approved use of devices, and have they
4 made any --

5 DR. AYRES: That's coming up.

6 DR. CERQUEIRA: You're going to have that, okay.

7 DR. AYRES: Again, right now, I'd say the four
8 criteria to look at for routine licensing, of course, always
9 is the sealed source and device evaluation registration;
10 that it's done and it's for the proper use.

11 Now, instead of an IDE, in order to be used for
12 routine use, it needs an FDA PMA, Pre-Market Approval, which
13 is at the successful conclusion of the IDE process, if you
14 will.

15 An appropriately qualified physician as an
16 authorized user, and I think under the old Part 35, there's
17 just no question that it's 35.400, that's it. There's no
18 discussion there.

19 And we'll need to grant the exemption to the
20 requirements of 35.400 because it doesn't authorize this
21 type of use. No problem; pretty straightforward there.

22 And I'd say there are really three levels of
23 licensing complexity: Simple, the Best/Cordis system is
24 really a traditional radiation oncology treatment system for
25 a different use. That's about it.

1 There are some other issues that the Regions will
2 have to be cautioned about, you know, using these
3 non-shielded cath labs that could be radiation protection
4 problems, and compliance with Part 20 issues. It's not all
5 that simple, but it's pretty straightforward.

6 The monitor of pure beta-emitting sealed sources,
7 there, we just have a lot of requirements in the current
8 regulations that really are not applicable; in other words,
9 all the shielding interlocks and that sort of thing are
10 really not applicable to those kinds of sources.

11 And the more complex ones, which we haven't yet
12 dealt with, are these unsealed sources.

13 DR. NAG: One question I have: You said -- why
14 wouldn't it be less, less shielding.

15 DR. AYRES: The what?

16 DR. NAG: The -- sources.

17 DR. AYRES: No, they're not, because that means
18 we've got a grant now, exemptions to all the requirements
19 requiring the shielding, because we're under old Part 35
20 territories.

21 So from a licensing perspective, it's a heck of a
22 lot more complex. From a use perspective, it's not. It's
23 simpler. I'm talking licensing issues.

24 DR. WILLIAMSON: That may or may not be, actually.

25 DR. AYRES: Under new Part 35, when you start with

1 a clean sheet, you're -- it's easier.

2 And somehow I mixed up my files here, and this was
3 supposed to go at the end. But as I said, 1000 is added to
4 accommodate this sort of thing, and it allows a lot more
5 flexibility, and applicable existing requirements are most
6 likely the way to go.

7 Those things that are relevant would be applied,
8 and then you write the new part.

9 DR. WILLIAMSON: Well, with regard to handling
10 this under the old Part 35, why couldn't you do it by
11 license conditions, just like you did for high-dose rate
12 therapies?

13 DR. AYRES: That's what I think I'm going to do.
14 And when -- in a just a minute, I'm getting to where I want
15 feedback from the Committee on what license conditions are
16 appropriate, okay?

17 Exactly, the mechanism isn't so important. We'll
18 certainly try to do it the best and least burdensome way on
19 the Staff here.

20 The present status of the FDA approvals: Like I
21 said, there are numerous systems undergoing clinical trials,
22 and two vendors have submitted trial results for the
23 authorization, and they have both been approved.

24 The Best/Cordis Iridium-192 seeds and the Nova
25 Strontium-90 seeds, and the hydraulically driven remote

1 afterloading device.

2 In both cases, the FDA circulatory systems device
3 panels have recommended approval with conditions. And these
4 conditions are varied, but in both cases, it's a mandated
5 team of an interventional cardiologist, a radiation
6 oncologist, and the medical physicist.

7 There are other things like tracking device
8 problems, and in both of the trials, they wanted the
9 patients followed out for further periods of time, because
10 what is unknown is any long-term adverse health effects.

11 There's reason to expect from traditional
12 radiation oncology that there might be problems five years
13 or so down the road, and this patient population hasn't been
14 followed out that far.

15 The Best/Cordis system, it was recommended -- the
16 Committee recommended on June 19th, 2000, that they approve
17 it with label changes, patient followup, and the team.

18 And it was recommended for approval for the
19 treatment of in-stent re-stenosis only. It's the same thing
20 for the Novoste system. On September 11th, it was
21 restricted to a 30 mm. device. They have a larger device,
22 and that's undergoing ongoing trials to establish its
23 approval.

24 The labeling changes and that included the team,
25 patient followup and post-market surveillance of the device,

1 failure and malfunction events.

2 In addition to the ones that I described to you
3 where the source movement was blocked, with the Novoste
4 system, there was a lot of source drift problem where if you
5 don't hold that constant pressure, the train of seeds drift
6 apart, and there are issues about whether that should be a
7 misadministration, too, of course.

8 DR. MCBURNEY: Have they made those labeling
9 changes, or was that just a recommendation?

10 DR. AYRES: They had to comply with these
11 requirements to FDA satisfaction before they would approve
12 the PMA, which has been approved, and includes good
13 manufacturing practice, inspections of the manufacturer, and
14 there's a lot of procedures. I'm sure our FDA
15 representative could address them in more detail than I.

16 Both these were approved simultaneously on Friday.
17 Okay, now, we're at the meat of this. Conditions of use: I
18 think it's important that we shouldn't approve them, license
19 them for the treatment of stenosis or re-stenosis. I think
20 we should restrict it to what the FDA has established as
21 safe and effective use, which is the treatment of in-stent
22 re-stenosis.

23 There are ongoing trials to try and establish
24 safety and efficacy in other things. I've received numerous
25 calls that we can do de novo lesions or it's good scientific

1 reasons why that might not be appropriate.

2 And the trials are ongoing to establish those
3 uses. If we condition it this way, what does that mean?

4 Well, that means that our limited, specific scope
5 licensees, that's the only thing they could do. Our broad
6 scopes could conduct their own trials if they wanted to do
7 something else, either under an IDE, if they are trying to
8 establish FDA approval, or simply under 35.6, informed
9 consent and their IRB approval for an inhouse trial. They
10 have more flexibility.

11 But I think the condition of the use that we
12 approve would be -- and limited specific could go with 35.6,
13 too -- that the use which has been established as safe and
14 effective should be what should be approved, and anything
15 outside that would be a clinical trial. That's the way I
16 think we should go with how we would approve the use of
17 these devices.

18 DR. CERQUEIRA: Jeff, you had a comment?

19 DR. WILLIAMSON: Well, yes. I mean, I think
20 perhaps that's certainly sound medical advice, and, no
21 doubt, what people will do. But if you're going to sort of
22 cast this into stone as the sole licensing criteria, at some
23 point it could become an anchor or dead weight on clinical
24 research.

25 So one could ask, FDA has its laws about following

1 the labeling, medical practice has its own internal control
2 mechanisms, so what is NRC doing in the business of
3 specifying by law, that this is the only clinical indication
4 for this device?

5 DR. AYRES: Well, FDA's is not binding on the
6 medical institutions, of course. That's called off-label
7 and not binding on the vendor.

8 DR. NAG: I have a strong feeling about this. I
9 think the job of the NRC is to deal with the radiation
10 safety issue. In terms of the medical necessity or medical
11 condition, NRC does not have any business to say about the
12 medical requirement of that.

13 So we can say yes, you know, to use that, we
14 license the use in intravascular and so forth. And it is
15 the FDA or the medical community that would decide whether
16 this is to be used, whether they are to be used for in-stent
17 or --

18 Today we have shown in-stent re-stenosis; tomorrow
19 is really possible that other uses can be possible, and FDA
20 should license that.

21 DR. AYRES: And that could, in turn, be authorized
22 fairly easily.

23 DR. CERQUEIRA: I think that's pretty much in line
24 with everything else that we have done with the Part 35
25 revision. And you've got adequate approval process from the

1 FDA, and then you've got clinical indications, and
2 reimbursement will obviously drive part of that.

3 So we really need to focus on the radiation safety
4 aspects under the existing Part 35, which is what is out
5 there right now.

6 DR. AYRES: Which I believe this to be one. I
7 mean, this is the only indication that has shown to be safe.

8 DR. WILLIAMSON: I think you should apply the test
9 of the medical policy statement to this suggestion.

10 DR. AYRES: Yes. I have, and I come out that we
11 should license for in-stent re-stenosis.

12 [Laughter.]

13 MR. LEEDHAM: Just real quickly, we do have
14 regulatory criteria for when an IND or NDA or IND or IDE is
15 required.

16 DR. AYRES: Exactly.

17 MR. LEEDHAM: So it's not like you just approve
18 something for one condition and then the world is out there
19 and is using it under the practice of medicine. So there is
20 clear criteria, regulatorily.

21 DR. AYRES: My understanding, talking with Bob
22 Phillips -- and maybe you can correct me -- is if they
23 wanted to go off-label and do it to establish clinical trial
24 data to get authorization for other uses, then it needs to
25 be under an IDE.

1 If they have no intent of using that data to
2 establish with FDA, other uses, they could do it under our
3 regulation with informed consent and their IRB approval and
4 so forth to meet the federal requirement.

5 DR. CERQUEIRA: So there is still a mechanism out
6 there.

7 DR. AYRES: There is still a mechanism.

8 DR. CERQUEIRA: And the radiation safety issues
9 are going to be identical, regardless of whether it's being
10 used in the context of a trial or for clinical applications.

11 DR. AYRES: Except that the advantage I see is
12 that a patient would be informed that they are in an
13 experimental or getting an experimental treatment, rather
14 than one that has been proven to be safe and effective.

15 DR. ALAZRAKI: But that's what happens in the
16 absence of any NRC involvement in these things.

17 DR. AYRES: Well, some places, that may happen.

18 DR. ALAZRAKI: That's exactly what happens, and I
19 can give you some concrete examples.

20 DR. WILLIAMSON: Why do you want to put this
21 additional requirement? You would prevent clinical studies
22 like this from occurring, it seems to me, by licensing a
23 specific scope.

24 DR. AYRES: The licensees of specific scope can
25 perform research under 35.6, too. It's not restricted to

1 broad scope, 35.6 authorization.

2 DR. NAG: I think the other point is that the NRC
3 has certain limits, and I think you are overstepping the
4 limit by saying that under this condition only. I mean, so
5 long as the radiation safety aspects are met, I don't think
6 you can regulate the non-radiation safety portion.

7 Otherwise, you can say that you shouldn't use the
8 I-131 for use of anything other than thyroid disease.

9 DR. AYRES: I guess the only thing I can say is
10 that the FDA panel disagrees with you with being primarily
11 radiation -- I mean, interventional cardiologists, and they
12 deemed that this is the only safe and effective -- proven
13 safe and effective use.

14 Now, that's not to say that there are not a lot of
15 other uses that wouldn't be, but they're not proven.

16 DR. CERQUEIRA: But that's not really our issue.
17 I mean, I think the FDA has been very clear on what the
18 requirements are. It's a team approach. They've clearly
19 specified who should be doing it.

20 Under the current existing Part 35, the training
21 and experience requirements are fairly clearly spelled out.

22 DR. AYRES: That is only binding on the marketing;
23 it's not binding on the use.

24 DR. ALAZRAKI: Yes, it is binding on the use.

25 DR. AYRES: No. The FDA does not -- if Washington

1 University gets one of the devices and decides that they
2 wish to treat de novo lesions, the FDA has no issue with
3 that.

4 DR. CERQUEIRA: But that shouldn't be the NRC's
5 issue. As long as they're doing it in an efficient
6 radiation safety arena --

7 DR. AYRES: It is a question of is it or is it not
8 a radiation safety issue? I think it is, and obviously not
9 everyone agrees here.

10 DR. ALAZRAKI: I think everyone disagrees.

11 DR. DIAMOND: Not me.

12 DR. NAG: If we had a vote here -- I think if we
13 had a vote here, I think we'd all disagree.

14 DR. CERQUEIRA: Let's hear Dr. Diamond then.

15 DR. DIAMOND: I'd like this for the record as a
16 point of dissent from what I'm hearing. I fully understand
17 that the FDA has no statutory authority to regulate the
18 off-label use of a drug or a medical device, and I fully
19 understand that it's not the NRC's job to go and dictate
20 what is good medical practice or not.

21 But let me just make a very clear practical point:
22 If the NRC provides guidance that there will be no
23 restriction on the off-FDA-label indication of this
24 technology, then as soon, in the next two, three, four
25 weeks, when the Agreement States and the NRC States are able

1 to get certain centers through on the final nuts and bolts
2 of using these devices commercially, what you will have is,
3 you will have individuals using these devices in the carotid
4 arteries, for AV dialysis shunts, in the infrainguinal
5 arterial system, perhaps in the great venous circulation for
6 stenoses.

7 And we really need to ask ourselves, do we want to
8 contribute into the death of any, in my opinion, reasonable
9 clinical study of this technology, because I think that's
10 what's going to happen.

11 I think what will happen is, this will become a
12 device or a technology which is going to be used in a form
13 without any proven safety and efficacy data. So we are now
14 in a predicament.

15 We recognize the statutory restrictions that both
16 parties hold, and we're in a gray zone. But from a
17 clinician's standpoint, from my particular bias, I'm very
18 concerned that in one month or two months from now, we start
19 using this for a lot of different indications, with no
20 efficacy and no safety data.

21 DR. ALAZRAKI: In my institution, if someone
22 wanted to try something like this at a site which is not a
23 recognized approved and validated therapy, they would have
24 to go through the IRB, the Radiation Safety Committee, and
25 get all the approvals, because it would clearly be

1 investigative work.

2 MS. SCHWARTZ: Right.

3 DR. ALAZRAKI: And this is an institutional
4 prerogative to enforce that type of a practice and thinking
5 when it comes to doing things which aren't clearly
6 clinically proven.

7 DR. DIAMOND: And I think there is a mechanism in
8 existence, as Dr. Ayres just mentioned, where that can be
9 done.

10 DR. AYRES: Yes, that's what point was. If there
11 are other uses to be allowed, they would have to go through
12 the clinical trial process.

13 DR. ALAZRAKI: But the NRC doesn't have to be
14 involved in that.

15 DR. AYRES: Well, I'll mention one other thing
16 where we do exactly this now, and back historically, as I
17 understand it, was that --

18 DR. CERQUEIRA: This is going to get
19 controversial, so let's get everybody's input on this, and
20 then, Ruth, you were next.

21 DR. MCBURNEY: I think there are radiation safety
22 issues when you start using the devices routinely. I mean,
23 we're already looking at a big increase in the use of HDR
24 for IVB.

25 And that's going to have operator implications,

1 the occupational dose and shielding, we're going to be
2 looking at shielding.

3 And as you add to that, use of that device, even
4 for other types of things, then you're going to add to the
5 own time and there are radiation safety issues involved
6 there.

7 DR. WAGNER: There are different radiation safety
8 issues involved.

9 DR. WILLIAMSON: That can be handled by existing
10 rules.

11 DR. AYRES: Well, one of the parallels where we do
12 this is the Strontium-90 I applicator which is restricted to
13 treatment of eye disease and is disallowed for further uses,
14 and that was on at least several times, the recommendations
15 of this Committee.

16 That's a parallel to this.

17 DR. CERQUEIRA: Jeff, you had a comment?

18 DR. WILLIAMSON: Well, I guess I have a question.
19 It seems that you're saying, on the one hand, this doesn't
20 mean anything because you could get around it by having a
21 clinical trial, and on the other hand, you're reluctant to
22 dispense with it.

23 So could you tell me, if we had this restriction
24 as you wanted, what would be prevented, exactly?

25 DR. AYRES: The routine use without informing the

1 patient that they're receiving a therapy which has not been
2 proven safe or effective and is experimental.

3 DR. WILLIAMSON: Outside of a clinical trial?

4 DR. CERQUEIRA: Let's try to keep the discussion
5 going.

6 DR. WILLIAMSON: I'm trying to. This is a point
7 of clarification. So you think that this could happen then
8 without informed consent and without IRB approval?

9 DR. AYRES: If we don't restrict it to
10 intravascular treatment of re-stenosis, yes. They could
11 treat de novo lesions. If we said just stenosis, they could
12 treat de novo lesions, they could treat any -- if we don't
13 say intravascular, they could -- coronary intravascular,
14 they could treat any location.

15 DR. WILLIAMSON: I really don't think that's true.
16 I think there are institutional protections.

17 DR. CERQUEIRA: Well, we've got the FDA here.
18 Let's perhaps --

19 MR. LEEDHAM: You're making some kind of comments,
20 Dr. Ayres, that talks about the device has been through a
21 review cycle once for another indication.

22 Now, practitioners want to use it in a different
23 area. Now, that body of information on its safety and
24 effectiveness is a building block.

25 Okay, so your statement that they're not safe and

1 not effective --

2 DR. AYRES: I was just saying that they're not
3 proven as safe.

4 MR. LEEDHAM: They're not proven, but there is a
5 basis for its safety and effectiveness for use in human
6 subjects and patients in a certain patient population.

7 DR. AYRES: Partially.

8 MR. LEEDHAM: Now, no, the trial, when we say we
9 approve a product that's been proven to be safe and
10 effective, it's safe and effective for that indication.

11 Now, if you're going to use it, as Dr. Diamond
12 said, in an off-label use, we can, in fact, and many times
13 we do restrict the off-label use of items by very clear
14 labeling.

15 We monitor the use of those devices and drugs in
16 many other mechanisms so to give the impression that once it
17 is approved and out there in clinical practice and it wants
18 to be used for an off-label use outside the jurisdiction of
19 the FDA is not true.

20 DR. AYRES: Well, I spoke yesterday with the
21 cardiology group and I think it is but I will have to
22 actually see the labeling, which I have not.

23 They seemed to indicate that they were hoping that
24 we would take this approach because they couldn't prevent
25 the off-label use.

1 DR. CERQUEIRA: Well, we have had these
2 discussions before in the sense that when the FDA approves a
3 drug physicians can use it, and these drugs potentially can
4 be, you know, deadly, harmful, and we don't put any further
5 restrictions on it.

6 I am not sure in this situation, you know, is it
7 going to be limited applications to this particular in-stent
8 re-stenosis and how much leeway does the cardiologist -- I
9 mean this is not cardiologist. This is still a team
10 approach that we are dealing with, so it is not a turf
11 issue.

12 DR. AYRES: Well, that is one of the proposals.

13 DR. CERQUEIRA: Yes. John?

14 MR. GRAHAM: I guess I need to go back to your
15 last comment.

16 You were talking to the group at FDA from
17 cardiology that doesn't potentially have the legal ability
18 to restrict this.

19 DR. AYRES: Well, he made an important point. I
20 have not read the label and the label can -- and I need to
21 do this as part of this. I mean this process is just
22 occurring and I admit that all of the information is
23 developing but I spoke with them the day before yesterday on
24 the issue.

25 DR. CERQUEIRA: Have they submitted anything in

1 writing?

2 DR. AYRES: What?

3 DR. CERQUEIRA: Have they submitted anything in
4 writing to you?

5 DR. AYRES: Well, certainly the labelling will be
6 available.

7 Now I will get it for review, but --

8 DR. DIAMOND: But this is a very important point.
9 This is directed towards Mr. Leedham.

10 Does the labelling that will accompany this
11 product, does that labelling have any statutory authority to
12 restrict the use of that product or not?

13 MR. LEEDHAM: In the sense that we could come out
14 and say that it was used off-label that it would be
15 misbranded, yes.

16 We could have that authority but we would have to
17 have a compelling public health reason to do it.

18 DR. AYRES: And I don't think that was done, but I
19 can't say for certain.

20 DR. DIAMOND: See, that is a very important
21 point --

22 MR. LEEDHAM: And I can't make a comment on the
23 labelling until I actually see it either.

24 There are a number of different things we can do
25 as far as restricted distribution to who receives the

1 products that we approve, labelling restrictions.

2 Also there have been a number of cases about
3 training programs required for physicians who will be
4 receiving devices to be used.

5 So just to say that something was approved and
6 then it just goes out there for general use without any kind
7 of oversight or further follow-up by FDA is not true.

8 DR. AYRES: No.

9 My understanding is that restrictive labelling is
10 not on this device but I don't know for certain one way or
11 another.

12 MR. GRAHAM: But even if that restrictive
13 labelling is not on there we spent two years reviewing a
14 medical policy that specifically stated the NRC will not
15 intrude into medical judgments affecting patients except as
16 necessary to provide for radiation safety of the workers and
17 the general public.

18 So if you are telling me if I use this for an
19 in-stent re-stenosis and the FDA with input from the NRC you
20 have decided that this is safe to the point of going into a
21 PMA, then if an institution wants to define a clinical
22 protocol which is within the FDA regulatory guidelines,
23 which is going to be governed by IRB, which is setting up
24 the parameters in which they want to do research on a
25 different application, that sounds like pure medicine to me

1 and that is the piece --

2 DR. AYRES: I am saying this doesn't interfere
3 with research aspects at all.

4 DR. CERQUEIRA: Let's -- let's hear from a couple
5 of the other people.

6 I mean Sally, do you have any input on this, and
7 we will come back to the other people.

8 DR. VETTER: I am speaking to this point though.
9 Go ahead.

10 DR. CERQUEIRA: Well, we will come back.

11 MS. SCHWARTZ: I just feel that this issue at hand
12 is really the practice of medicine and that essentially what
13 you are trying to regulate through NRC regulations is
14 infringing upon the practice of medicine, but if this device
15 is out there and it is safe, essentially you are relying on
16 physicians to appropriately use this device if they feel in
17 their educational abilities that they can use it for another
18 indication.

19 You are left with the basic situation that
20 patients have to rely on the doctor to tell you, you know,
21 this is what I believe is something that is good for you,
22 and if for some reason that fails, what the physician has
23 tried, I mean certainly the patient is dealing with
24 malpractice, I mean possibly, and there are avenues to
25 address this, but certainly I don't think this needs to be

1 regulated from the NRC's standpoint if the safety is
2 addressed in terms of the workers who handle the device and
3 the patients who are receiving the device.

4 DR. CERQUEIRA: Richard, do you have any thoughts?

5 DR. VETTER: No, I think I agree in general with
6 the discussion.

7 Another disadvantage of specifying that this is
8 approved only for in-stent re-stenosis, if FDA approves it
9 for some other use then we have to go through a rulemaking
10 to get that added on.

11 DR. AYRES: It's really not rulemaking since we
12 are outside of it anyway. We are granting exemptions --
13 didn't authorize it at all under old Part 35. We have got
14 to exempt the rules.

15 DR. CERQUEIRA: Let me get comments from Ruth and
16 then Lou --

17 DR. MCBURNEY: What we are doing in our IVB
18 licensing is adding a license condition that clinical
19 research of radioactive material for human use specified
20 in -- whatever it -- where we list those isotopes and forms
21 shall only be used by a licensed physician and other
22 authorized users designated by the FDA through a current
23 IDE, so it is just a license condition that authorizes them
24 to use it under an IDE.

25 DR. CERQUEIRA: Neki, from a patient's

1 perspective, do you have any --

2 MS. HOBSON: Well, yes. From the patient's
3 perspective, I think that we would very much favor the
4 system that relies on the FDA and the hospital boards and
5 institutional controls and the local level and our personal
6 physician to make decisions that are not related to
7 radiation safety.

8 NRC is the expert and has the responsibility for
9 protecting us against undue radiation hazards and I think
10 that it would be kind of over-stepping the bounds to begin
11 to prescribe -- I mean basically it is a prescription
12 here -- that the NRC would be issuing if this is put in.

13 DR. CERQUEIRA: Maybe -- we had comments from two
14 different, three different groups.

15 DR. DIAMOND: Mr. Chairman, let me just speak to
16 what you just said.

17 DR. CERQUEIRA: Yes, please.

18 DR. DIAMOND: I fully support the use of this in
19 other sites with other indications on a clinical study,
20 whether it be an individual hospital or individual
21 university, institution, on a national or local scale. I
22 have no problem with that. I encourage it. That is how
23 medicine advances.

24 What I do not want to see is this being used for
25 an indication that has no data to support it with no

1 requirement that the patient understand that this has no
2 data to support it and with no trial being undertaken.

3 I can tell you there are many, many institutions
4 in this country where the hospital would allow it to proceed
5 without any IRB review.

6 I guarantee you that.

7 If I were a patient and this were being used in my
8 renal artery or my superior vena cava or my graft or
9 arteriovenous graft, I would want to know about it and I
10 would want it to be done on a trial basis, so if we include
11 any -- so if we had that understanding that it is on a
12 clinical trial, I agree with you and everyone else here 100
13 percent but I don't want it in a month's time to be used --
14 this is just as a physician in general -- destroying the
15 clinical science, so I wouldn't go and for conditions of use
16 use the term "treatment of in-stent re-stenosis."

17 I would say "treatment of indications as approved
18 by FDA plus other indications under study." Very simple.

19 DR. WILLIAMSON: Mr. Chairman, can I point out one
20 thing?

21 DR. CERQUEIRA: Yes, Jeff.

22 DR. WILLIAMSON: Okay. Point number three of the
23 medical policy statement, I just want to read it: "NRC will
24 when justified by the risk to patients regulate the
25 radiation safety of patients primarily to assure the use of

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

3 DR. CERQUEIRA: The physician's direction is still
4 the key thing there. I understand your concerns but I just
5 don't think that the NRC is necessarily the body to deal
6 with that, and I think you have kind of heard the feelings
7 of the people in the group that -- you know, your concerns
8 are valid but they are handled by other areas within the
9 practice of medicine.

10 One last comment and then let's hear from our
11 speakers. Go ahead. Dr. Nag?

12 DR. NAG: Yes. I mean on a similar line, I mean
13 quite simply brachytherapy is useful for cancer of the
14 cervix.

15 If I want to use it on cancer of endometrium or
16 any other cancer I don't need the NRC mechanism. I mean
17 there are other mechanisms, FDA and IRB -- I certainly agree
18 with you, Dave, but it is not the NRC's position to make
19 that distinction. It is FDA and others and not the NRC's.

20 DR. CERQUEIRA: Okay. We have several groups who
21 want to make comments related to the use of intravascular
22 brachytherapy, and I am not exactly sure they were prepared
23 in terms of what this discussion ended up eventually dealing
24 with, but the first presentation will be by Dr. Albert
25 Raizner, who is a cardiologist from Baylor College of

1 Medicine, and he is here representing the ACC and the
2 Society of Catheterization, Angiography and Interventional
3 Cardiology.

4 Isn't that it?

5 DR. RAIZNER: Well, thank you. I certainly am
6 pleased to speak to the Committee. I hope you don't mind my
7 reading some of my notes and comments.

8 My son is getting married this weekend, and the
9 only thing freely floating in my brain is toasts to him, his
10 wife to be, and my in-laws to be. So I'm going to stick to
11 my comments on paper.

12 I'm an interventional cardiologist at Baylor
13 College of Medicine. I've been involved in intravascular
14 radiotherapy or brachytherapy since 1992 when we started our
15 first studies in pigs, and have been active in this field
16 since that time.

17 The purpose of my presentation is to enlist the
18 support of the ACMUI to endorse the concept of changing the
19 training and experience requirements, which would ultimately
20 allow appropriately knowledgeable and trained
21 interventionalists to be authorized users for the specific
22 use of intravascular application to prevent re-stenosis.

23 By way of background with some clinical
24 background, the most common cause of death among adults in
25 the United States is coronary disease. Since 1979,

1 angioplasty has been performed to relieve the obstructions
2 in coronary arteries by expanding balloons.

3 In the past six years, stents have been used to
4 add internal support to the expanded artery. Currently,
5 over a half of million of these procedures are performed in
6 the United States.

7 The problem is that re-stenosis or re-narrowing of
8 the artery occurs in approximately 40 percent of patients.
9 Twenty-five percent of all patients require another repeat
10 intervention to reopen the re-stenosed artery.

11 While stents have improved the safety and slightly
12 reduced the re-stenosis, those who re-stenose within a stent
13 have a particularly severe problem. While most can be
14 reopened with balloons, the chance of repeat re-stenosis
15 within a stent is higher, in the range of 50-60 percent. So
16 it represents a very vexing and bothersome problem to the
17 interventional community.

18 Intravascular radiotherapy has proven effective in
19 significantly and clinically meaningfully reducing
20 re-stenosis, and you've heard that two systems have recently
21 received FDA approval.

22 Now, angioplasty or coronary intervention is
23 performed as follows: First, a catheter is inserted into an
24 artery, usually in the leg, and advanced to the coronary
25 artery and dye is injected and pictures taken of the artery

1 and the lesion identified.

2 Then through this catheter, a soft wire is
3 introduced into the artery and beyond the obstruction. This
4 wire is used as a rail and remains in the artery from the
5 beginning of the procedure till completion to allow bringing
6 in and out, the different balloons and devices that are used
7 to complete the procedure.

8 These devices include Roto-Rooters, lasers,
9 stents, and now, the intravascular brachytherapy devices in
10 these systems.

11 At the end of this, the angiogram is repeated.
12 Sometimes other catheters are used, like intravascular
13 ultrasound catheters to measure the effectiveness of the
14 procedure.

15 And the procedure, in whole, takes from 30 minutes
16 to two hours, in general, depending on the complexity.

17 The interventional cardiologist performs the
18 procedure from the start to the finish. He or she alone is
19 responsible for the safety of the procedure. In the cath
20 lab, as in the operating room, the captain-of-the-ship
21 concept rules. It is the cardiologist that's morally,
22 ethically, and legally responsible for the standards of
23 performance and safety of the entire procedure.

24 No matter what goes wrong, the medication or
25 other, the cardiologist bears the primary responsibility for

1 that procedure.

2 During these procedures, speed is essential. It's
3 an essential safety requirement. The longer wires are left
4 in arteries, the more complications. The longer patients
5 are exposed in these procedures, the greater the extent of
6 anticoagulation, and the greater discomfort to the patient.

7 All technologies to date have attempted to speed
8 up these procedures, and one of the major accomplishments of
9 stents is to allow us to do fairly complex blockages in a
10 much shorter period of time, because of the firm scaffolding
11 effect.

12 So we're very much concerned about getting the
13 procedure completed in the most reasonable amount of time.

14 Now, intravascular brachytherapy is performed as
15 an add-on step to the interventional procedure, but it is
16 part of the interventional procedure.

17 The difference is that the guide wire is left in
18 place, that soft wire that remains in the artery. The
19 patient is generally anticoagulated to an additional extent.

20 And the major treatment parameters are determined
21 by the cardiologist. The location of where the radiotherapy
22 is required, the dimensions of the artery, these are
23 dimensions, the diameter of the artery, the length of the
24 lesion, these are the dimensions that are necessary to
25 establish the proper dose prescription.

1 What follows then depends on the system. The two
2 systems that have been approved require insertion of a
3 delivery catheter. This is essentially a hollow tube
4 through which the source wire travels.

5 And positioning and assurance of the proper
6 position of this delivery catheter, this is done entirely
7 and solely by the cardiologist.

8 Then the delivery catheter is connected to a
9 delivery unit or the source is delivered through the
10 delivery catheter. In most beta procedures, the actual
11 delivery is done by the cardiologist.

12 In others, the entire procedure, for example,
13 radioactive stents, can solely be done by the cardiologist,
14 despite the fact that it's a radioactive instrument.

15 After this is accomplished, the source is removed,
16 and appropriately stored. Who removes it depends on the
17 system. In some instances, it's a source delivery unit, and
18 in others, it's hand removal or crank removal.

19 Finally, the delivery catheter is removed, and
20 this is done by the cardiologist.

21 Arteriograms are done to assure that no injury has
22 occurred by the catheters. If so, additional work is
23 performed by the cardiologist to repair whatever affected
24 the artery. Finally, the wire is removed and the final
25 arteriograms are obtained.

1 Now, for intravascular brachytherapy we've heard
2 much about the team, the team consisting of the radiation
3 oncologist, medical physicist, and in some instances,
4 radiation safety officers, and the cardiologist.

5 And we certainly support the concept of the team.
6 There is redundancy in the safety features that the team
7 performs. Many of these safety features can be performed by
8 more than one member of the team.

9 Quality assurance, the medical physicist; room
10 preparation, the medical physicist; measurement radiation in
11 the room, medical physicist; after removal assurance of the
12 removal, medical physicist, in addition to radiation
13 oncologists.

14 So there is redundancy in the team. However, it's
15 not a team but a single individual when it comes to the
16 actual source measurement. Nobody in the team but the
17 radiation oncologist, to date, can administer the
18 therapeutic isotope.

19 And the team concept breaks down here. Picture a
20 basketball team in which only one individual was authorized
21 to shoot. The rest of the team would be passing the ball
22 around, moving up court, would have to get it to that one
23 individual who would shoot.

24 Let's say that individual was not on the court at
25 the time. You'd have to stop, bring him onto the court, and

1 then get him the ball and he would shoot.

2 So the team breaks down. And this breaks down by
3 the requirement that in all of these procedures only the
4 radiation oncologist can deliver that therapeutic isotope.

5 Now, the cardiology community is concerned about
6 safety, but a with broader definition: Safety of the
7 overall procedure. This can be jeopardized in several ways:

8 One is manipulation of catheters within the
9 coronary arteries. In some of these systems, this is done
10 by others, and we have seen some instances where catheters
11 were inadvertently pulled out, where catheters were
12 advanced. The person most skilled at manipulation of the
13 catheter, the cardiologist, may not be the one administering
14 the radiation.

15 Time, as I mentioned, is of the essence. Despite
16 the excellent intentions of our radiation oncology colleague
17 -- and we work very closely with them -- they are not
18 sitting around in our labs waiting for these procedures to
19 reach a point where they come and do their thing. They're
20 often busy in other areas, and often these other areas are
21 at entirely opposite ends of the hospital.

22 We then have to sit with that patient, with the
23 devices in these arteries, with the discomfort that the
24 patient is experiencing, and with the extra anticoagulation
25 needed, while we wait for the radiation oncologist to come.

1 Furthermore, some institutions have limited
2 availability of radiation oncologists. We're fortunate in
3 that we have a team of them involved in many projects, and
4 we generally do not have great difficulty, but it's usually
5 five to 15 minutes before one of them comes. This is added
6 time to the procedure, and in some institutions, the
7 radiation oncologist may not be available for hours, and you
8 do not know when that procedure reaches that point that you
9 need it.

10 Furthermore, some procedures occur as emergencies.
11 Patients with in-stent re-stenosis often come in very
12 unstable. The procedures have to be performed on weekends,
13 middle of the night, and times when traditionally, the
14 cardiologists are present, but some other members of the
15 team may not be readily available.

16 Since we, the cardiologists, are responsible for
17 the patient's life and safety, we're very uncomfortable
18 about the logistic problems inherent in the requirement that
19 only a radiation oncologist can prescribe and administer the
20 therapeutic isotope.

21 We're urging the Committee to consider support and
22 perhaps recommend to the NRC that training and experience
23 requirements be modified to allow a properly-trained and
24 experienced interventionalist, in addition to radiation
25 oncologists, to co-captain the radiation team.

1 This entails a reconsideration of the current
2 requirements for 200 hours of didactic teaching and 500
3 hours of practical experience currently needed to perform
4 brachytherapy or to use therapeutic medical devices.

5 Let me expand a little bit: The specific use of
6 isotopes for intravascular --

7 DR. CERQUEIRA: Dr. Raizner, you don't have too
8 much longer, so if -- I'm going -- you may have to
9 summarize, because we've got three other speakers.

10 DR. RAIZNER: Okay.

11 The interventional cardiology community has
12 emphasized radiation safety in our training programs. An
13 example is American College of Cardiology Consensus Document
14 published in 1998, entitled Radiation Safety in the Practice
15 of Cardiology.

16 There currently is a Board certification
17 examination in interventional cardiology, a significant
18 portion of which is dedicated to radiation safety. Joint
19 committees of the ACC and SCNAI are developing a knowledge
20 base and curriculum in intravascular radiotherapy.

21 We'd like to work with the members of the
22 radiation oncology community to assure that such knowledge
23 and training would assure the safe use of isotopes.

24 I will mention that there is no radiation
25 oncologist and there is no track record in which

1 intravascular application of radiotherapy is an existing
2 knowledge base. All has arise in the last several years in
3 conjunction with the cardiology community. No prior
4 brachytherapy is applied to intravascular brachytherapy.

5 In summary, we believe that appropriately trained,
6 experienced, tested, and certified cardiologists should be
7 allowed to administer therapeutic isotopes for the limited
8 application of intravascular radiotherapy for re-stenosis
9 prevention.

10 We believe that the logistics of the procedure
11 dictate this, the logic is clear, and the safety of the
12 patient enhanced, not diminished by such a policy. Thank
13 you.

14 DR. CERQUEIRA: Thank you very much, Dr. Raizner.
15 I think what I'm going to do is let all three of the
16 presenters present, and then we'll take specific questions.
17 Thank you.

18 Our next presentation will be by Dr. Tripuraneni,
19 representing the American Board of Radiology and ASTRO.

20 DR. TRIPURANENI: Thank you, Mr. Chairman for
21 giving me the opportunity. Just like Dr. Raizner, I'm going
22 to use the slides instead of the paperwork, so that I make
23 other points.

24 I'm representing the American College of Radiology
25 and the American Society of Therapeutic Radiology and

1 Oncology. I'll also make one personal comment at the end
2 regarding some of the indications.

3 The American College of Radiology is a
4 organization that is representing --

5 DR. CERQUEIRA: We don't have your slides, and
6 we'll stop the timer, so you can get ready.

7 [Pause.]

8 American College of Radiology is a professional
9 organization representing both the diagnostic and the
10 therapeutic radiologists and also medical physicists, with
11 approximately 33,000 members.

12 American Society of Therapeutic Radiology and
13 Oncology is an organization that's representing mostly
14 radiation oncologists but also a broad spectrum of radiation
15 biologists, hospital administrations, and radiation labs,
16 and we have about 6,000 members.

17 I personally have an experience of vascular
18 brachiotherapy of doing more than -- close to 400 cases in
19 the past five-and-a-half years.

20 We have done the first case in March 1995 in La
21 Jolla at our institution. I think we have done close to 600
22 to 700 cases.

23 And also, I take pride that we have experience in
24 using multiple systems, with the multiple isotopes, just
25 about all catheter-based systems, I think, at best count, in

1 looking at the broad spectroscopy of the vascular
2 brachiotherapy rather than looking at one system only.

3 ASTRO would like to congratulate our Nuclear
4 Regulatory Commission for successfully completing the
5 process of the new CFR Part 35, and I think -- we think it
6 actually was done in a really open and professional manner,
7 and also, we appreciate the opportunity that was given to us
8 several times to present our professional community
9 involvement.

10 Intravascular brachiotherapy -- we feel that it's
11 a temporary, sealed-source delivery of high dose rate, with
12 therapeutic intent, and so, we feel that it's actually
13 covered under the Part 35 training requirements, that there
14 is no further need for any discussion to look at the
15 training requirements.

16 On the other hand, if the NRC intends to include a
17 separate section for IBV, both ACR and ASTRO recommends
18 using the same rule-making process for establishing
19 intravascular brachiotherapy requirements, and we would like
20 to fully participate in that process, just like the last
21 time.

22 The intravascular brachiotherapy requirements -- I
23 think the focus should be not only on the safety of the
24 patient, along with the efficacy, but also, we would like to
25 be absolutely certain of the safety of the operators, not

1 only the radiation oncologists but the whole team and also
2 the public at large, and as you know, the team approach has
3 been used in clinical trials going back to March 1995, and
4 also, just about all the clinical trials that have been
5 conducted so far are right in there.

6 As you know and heard from several speakers this
7 morning, the FDA has mandated the team approach, consisting
8 of cardiologists, radiation oncologists, and medical
9 physicists, in both the systems that they have given their
10 approval, and I think Dr. Reizen has made several comments
11 that are practical issues, and I think, having done close to
12 700 cases, the coordination of the team can be worked out
13 and has been worked out with a relatively small group of
14 three radiologist oncologists, and at no time patients wait
15 no more than a few minutes on the cath lab table for the
16 arrival of the radiation oncologist.

17 It's just a matter of working out the details.

18 Also, we radiation oncologists have a great deal
19 of experience working with the urologists and the
20 gynecologists and neuro-surgeons in the operating room, and
21 we do work in the team setting, and we do understand that
22 the urologist is the captain of the team in the operating
23 room, as the cardiologist is the captain of the team in the
24 cardio cath lab, but we have successfully worked with those
25 other specialists for the optimal delivery of the radiation

1 and also the optimal treatments for whatever ailment that
2 they have.

3 Likewise, the radiation oncologist is solely
4 responsible for the safety of the public at large, and also
5 the operator and the patient, for that particular delivery
6 of radiation therapy in the cath lab.

7 I think there is a major source between the
8 sealed-source delivery with the therapeutic intent, as
9 opposed to the diagnostic delivery.

10 There are 16 misadministrations that are done so
11 far, and I really want to emphasize that these 16
12 misadministrations -- I do know that they have happened for
13 a variety of reasons.

14 They happened in the hands of the highly-trained,
15 very focused and motivated, coordinated expert teams. I
16 tried to use multiple adjectives so it actually comes across
17 that these are the cream of the crop that you have in the
18 United States, these 20 or 30 institutions that really want
19 to do clinical trials.

20 In the best of the hands, actually 16
21 misadministrations happened out of 2,000 patients. That's
22 one order of magnitude more than what is normally seen.

23 We are concerned that the potential for
24 significantly higher rates of misadministration in the hands
25 of a lesser-trained user can happen, so we strongly propose

1 that the training requirements be kept the same for the
2 radiation authorized user.

3 Looking at the small practice where they do few
4 angioplasties, I do not think that is the reason to relax
5 the rules for the radiation delivery, especially considering
6 the safety of the public at large and also the operators and
7 the patients.

8 If there is enough volume, the medical practice is
9 going to dictate that they will have a team in place to
10 delivery the intravascular brachiotherapy. If they don't
11 have enough volume, automatically the patients will be
12 referred to the regional centers, like it happens in so many
13 other medical procedures.

14 Emergencies -- we do not have any data what the
15 radiation therapy is going to do when a patient has acute
16 coronary syndrome.

17 Most of the patients -- just about all of the
18 patients are actually schedule two to three weeks in
19 advance, and I don't think that, actually, we need to do
20 radiation therapy at this point in time for the approved
21 indication of restenosis. So, really, that is not a reason
22 to actually worry about that.

23 In conclusion, ACR and ASTRO recommend that the
24 same training requirements be kept as we have at this point.
25 On the other hand, if the NRC intends to look at them, we

1 would like to stand by and basically participate in any
2 recommendations that we could provide.

3 On a personal basis -- this is the last slide, and
4 this is not representing ACR or ASTRO, this is my personal
5 recommendation.

6 I personally feel that I think the indication
7 should be restenosis only; that is, routine clinical use.
8 Any other use other than restenosis should be done under
9 some sort of clinical usage protocol, whether it is
10 FDA-approved doesn't matter, but I really think that
11 actually it should be done under clinical usage protocol
12 setting, whatever the mechanism may be.

13 I think I'll stop there. Thank you very much for
14 your time.

15 DR. CERQUEIRA: Thank you. Very good
16 presentation, and if we can get our next speaker to come up,
17 it's going to be Dr. Peter Blitzler, representing the
18 American Board of Radiation Oncology.

19 For those of you that are new to the board, we
20 spend a lot of time trying to keep NRC out of the practice
21 of medicine, and we adjudicate differences between different
22 sub-specialty societies in terms of training and experience.
23 So, this is a continuation of that.

24 DR. BLITZER: My name is Peter Blitzler.
25 Thank you very much.

1 I am here representing the American College of
2 Radiation Oncology. I'm past president.

3 About 20 years ago, I did three years of radiation
4 oncology residency at Mass. General Hospital.

5 Why did it take three years to do that?

6 We had extensive clinical experience, radiology
7 biology, didactic and laboratory work, and extensive work in
8 radiation physics.

9 We in radiation oncology walk a tightrope. When
10 we treat a patient, we're exploiting a subtle and complex
11 biologic principle, and that biologic principle is that
12 radiation, in certain circumstances, damages pathologic
13 tissue more than it damages normal tissue. But it's a very
14 fine line.

15 If you give a little too much radiation, you
16 damage the normal tissue beyond repair, and if you don't
17 give enough, you don't accomplish what you're trying to help
18 the patient with.

19 Let me reiterate that the job of the NRC, as I
20 understand it in their charter, is to protect the public,
21 and the public in this case is the patients, and if we have
22 people who aren't adequately trained, if we somehow decide
23 that there is now this one instance where we're using
24 radiation to damage pathologic tissue and spare normal
25 tissue and that this is a certain special instance where you

1 don't need as much training, I really think that's a
2 dangerous precedent for the NRC to take, and I think it
3 would be abrogating their responsibility to the public.

4 Let me mention, before the NRC was ever created,
5 there is history of inappropriate use of radiation in
6 treating benign disease by non-radiation oncologists.
7 Dermatologists used radiation to treat acne. ENT doctors
8 used radium sources to shrink lympho-proliferation in the
9 nasopharynx. Gynecologists/obstetricians used radiation to
10 treat post-partum mastitis, and if you're familiar with the
11 literature in any of those, you'll know that there was dire
12 adverse consequences.

13 The adverse consequences didn't happen right when
14 they were administering the radiation but happened five to
15 20 years later, and I think that, to some extent, the
16 cardiologists have kind of a cavalier attitude as to
17 radiation.

18 They want to get in there, do their thing, and get
19 out, but they don't realize what may happen five to 20 years
20 later, and that's something that we're trained to deal with,
21 and I think that we either need to be members of the team in
22 there to protect the patients or the cardiologists need to
23 undergo the full same training requirements that we have.

24 So, in summary, I support what Pravacar just said
25 to you in the ASTRO and American Board of Radiology

1 recommendations.

2 Thank you.

3 DR. CERQUEIRA: Thank you, Dr. Blitzer.

4 We sort of have two -- we have Bob, who presented
5 some questions that this panel needs to help address. We've
6 also heard three comments really related to training and
7 experience, and what's the panel's -- the committee's wish?
8 Should we take questions to the training issue? Should we
9 try to deal with Bob's problem first?

10 DR. ALAZRAKI: I thought we dealt with Bob's
11 problem.

12 DR. CERQUEIRA: Okay. We're done with Bob's
13 problem.

14 MS. HANEY: Maybe what we could do is, since we're
15 dealing with these other nine issues -- and I think they're
16 closer to radiation safety issues than medical issues --
17 maybe if we could try to go through them really quickly and
18 at least maybe get some real quick preliminary views from
19 the committee, because these are -- that's a real time issue
20 for us right now as far as doing license amendments under
21 the current Part 35, and then I think maybe spend a couple
22 of minutes just on the training and experience, almost from
23 the standpoint of maybe setting the stage for the next
24 meeting, where I think each one of these meetings will be
25 moving more and more into dealing with the intravascular

1 issues and with the training.

2 So, maybe if we just spend a couple of minutes
3 setting the stage for where we would go from here but not
4 trying to resolve anything, because I don't think we can do
5 that, and then we'll move on to the next topic.

6 DR. DIAMOND: During our break, a couple of us
7 were discussing a very important issue, which is, earlier,
8 we were discussing some concerns, whether it be with the
9 medical physicist training, the gamma knife training, and so
10 forth, and there was some discussion of how we would give
11 recommendation that there would be some guidance document
12 that would reflect some of these wishes or concerns, and my
13 question is very simple.

14 Does a guidance document or does a
15 question-and-answer supplement that addresses some of the
16 issues that were brought up -- there were three or four very
17 important issues -- does that guidance document have any
18 statutory bearing or not, because we're getting different
19 perspectives here.

20 MS. HANEY: Any of the guidance documents do not
21 carry the weight of the rule.

22 For the most part, they do carry a weight from the
23 standpoint of explaining what was intended, and unless they
24 fall into conflict with the rule, they're a tool, they're a
25 benefit.

1 If you run into a -- we can't have a situation
2 where a rule and a guidance document are conflicting,
3 because the rule will always override any guidance document,
4 and this is a non-lawyer's interpretation of what's going
5 on, so when OCG sees these minutes.

6 So, I think, David, at least what was identified
7 first thing this morning, there's nothing from my standpoint
8 that puts us in conflict with the rule that's on the book.

9 So, I think a lot of these issues, maybe not all
10 of them that came up this morning, but a lot of them I think
11 can be resolved by adding either something to the statements
12 of consideration or by adding something in a
13 question-and-answer sort of format.

14 DR. DIAMOND: I understand.

15 DR. CERQUEIRA: And then, sort of, again, to
16 follow up on David's question, I mean -- and what he
17 proposed was actually going back and trying to revise what
18 has already gone to the commissioners, so that it was more
19 direct.

20 DR. DIAMOND: I hope we don't have to do that. I
21 pray to God we don't have to do that.

22 MS. HANEY: I think, from this standpoint, we're
23 in a situation where the document, as modified, with the
24 items from the statements of consideration that the
25 Commission approved -- if I change that any, I would need to

1 go back to the Commission.

2 I don't believe that, unless there was a fatal
3 flaw, that the rule would get opened again, only because
4 then we get back into a proposed stage, public comment
5 stage, things like that.

6 I think if we went back to the Commission and
7 suggested some minor changes or addition of a sentence here
8 or there to the statements of consideration, I can do that
9 in a less formal manner, as stepping into the Administrative
10 Procedures Act, because it is just saying what was the
11 intent in helpful guidance.

12 Now, I have to get all that cleared through Office
13 of General Counsel and, you know, the powers that be here at
14 NRC, but I believe that we can work some type of arrangement
15 to get some of these issues into the document that goes out
16 in the Federal Register, and if not, we would handle it as a
17 separate document, as an addendum.

18 We're in a good position, because theoretically,
19 we don't have implementation for a year from now. So, if it
20 requires another Commission paper and another SRM, things
21 like that, we have time to go through the more formal
22 process, but the first things that I would attempt to work
23 with would be, say, a less formal process and just say --
24 because I think, really, all we are doing is clarifying the
25 intent of what was intended over the last three years.

1 We're not really changing anything.

2 DR. CERQUEIRA: And I think it was pretty much our
3 understanding that, you know, in terms of the radiation
4 therapy treatment, that if you didn't require everything --
5 but that it's only when we basically started the
6 implementation by doing the boards that the issue came up.

7 I am certain there's other things where we had
8 assumptions which, if you really question them, there may be
9 some variability of interpretation and we have to basically
10 do that for everything, and I think it's not worth this
11 committee's time.

12 DR. DIAMOND: I understand.

13 DR. CERQUEIRA: Okay.

14 DR. AYRES: The specific safety precautions are
15 addressing the issues I brought out in our misadministration
16 presentation.

17 The most likely over-exposures to personnel with
18 many of these devices is actually grabbing the catheter
19 where the sources are.

20 So, I think one appropriate radiation safety
21 precaution would be to wear extremity dosimeters when doing
22 this kind of work. This would be, you know, a license
23 condition type of requirement or proposed license condition
24 type requirement.

25 The other one is, as I said, in the one device, we

1 identified two failure modes, which the vendor has supplied
2 corrective actions. However, they're not required. The two
3 corrective actions are a back-up already attached, a fluid
4 supply, in case you have premature exhaustion of fluid, and
5 the other is what's called an introducer sheath to prevent
6 crimping in the catheter, and the issue is whether we should
7 require those by license.

8 DR. WILLIAMSON: I'm sorry. These sound like
9 they're very specific precautions for individual devices.
10 Is it your intent to require a license amendment for every
11 single device?

12 DR. AYRES: Well, we're going to have to do these
13 individually by license amendment, because Part 35 -- we're
14 talking -- I'm only talking old Part 35, that's what we've
15 got to do now -- requires each one to be addressed
16 individually, because they individually have to be exempted.
17 There is no provision to licensees now.

18 DR. CERQUEIRA: The paperwork and costs and
19 everything else associated with that is tremendous.

20 DR. WILLIAMSON: If one has the CORDIS system and
21 then wants to go with one of the other iridium-based or
22 photon-emitting systems, a separate license amendment is
23 going to be required.

24 DR. AYRES: Yes.

25 DR. CERQUEIRA: Cathy has informed me that there's

1 no way of getting around that. So, that's a given.

2 MS. HANEY: But that's one of the reasons why
3 we're trying to fix Part 35.

4 DR. AYRES: Right now, we've got to do it with the
5 least flexible capability.

6 DR. ALAZRAKI: With the new Part 35, how would
7 that be different?

8 MR. GRAHAM: This could be up to four years from
9 now with states. So, we're not talking just a year.

10 DR. AYRES: There's also a lot of this that's not
11 likely to be a compatibility requirement either with
12 agreement states.

13 DR. ALAZRAKI: Cathy, with the new Part 35, how
14 would that be any different?

15 MS. HANEY: Well, if we would make the decision
16 once and for all that this is, in fact, 35.1000 and we have
17 enough experience, we theoretically would move into a
18 proposed rule stage that would deal with this type of use,
19 and you'd almost set up a whole new set of regulations, so
20 you're not dealing with it by license amendment.

21 The other way you can deal with it is 35.400 in
22 the new rule says that you can use any source as long as it
23 is approved in the sealed source and device registry for
24 that type of use, and I'm not familiar enough with the SS&D
25 sheets on these, but if the sealed source and device sheet

1 allow this type of use, then it actually does fall under
2 35.400 in the new world, in the new Part 35, and then you
3 could go ahead and start using it.

4 Now, the one issue that would have to be addressed
5 under that is there may be some requirements in 35.400 that
6 do not apply to this type of use, and then you would need to
7 be exempted from those couple of requirements, but that's --
8 a little bit of this is waiting to see when -- you know, how
9 things all fall out with the uses and what's being used, but
10 we're closer to not having to require an amendment for each
11 one of these with the new 35.

12 I mean we're not completely there, but we're a lot
13 closer than we are right now.

14 The problem with the current regulations is the
15 35.400 has specific sources tied to specific uses, and this
16 is just not there.

17 DR. AYRES: The way we hope to go is issue some
18 guidance to the regions and out through the agreement state
19 programs and the way we think this out to go, and that would
20 be the first thing, and ideally, later on, we could set
21 conditions for classes of device, such as proton-emitting,
22 beta-emitting, un-contained, but it's a little earlier right
23 now.

24 DR. CERQUEIRA: So, I guess the feedback is we
25 feel that this is burdensome, but there doesn't seem to be

1 any way out of it.

2 DR. WILLIAMSON: I think that we ought to be
3 fairly parsimonious and not be more specific than is
4 necessary for safety.

5 So, for example, the ALARA program requires
6 badging and wearing of finger badges whenever there is a
7 possibility of exceeding the MPD. It really does.

8 So, why is it necessary to have a specific
9 regulation for that, because maybe you might have some
10 system where, in fact, it's not necessary to touch it, like
11 a high dose rate.

12 DR. AYRES: That's why I'm just putting it out for
13 comment.

14 DR. WILLIAMSON: Well, I'm commenting, okay?

15 I don't think we -- I think you should really,
16 really avoid narrow technical requirements that apply only
17 to single systems and do your best to try and make them
18 generic as you can be under the circumstances and realize
19 this is going to propagate through the whole agreement state
20 system, and we may, indeed, be saddled by these restrictive
21 regulations, even in the 35.1000 area, because you know,
22 that certainly happened with the temporary licensing
23 guidance for high dose rate and remote after-loading. It
24 was very difficult to undo some of that.

25 DR. AYRES: Well, I can give you one of the

1 reasons why it should be.

2 I can tell you from experience and very recent
3 experience that, if we have mis-administrations that are
4 device-oriented -- in other words, due to some weakness in
5 the device -- they're always rapidly addressed and
6 corrective actions are demanded, and if we can prevent
7 those, we're way ahead of the game.

8 It can result in, you know, barring the use of the
9 device till redesign or something. If we can take care of
10 it administratively and prevent it, we may be ahead of the
11 curve.

12 So, if we know there's a weakness and we don't
13 address it and we start running into -- several
14 misadministrations is all it takes.

15 DR. WILLIAMSON: I'm talking about, you know,
16 finger dosimeters. It's certainly easy to punish somebody,
17 and everybody will know that, and then they'll do the right
18 thing. Why is it necessary to impose a big regulatory
19 effort?

20 DR. AYRES: That's not a big issue.

21 DR. CERQUEIRA: Hold on for one second.

22 We have a representative from Novost who Cathy
23 feels has some information that may help clarify a few of
24 these issues, and I suggest we let them -- a very brief
25 presentation, perhaps.

1 DR. REED: Thank you for giving me this
2 opportunity to speak.

3 The first thing I'd like to say is -- well, I'm
4 Craig Reed. I am a health physicist. I am also a former
5 radioactive material license reviewer and a seal source and
6 device evaluator with State of Illinois, and I'm currently
7 the radiation regulatory manager with Novost Corporation and
8 have been for several years, and let me say this up front.
9 I have, you know, had the opportunity work around Dr. Ayres
10 and see his work, and I have been very impressed with the
11 level of detail and the tenacity at which he has taken this
12 effort, and only a former regulator can appreciate that.

13 So, I would like to commend the effort that Dr.
14 Ayres has done. I know he's done a lot of work on this, and
15 there are a lot of devices and a lot of issues.

16 DR. CERQUEIRA: We need to be very focused,
17 though, because of the time restraints.

18 DR. REED: Okay.

19 I think Dr. Ayres has presented a lot of
20 information about devices, but let me say this right up
21 front about the Novost Beta Cam System.

22 The device has been evaluated. There's a sealed
23 source device registration certificate for the device. The
24 State of Georgia has evaluated it and deemed it suitable for
25 licensing, and that's typically acceptable by the states and

1 NRC systems.

2 It's also been through the FDA PMA process. We've
3 treated a significant number of patients, and we can say the
4 device is safe and effective, and I think to come to a
5 committee meeting here and attempt to dissect the device
6 design or, you know, present, you know, regulatory barriers
7 to a treatment that might be very significant to the
8 population of the United States is a mistake, and I think we
9 need to focus on the big picture, on how we can accomplish
10 getting this device into use.

11 Currently, everyone under limited scope needs an
12 amendment to get this device because of the way the existing
13 rules are written, and to the extent that that could be
14 avoided in the future, that would be great.

15 I've read the proposed 1000, and it doesn't seem
16 to preclude that, okay? It seems to suggest that anything
17 you use that's not existing in the current regulations is
18 going to need an amendment.

19 So, you know, I don't see that that's being
20 resolved here.

21 You know, what I would like to see is the medical
22 use committee focus on, you know, what it takes to get this
23 new device into use.

24 So, I just want to say that.

25 Thank you.

1 DR. CERQUEIRA: Jeff, a quick comment?

2 DR. WILLIAMSON: I take that as supporting what
3 I'm saying.

4 I think tiny little things that apply to
5 individual systems should not be there, and I think there
6 should be like a guideline that says the license amendment
7 should address known mechanisms of the device that cause
8 source retraction failure.

9 That would be a nice general requirement and would
10 force all of the users to look into the sort of history of
11 the use of the device and make individual precautions as
12 necessary and in a flexible way, because what happens if
13 they fix the catheter so you don't need an introducer sheath
14 anywhere? Then you have to write a license amendment to get
15 rid of that small technical provision.

16 So, I think this is not a reasonable approach.

17 DR. REED: From a risk-based perspective, the
18 device has been evaluated safe and effective, and what else
19 do we need to say here? The device design has been
20 evaluated. It's safe and effective.

21 DR. AYRES: Well, of course, that's always
22 subjective.

23 Now, understand, safe and effective means that, in
24 risk-benefit, benefit outweighs risk. There are risks with
25 all of these intravascular brachiotherapy systems.

1 DR. CERQUEIRA: So, you've got like nine things.
2 Maybe we could -- why don't you just run through the list,
3 and we can go back, perhaps?

4 DR. AYRES: These are just considerations, and
5 part of them are based on, during the trials, observed
6 problems and attempts to avoid them.

7 Others are just cautions to users. Clearly,
8 they're going to need to amend their quality management
9 plan, because this is a new modality.

10 What about written directives? There are certain
11 things, one needs to review that, but there are known things
12 that are done that are done differently in cancer therapy.

13 In other words, when a patient suffers ischemia, a
14 non-fractionated treatment becomes fractionated. There's
15 really no problem with that, but is there a problem with the
16 language? We need to look at that. And clearly, treatment
17 is terminated if medical complications necessitate it
18 prematurely, and that shouldn't constitute a violation of a
19 written directive or anything.

20 Those issues need to be looked at. I understand
21 -- and if there's any others --

22 DR. CERQUEIRA: You don't have the list for us,
23 but those are the items that you specifically need to make
24 decisions on, right?

25 DR. AYRES: If anybody had any comments about

1 things that could run afoul of our regulatory requirements
2 because of some requirement, new modality, we should try to
3 remove that barrier, if it's reasonable to do so.

4 DR. CERQUEIRA: And I think you've heard the
5 committee say that, you know, there's been testing with the
6 device by the FDA. You've heard the manufacturer make some
7 comments about approval in Georgia.

8 DR. AYRES: I understand all that.

9 DR. CERQUEIRA: And we should try to basically
10 either, you know, make those requirements that you've
11 listed, you know, a one-amendment thing that can be done for
12 the license, rather than multiple, in the best way possible.

13 Some of the other issues, again, I think we can
14 try to incorporate.

15 Some of those things are the practice of medicine,
16 you know, the decision to stop a procedure.

17 DR. AYRES: What's I'm saying is we want to avoid
18 realistic practice of medicine issues causing violations
19 with our existing regulations, which it can happen if we
20 don't write the licensing properly.

21 DR. CERQUEIRA: Okay.

22 Jeff?

23 DR. WILLIAMSON: I am sympathetic. These are
24 certainly all problems, but they are all problems that exist
25 with, you know, all existing brachiotherapy modalities.

1 The amendment to the QMP, if this falls, it's
2 licensed under the existing 35.400. Why is the current QMP
3 language not adequate?

4 Secondly, you know, a treatment -- any
5 brachiotherapy treatment can be interrupted by the
6 authorized user based on the medical condition of the
7 patient, and that entails, you know, a verbal order to
8 terminate the treatment and then a follow-up amendment or
9 revision to the prescription within 24 hours.

10 So, why isn't that language okay?

11 DR. AYRES: Well, the unusual aspect that isn't
12 covered is going from un-fractionated to fractionated just
13 because of temporary ischemia, and then they retreat, and so
14 on.

15 DR. CERQUEIRA: I guess what we're trying to do is
16 keep it simple, and if you've got rules out there that may
17 already be in place for other types of radiation therapy,
18 then they should be applicable here, and so far, none of the
19 things that you've identified are unique for this
20 application.

21 DR. AYRES: Not entirely, no.

22 DR. NAG: As I'm listening to all of these points
23 -- I've been doing brachiotherapy for a long, long time, and
24 similar problems have come up with all the other kinds of
25 brachiotherapy I have done.

1 So, why do we not make life a lot simpler for
2 everyone, a lot easier for rulemaking? Place intravascular
3 brachiotherapy in the same context as 35.400, and all the
4 problems are the same.

5 DR. CERQUEIRA: That's where it is under the
6 current rule.

7 DR. WILLIAMSON: It's not possible to do that
8 under the existing framework. That's the answer.

9 DR. CERQUEIRA: This is for licensees of specific
10 scope. That means anything that's not identified in Part
11 35, like iridium-192 for cancer, iodine-125 for cancer,
12 requires a license amendment. There's no way around that.

13 We can't argue away the license amendment. So,
14 what we're trying to do is decrease the amount of paperwork
15 that's involved.

16 DR. WILLIAMSON: I'm mean there's just no question
17 that this is a license amendment issue.

18 DR. CERQUEIRA: So, what other specific things
19 have we not addressed? I would suggest, in the future, if
20 you could give us a list, preferably ahead of time, people
21 on the plane could at least begin to --

22 DR. AYRES: Well, there was a little mix-up on the
23 distribution of the hand-outs which I had prepared a couple
24 of weeks ago. The intention was there to do that. I made a
25 deliberate effort to do that. There was an administrative

1 problem, so it didn't happen. My apologies.

2 DR. CERQUEIRA: So, what other specifics can we
3 answer for you? I mean we've got this body of experts here.

4 DR. AYRES: I think everybody recognizes we've got
5 specific licensees and exemptions for each and every one,
6 and I just listed some sample issues, and if the committee
7 has any, I'd be glad to hear them, but we're going to have
8 to get some guidance to start down that path.

9 MS. HANEY: We'll also take e-mails after the
10 meeting.

11 DR. CERQUEIRA: If you could send us the specific
12 list of items in an e-mail, we could basically --

13 DR. AYRES: Well, I think the next thing that will
14 happen will be the guidance getting out. We're kind of up
15 against it right now.

16 DR. WILLIAMSON: I think the only thing on here
17 that looks like it's unique -- number two, licensing issues,
18 number two -- is the emergency procedures and response
19 training. I think, indeed, that is specialized, and there's
20 probably reason to expect a special plan, more like
21 high-dose-rate brachiotherapy.

22 Use in un-shielded cath labs -- I mean that's
23 covered by existing regulation. I don't see a problem.

24 DR. AYRES: My intent with that is -- I would
25 caution our regions to be conscious of evaluating the 10 CFR

1 Part 20 requirements, because it could easily be exceeded.

2 DR. WILLIAMSON: But existing 35.400 and Part 20
3 covers that quite adequately. Everybody knows what they
4 have to do.

5 DR. AYRES: Nothing new, just a caution.

6 I don't think we should get into new Part 35.
7 It's too premature. We can talk about that after we get
8 more experience and it gets closer.

9 DR. CERQUEIRA: Maybe we could bring our three
10 speakers back. We'll take like 10 minutes of questions and
11 we'll break at 3:30 for like 10 minutes and then we'll come
12 back and finish the agenda.

13 DR. NAG: I have a question and comment.

14 One of the major problems in intravascular
15 brachiotherapy was the fact that the radiologist had no idea
16 that the radiation source -- you will not have the
17 three-dimensional knowledge.

18 All of these require more than just a few hours of
19 training in radiation oncology, because you have to have a
20 three-dimensional radiation dosimetry that requires a few
21 hundred hours, and when you have a radiation oncologist with
22 all that background, it is to your benefit.

23 You want the procedure to go quickly. If you are
24 administering the catheter in and out and you have someone
25 else, that will be faster for your patient to have two

1 people rather than to have the same individual.

2 DR. CERQUEIRA: You're making a lot of statements.
3 You need to ask some specific questions and give them a
4 chance to respond. I don't mean to cut you off, but we have
5 them sitting there, and let's not think of this as
6 oncologists versus, you know, radiologists. We're dealing
7 with patient safety issues.

8 DR. NAG: Having both together will help the
9 patient safety.

10 DR. CERQUEIRA: Try to make the comments brief and
11 ask specific questions rather than making more comments.

12 DR. NAG: In terms of the emergency issue, what
13 happens in your hospital when a patient with a radiation
14 implant needs an emergency to have the implant out? Don't
15 you have a radiation oncologist who can come within the next
16 15, 20 minutes to remove an implant?

17 DR. RAIZNER: Well, I can't say, because we're not
18 involved with the emergency implants in other departments,
19 and yes, that is likely to be available in our hospital but
20 not necessarily available in other institutions.

21 Now, I'm not advocating that every hospital in the
22 United States or in the world have this resource available,
23 but the availability of radiation oncologists is variable in
24 different institutions.

25 DR. BLITZER: I would challenge that statement.

1 There are over 4,000 board-certified radiation oncologists
2 in this country. If you care to look at the ASTRO
3 directory, you'll find radiation oncologists in virtually
4 every even small medical community.

5 DR. CERQUEIRA: Well, this isn't a fact-finding
6 group here. We're not here to address those kind of issues.

7 We'll keep going. One question -- really, try to
8 make it a question rather than a statement.

9 Dr. Diamond.

10 DR. DIAMOND: Dr. Raizner, at your institution,
11 who provides the radiation consent for your vascular
12 brachiotherapy procedures?

13 DR. RAZNER: All of these patients are done on
14 protocol. The protocol requires not only the cardiologist
15 to explain the procedure but the radiation oncologist to
16 meet with the patient beforehand and discuss the radiation
17 specific issues.

18 DR. CERQUEIRA: Jeff?

19 DR. WILLIAMSON: Couldn't the conflict between the
20 training and experience requirements requested by Dr.
21 Raizner and the two radiation oncology representatives be
22 dealt with by more flexible technical requirements that
23 would, say, not necessarily require the physical presence of
24 the radiation oncologist to actually load the source into
25 the patient but be involved up front with the signing of the

1 written directive and the consenting of the patient?

2 DR. BLITZER: I'll take a stab at that.

3 Each patient -- we're walking that tightrope
4 between delivering too much radiation and too little.

5 There's decisions that have to be made based on the
6 distribution of the radiation in an individual patient.

7 There's no way to do that in a a priori way.

8 You've got to be there, and you've got to take an active
9 decision-making role.

10 DR. TRIPURANENI: When things are going well, I
11 think they do go well. I think the training and expertise
12 really comes into practice when things go wrong, such as
13 basically a misadministration or basically some sort of
14 accident.

15 That's where I think the authorized user can
16 really make a difference.

17 DR. RAIZNER: I would argue that all of the
18 current use of radiation for restinosis in an artery is
19 recent data and none of this is present in traditional
20 radiation oncology literature or training prior to the
21 introduction of this field five or six years ago.

22 DR. BLITZER: There's nothing unique in the way
23 radiation affects the cells in coronary arteries. The
24 radiation biology has been established for 20 or 30 years.
25 That's not true. And there's nothing unique about the

1 physics of the way this brachiotherapy is done, as Dr. Nag,
2 I'm sure, can tell.

3 DR. MCBURNEY: If there were to be some other
4 training and experience requirement for the specialized
5 procedures, either for stents or for the remote
6 after-loaders, what would you recommend?

7 DR. RAIZNER: I would recommend something more
8 akin to the use of radio-pharmaceuticals, in which the same
9 safety issues potentially prevail, perhaps some blend
10 between the two requirements, but the requirement of 500
11 hours of didactic training and 200 hours of practical
12 experience seems very excessive to us for this field of
13 recent knowledge and very limited application.

14 It is not cancer. It is not cancer of other
15 organs, and we agree that the radiation oncologists have
16 vast knowledge in these other areas. This is a very limited
17 and specific use.

18 DR. CERQUEIRA: I'm here as a cardiologist, as
19 well, so I'm kind of in an awkward position, to some extent,
20 but do you envision every cardiologist doing this, or what
21 do you see as the requirements? Which cardiologist and what
22 kind of training should they have to do this?

23 DR. RAIZNER: I certainly do not see every
24 cardiologist doing this, and I believe that, if one sets
25 training requirements at levels which require a full and

1 exhaustive knowledge of this specific field, that we will
2 eliminate probably 80 percent of cardiologists from seeking
3 that kind of training.

4 I'm not asking for a weekend course. I'm asking
5 for a full in-depth training program covering the full body
6 of knowledge that's needed and the experience, and not many
7 cardiologists would have the wherewithal to achieve either
8 that education or that experience.

9 So, it would not be thrown open to the cardiology
10 public in general.

11 DR. CERQUEIRA: There is a fourth year, you know.
12 Basically, people are doing three years of cardiology
13 training, and there is an interventional cardiology program.
14 Do you see that as the people who would be doing it,
15 basically three years of medicine, three years of
16 cardiology, and then an additional year of interventional
17 cardiology?

18 DR. RAIZNER: I would see this as either
19 incorporated into that year of the training or as an
20 extension beyond that year of training.

21 I do not see the current training as adequate for
22 this field.

23 MR. LEEDHAM: This question is for Mr. Reed.
24 Did your investigators in the clinical trials have
25 training programs that they were required to go through?

1 DR. REED: Yes, there was proctoring required as
2 part of the clinical trial for those positions.

3 MR. LEEDHAM: Okay. And criteria for who could
4 participate in the trials?

5 DR. REED: Yes, cardiologists, oncologists,
6 medical physicists, radiation safety officer, as a team,
7 yes.

8 MR. LEEDHAM: It might be helpful if that kind of
9 training program would be provided to the NRC staff, so they
10 could see what training was provided or participated in.

11 DR. REED: Of course, that is part of our required
12 FDA approval, and the training manual has been submitted to
13 State of Georgia as part of our sealed source device
14 registration.

15 DR. CERQUEIRA: Richard?

16 DR. VETTER: From the patient's perspective, I've
17 heard various numbers, up to several hundred thousand people
18 who are going to need this procedure. Will the radiation
19 oncology community be able to assist the cardiology
20 community in meeting that need?

21 DR. TRIPURANENI: We looked at the numbers, and I
22 think it's estimated that there will be approximately
23 100,000 patients.

24 At this point, the current estimates are radiation
25 oncologist time involvement would be approximately 60 to 90

1 minutes per patient, and if you look at the regional
2 centers, relatively medium to large-volume centers, it is
3 anticipated that it will be covered adequately, with some
4 modifications in the personnel moving back and forth.

5 DR. WAGNER: I think the issue here is quite
6 clear.

7 The issue just boils down to a matter of adequate
8 radiation safety training in order to get these procedures
9 done, and the question has been raised as to whether or not
10 the 200 hours of classroom and the laboratory training is
11 excessive and whether or not the 500 hours of work
12 experience is excessive, and I think that's what Dr. Reizner
13 is raising, this issue.

14 Do you have any recommendations, Dr. Reizner, as
15 to specific changes that could take place that would
16 adequate meet the radiation safety needs of these
17 procedures?

18 MS. HANEY: I think when you're answer that
19 question, though, I think you need to go beyond the 200 and
20 the 500 and look at the three-year requirement, because I
21 don't really think -- and that's in the current regulations,
22 as well as the new Part 35, because I don't think -- at
23 least over the last three years, the issue that I've heard
24 is not so much whether someone has 200 hours of didactic and
25 500 of practical, it's the three years in radiation

1 oncology.

2 DR. CERQUEIRA: The last time we had heated
3 discussions on this -- I mean the issue was the three
4 clinical years.

5 I mean should a cardiologist have to do three
6 clinical years?

7 DR. WAGNER: Yeah, I think that's the issue that
8 really has to be addressed.

9 Dr. Reizner, did you have any specific
10 recommendations as to how the current rules should be
11 changed to meet those needs?

12 DR. RAIZNER: I'm not prepared to give specific
13 hours, no.

14 I am prepared to say that I believe that some of
15 the training and experience requirements that are in place
16 for the use of radio-pharmaceuticals could provide a basis
17 from which T&E requirements for intravascular brachiotherapy
18 can be met.

19 DR. WAGNER: I guess I would have a comment with
20 regard to that, and that would be this.

21 I've seen most of the training and recommendations
22 that come out of the cardiology community, and they are
23 mostly related to diagnostic.

24 They are not really specified for the higher
25 intense and more risk higher doses that would come with this

1 kind of treatment, and they would have to be revised to meet
2 those standards, because this is a risk-based type of policy
3 now, and the question is what's the risk with regard to
4 radiation, what are the levels that are being used, and
5 what's the training that's really necessary to make sure
6 delivery is adequate.

7 I think, right now, the FDA is requiring that the
8 oncologist be part of that team. It's not us here. It's
9 the FDA that is requiring part of that team, and it's for
10 the purposes of meeting the needs of the radiation safety as
11 it presently exists.

12 So, I think this committee has always been willing
13 to review things on an as-need basis, but I think we would
14 have to have some specifications and better recommendations
15 with regard to specifics as to what is adequate to really
16 meet the needs in this higher-risk situation.

17 DR. CERQUEIRA: I think that's probably what we'll
18 end up going to at future meetings.

19 John, you had a comment.

20 I'd like to hear from sort of the non-medical
21 people on the committee, because they have less of a vested
22 interest in this.

23 MR. GRAHAM: Just a clarification of Dr. Reizner.

24 My understanding was that you thought this might
25 be only 20 percent of the cardiologists that would propose

1 to take the additional training to be able to perform this
2 procedure? I know that was a guesstimate.

3 DR. RAIZNER: Yes, that's a guesstimate based on
4 the fact that this is essentially a sub-specialty within
5 cardiology, that the numbers of patients are not
6 all-inclusive.

7 That is, not every patient would be applicable to
8 this, and so, the investment from the standpoint of a
9 cardiologist to seek the additional training and experience
10 would not pay for him in terms of the rewards in numbers of
11 cases that he might do.

12 So, I believe that, probably across the board in
13 the United States, no more than 20 percent of cardiologists
14 would have the volume and the need and the referral base to
15 justify getting the training and experience.

16 MR. GRAHAM: Just one other question to Dr.
17 Blitzer.

18 Other than the 200 hours/500 hours that's
19 enumerated as specific training related to radiation safety,
20 what percentage would you estimate of the additional three
21 years is tied to radiation safety versus learning the
22 clinical knowledge base to function as a radiation
23 oncologist?

24 DR. BLITZER: Well, maybe I'm naive, but I don't
25 make a distinction between the radiation safety that's going

1 to happen right in the room and the radiation safety that's
2 going to happen to the patient five years later, when his
3 heart is damaged by excess radiation.

4 MR. GRAHAM: The FDA is requiring that these
5 patients be followed for five years.

6 DR. BLITZER: Right. But I'm leading up to
7 answering your question.

8 So, I think that three years of clinical
9 experience are absolutely necessary. I think it's crazy to
10 decrease the training requirement on a new technology which
11 we don't even understand, as well as the more proven
12 technology.

13 Why would we have a new technology and say you
14 need less than three years of training?

15 DR. CERQUEIRA: Let me get comments from other
16 members of the panel. I always want to hear the patient's
17 perspective on this. And then we'll go to Dr. Diamond, who
18 had a question.

19 MS. HOBSON: Well, this is kind of a tough one for
20 me, because I'm not a technical person and I'm not trained
21 in medicine.

22 Just sort of my common sense response to what you
23 all have said is that, if it's a routine procedure, I don't
24 see why a radiation oncologist could not be present in the
25 room and ready to perform the procedure.

1 I mean I don't see why a patient should have to
2 wait, if it's a routine procedure, as a matter of scheduling
3 people to be there when they should be there.

4 I guess I'm ambivalent about what happens in an
5 emergency procedure. I don't have any idea how often that
6 happens, but perhaps there should be, you know, maybe some
7 provision -- and I don't know what that would be -- where,
8 in an emergent situation, someone other than a radiation
9 oncologist could remove the stent or whatever would need to
10 take place.

11 Is that practical?

12 DR. TRIPURANENI: With the experience we have in
13 the beginning, we had difficulty coordinating schedules, but
14 at this point in time, it actually flows very smoothly.

15 Some of the difficulties come because when Dr.
16 Reizner is doing angioplasty, sometimes it doesn't go as
17 planned. Sometimes they may require an additional
18 half-an-hour or 45 minutes.

19 So, we time it such that it can be worked out
20 within a particular institution, depending upon their
21 particular needs.

22 Regarding the emergencies, again, at this point in
23 time, having done close to 700 patients, at this point in
24 time, they can be scheduled.

25 In other words, within one to two days of leeway,

1 they can be scheduled.

2 On the other hand, if they have to have a
3 late-night angioplasty, I do expect it probably falls into
4 the practice of medical practice and the radiation
5 oncologist, whoever is working with the cardiologist, more
6 than likely will end up coming to the cath laboratory and
7 then basically provide the necessary service.

8 We do do this at this point for our patients with
9 cancer. So, I see these patients no different.

10 MS. HOBSON: But you do see that there would be
11 occasions when a radiation oncologist would not be
12 available.

13 DR. TRIPURANENI: It is expected by the hospital
14 medical staff that there is a radiation oncologist available
15 24 hours, seven days a week.

16 DR. BLITZER: We have cancer emergencies -- SVC
17 obstructions, spinal cord compressions, some brain
18 metastases. We're on-call 24 hours a day and we come in.
19 We will be available. We are available.

20 DR. RAIZNER: I would just say that I have no
21 doubts that, at Dr. Blitzer's institution and at Dr.
22 Tripuraneni's institution, the radiation oncologists are
23 top-notch, ready and available and more than willing to work
24 with the cardiologist.

25 I don't think that's universal, nor can it be

1 expected to be universal. It essentially, therefore, ties
2 the cardiologist's hands to perform these procedures only
3 with the good grace of the radiation oncologist, something
4 that realistically is not going to happen universally.

5 DR. CERQUEIRA: Dr. Diamond, you had a question?

6 DR. DIAMOND: Yeah, if I can ask my question for
7 more than eight seconds without being cut off by the chair.

8 That has to do with the issue of consent, and I
9 guess, if I can direct this to the members of the panel and
10 to Nikita, as well, what's going to happen when a person
11 suffers an untoward event, maybe because of the radiation or
12 maybe not because of radiation, five or 10 years down the
13 line, and what's going to happen if there's not an
14 individual with very, very extensive radiation training and
15 background when that comes in front of a jury?

16 I mean one great concern that I have is that there
17 will be an untoward event one night and that this will be on
18 the front page of the newspaper all across the country the
19 next day and a potentially very important therapeutic
20 modality may be destroyed, and in our practice of radiation
21 oncology, our prejudices that we face every day about the
22 use of ionizing radiation will be reinforced.

23 It's something that has to be considered, and I'd
24 like the panelists' opinion and I'd also like to hear Ms.
25 Hobson's opinion.

1 MS. HOBSON: I'll go first.

2 In a routine procedure, I don't think there would
3 be any excuse for not using the best available person, who
4 in this case appears to me to be the radiation oncologist.

5 In an emergency situation, as I say, I'm
6 ambivalent. If I'm going to just lay on the table and die
7 waiting for the radiation oncologist to get there or I could
8 let someone else do the procedure and I'm going to die five
9 years from now, I would probably elect to take the extra
10 five years.

11 DR. CERQUEIRA: I don't think it's ever that kind
12 of a situation.

13 DR. DIAMOND: It was more directed towards our
14 medical/legal environment. What's going to happen if
15 someone gets in front of a jury and a very clever prosecutor
16 says, you know, Dr. So-and-So, can you tell me where you did
17 your training in radiation oncology? Well, I really didn't
18 do it. Or Dr. So-and-So, where did you do your training in
19 nuclear medicine, and you say oh, do you intend to tell me
20 that you're fully qualified to go and counsel these patients
21 regarding informed witness consent, and that was the genesis
22 of my question.

23 MS. HOBSON: I understand your concern, and it's
24 sort of strikes a note with me, because today I have
25 listened to regulatory people who are interested in

1 protecting the regulatory environment, and we have medical
2 people, probably rightfully so, trying to protect themselves
3 against malpractice suits and prosecution, but you know, the
4 patient is the receiver of this, and the patient should be
5 the focal point of all of our considerations.

6 DR. TRIPURANENI: I want to provide the best of
7 care, whether the patient has cancer or whether the patient
8 has heart disease.

9 My primary focus and goal is to provide the best
10 of care, 24 hours, seven days a week, and I think most of my
11 colleagues across the country, I think, basically operate on
12 the same premise.

13 To answer Dr. Diamond's question, I think that's
14 going to be a tough one. That's the reason why FDA mandated
15 that patients be followed for at least five years, and in
16 our practice, we like to follow them for life.

17 When I come to the cath lab, I am not coming there
18 just with my expertise in radiation safety, but I bring in
19 what I have acquired during my three years of radiation
20 therapy training and lots of other things that actually I
21 have learned in my practice of radiation therapy in cancer
22 on other benign diseases.

23 So, I'm bringing actually a wealth of knowledge to
24 the cath lab and actually applying that.

25 We have actually learned over the past three to

1 five years.

2 So, actually, we are using technology to actually
3 welcome some of the problems.

4 So, I'm actually bringing more than radiation
5 safety to the cath lab.

6 So, I think I still go back to, I think, three
7 years of training, with the practice in radiation oncology
8 that has a broad-based experience.

9 DR. RAIZNER: In response to your question, there
10 is not a radiation oncologist in the world, including the
11 very bright colleagues here, that can tell you what they
12 should look for in five years after intravascular
13 brachiotherapy. There is no track record, there is no
14 literature, and there is no information.

15 We are all starting at the same stage and
16 knowledge of this and we are all learning together.

17 The problems that were mentioned earlier with edge
18 effects -- it was implied that our lack of knowledge of
19 volume and mass created this phenomenon of edge narrow.

20 Bear in mind, all of these were done with
21 radiation oncologists.

22 This is a field that's an infant field, and
23 neither cardiologists nor radiation oncologists began this
24 with any background knowledge of what happens when radiation
25 is applied from within an artery in a radial manner.

1 It's non-existent in any field of radiation
2 oncology to date.

3 DR. BLITZER: But we don't want have a lesser
4 training requirement for a new field.

5 It seems like a new field -- I would challenge you
6 that we can't extrapolate a lot of our current knowledge,
7 but be that as it may, we don't want to have a lesser
8 training requirement for a new and potentially very
9 dangerous modality of treatment.

10 DR. CERQUEIRA: I think we should take a break.
11 We're way past our break.

12 I'd like to thank our three presenters and the
13 committee, and we'll reconvene in 10 minutes, five of 4:00.

14 [Recess.]

15 DR. CERQUEIRA: Diane Case is going to present.

16 DR. CASE: Unlike many of the people that you've
17 seen today and you will see tomorrow, I haven't presented
18 before this committee before.

19 I've been in the audience before many times, but I
20 haven't actually participated myself, and I would really
21 like to thank Dr. Ayres for setting up such a nice
22 introduction for me, seeing that part of my presentation is
23 somewhat similar in nature.

24 However, I'm going to preface my talk about
25 theraspheres by saying what we want to do is come up with

1 some guidance for licensees to use this particular device,
2 and the guidance is not based on our intentions of providing
3 more regulations.

4 Actually, it's more of a point of providing
5 clarity, providing clarity at the same time as providing
6 safety to patient and safety to the personnel who are using
7 the material, as well as fitting in with our NRC strategic
8 plan and the NRC goals which Dr. Cool spoke of this morning,
9 and that is to decrease regulatory burden, but at the same
10 time still provide effective and quality radiation
11 protection.

12 So, let me just quickly go through some slides.
13 Hopefully you've all read my hand-out. I'm sure that you
14 did. It's probably the first thing that you did. I don't
15 know if you've War And Peace before, but if you have, you
16 can certainly get through my document, and once again, I
17 apologize if there were any typos, but the one that you
18 received fixed those up. I'm sure that you found all those
19 typos, as well, when you read it.

20 As you know, we have emerging technologies coming
21 up, types of medical devices to deliver radioactive doses or
22 radioactivity to treat patients for medical conditions, and
23 one of the reasons for our new Part 35 is to try to capture
24 the changes in technology that are occurring very rapidly.

25 This particular device that we have in front of us

1 now, therasphere device -- I'm using the word "therasphere."
2 That just happens to be the manufacturer's name for the
3 device that's out currently. However, the use of itrium-90
4 microspheres for this particular therapy -- the idea has
5 been around -- and the clinical trials have been around for
6 quite some time.

7 So, this is not necessarily to single out
8 theraspheres itself.

9 Regulations are applicable to the current 10 CFR
10 35, are applicable to certain uses for radioactive material
11 -- brachiotherapy, radiation therapy, diagnostic -- but if
12 you look at the brachiotherapy regulations, they are very --
13 somewhat prescriptive, and we're starting to see these
14 devices that don't meet a lot of the criteria, and the way
15 that one would regulate them is going to have to change
16 because of the particular unique characteristics of those
17 devices, and this itrium-90 microsphere or therasphere is
18 one such device.

19 I put the third bullet there, guidance necessary
20 for unique modalities. Please take the word "necessary"
21 with a grain of salt.

22 "Necessary" means we want to provide the licensees
23 with the best possible guidance that we can give them.
24 Licensees are actually asking us what do we do? So, we're
25 trying to provide them with assistance and guidance.

1 Again, immediate examples of therasphere device
2 and what is NRC's interest in this? It's not to
3 over-regulate, but we want to maintain that the requirements
4 and provisions of 35 are provided for, and that's the
5 protection of the public health and safety, as well as the
6 NRC mission and strategic plan.

7 Let me tell you quickly about the therasphere
8 device. It's the itrium-90 which is embedded in a glass
9 microsphere. The itrium-90 does not leach out. The
10 half-life of itrium-90 is 64.2 hours. It's a pure beta
11 emitter, and the average energy is .937 NEV.

12 So, contrary to external-beam therapy in which the
13 -- you have tissues that's being irradiated, as well as the
14 tumor tissue, the betas afford a short-range therapy to the
15 liver tumors.

16 The therasphere use right now -- the FDA has -- is
17 regulating it, if that's the right word, as a human use
18 device, humanitarian use device, and the manufacture and
19 distribution of this device is under an HDE, human device
20 exemption, and what this means is that users of this device,
21 the therasphere device, have to use it for a particular
22 reason and only that reason, and that reason, right now, is
23 radiation treatment or as an adjunct to surgery or
24 transplantation in patients with un-receptable cellular
25 carcinoma, and also, I just wanted you to notice that,

1 because of the status, you have the following sentence.

2 "The effectiveness of this device has not been
3 demonstrated."

4 So, this statement has to be provided in the
5 package insert of the therasphere device.

6 Again, the difference between a hard versus
7 pre-market approval is somewhat of an abbreviated clinical
8 trial prescription and an analysis that's required to use
9 something, as opposed to use the pre-market approval.

10 One of those things is that it's going to treat a
11 disease that is in a small fraction of the population, and
12 it also provides an incentive to manufacturers to develop
13 useful techniques that they may not do because of the
14 financial constraints.

15 If it's only going to be helping 4,000 people and
16 it's going to cost us a million dollars, two million dollars
17 to manufacture, then what's in it for the manufacturers?

18 And later one -- or you can read in the notes --
19 there are some other constraints on HDEs that again kind of
20 complicate the matter for us.

21 The glass microspheres come in a vial, and I'm
22 going to get to that picture in a minute, but really, the
23 therasphere device is a vial of itrium-90 microspheres, and
24 they're supposed to come in unit doses, anywhere from 135
25 millicurie up to 450 millicuries.

1 At the time it was first approved as an HUD, they
2 had three dosages that they came in.

3 So, you have a vial, and with this vial comes an
4 administration kit.

5 So, again, we're going to see in a minute it's the
6 administration kit that also causes this to be somewhat of a
7 very unique modality.

8 It's also unique because it's a pure beta emitter,
9 and we'll get into that in a minute, as well.

10 The glass microspheres remain in the liver
11 permanently, even though the itrium-90 eventually decays
12 away. There's no evidence that that causes any harm to the
13 patient.

14 And I don't know if you can see this bottom
15 bullet, but if you look at all the definitions that we have
16 available to us in Part 35, staff -- or the staff concerned
17 with this particular matter -- has determined that itrium-90
18 microspheres are, indeed, brachiotherapy sealed sources.

19 There's been a lot of discussion of why aren't
20 they called radio-pharmaceuticals?

21 Well, if you look at the definitions of drugs and
22 devices and you look at the radio-pharmaceuticals and sealed
23 sources, you will find that this -- these micro-spheres,
24 each one of them, individually, they meet all the
25 definitions of a sealed source and a brachiotherapy source,

1 not as a radio-pharmaceutical.

2 They don't act biologically in the body.

3 DR. WAGNER: Because of the way they're delivered,
4 do they get into the bloodstream and are eliminated through
5 the bladder?

6 DR. CASE: No. We'll get to the administration,
7 but I'll just say quickly it's administered by a catheter,
8 hepatic artery, goes right to the liver.

9 DR. WAGNER: It's 100-percent trapped in the
10 liver.

11 DR. CASE: If it goes to the liver -- whatever
12 goes to the liver will be trapped in the liver.

13 DR. WAGNER: Well, what if it doesn't?

14 DR. CASE: Well, whatever goes to the liver will
15 stay in the liver.

16 DR. CERQUEIRA: Is there any experience looking at
17 other parts of the body?

18 DR. CASE: I'm going to be getting to that, and if
19 I could go back, I would change it now and re-order my
20 slides.

21 The reason I'm here today is because I've been
22 tasked with coming up with some guidance that we can give to
23 licensees on how they can use this material.

24 For example, licensees have come and asked us what
25 is a mis-administration, what do we do for a written

1 directive, prescribed dose?

2 Also, the training and experience requirements,
3 which you're going to love.

4 DR. WILLIAMSON: Why do broad-scope licensees have
5 to submit license amendments?

6 DR. CASE: We're going to get to that, as well,
7 and I'll tell you why, because the unique characteristics of
8 the thetasphere device, because it doesn't fall into the
9 categories in Part 35 under brachiotherapy or under anything
10 else, as a matter of fact --

11 DR. WILLIAMSON: For a broad-scope licensee, it
12 doesn't have to.

13 DR. CASE: Well, broad-scope licensees also have
14 to meet the definitions of a mis-administration, a written
15 directive, and prescribed dose, and so, because the current
16 Part 35 definitions are not applicable to this device, then
17 all licensees are going to have to make some provisions for
18 what a mis-administration is or a prescribed dose is based
19 on the characteristics of this device.

20 DR. WILLIAMSON: Now, these two centers that are
21 using it -- can you give me the number of total doses that
22 have been administered to patients?

23 DR. CASE: We're going to get to that.

24 DR. WILLIAMSON: Okay. I think most of us have
25 read this, probably.

1 DR. CASE: Have you? Okay.

2 Some of the adverse events -- elevated liver
3 enzymes, gastro-intestinal toxicities, and this is
4 important, because when you look at the ulcers,
5 perforations, hemorrhages -- and there have been deaths
6 attributed to GI or stomach toxicities, and actually, they
7 are events that are -- that could be -- could have not
8 occurred but did occur.

9 You put three to six millicuries of technetium-99
10 into the artery and you take a look at the lungs and the
11 stomach and the GI tract to see if there's any shunting that
12 goes there.

13 From this, you determine patient eligibility. You
14 can determine the administration activity based on what kind
15 of dose you want to give, and then, after administration,
16 you're looking for any emergency, the efficacy, and also,
17 any mis-administrations.

18 Here's the assembly. The theraspheres come in
19 this vial right here, and the assembly kit, everything here,
20 comes pre-packaged with the vial of theraspheres.

21 Now, if you read the package insert, the package
22 insert advises that, to get the best administration, that
23 you do, in fact, use all of the included lines and syringes.

24 Contra-indications -- any deposition to the GI
25 tract which cannot be corrected or if there's any indication

1 that you could give more than 30 gray in a single treatment
2 to the lungs.

3 Now, actually, every clinical test that I have
4 looked up in any reference that I have -- in all of them,
5 they have always not given this therapy to anybody whose
6 shunt test did show that they were going to get more than 30
7 gray to the lungs, and also, they've never given it to -- or
8 from what I can tell, they do not give to anybody who shows
9 any deposition in the GI tract.

10 Administration is generally 5,000 to 15,000.
11 Licensees that have been using it so far have been using
12 approximately 3 gigabecquerel, about 80 millicuries or
13 15,000 centigray or 15,000 rem.

14 DR. DIAMOND: Hepatic tolerance is 15,000
15 centigrade to the whole liver? I'd like some clarification
16 on that hepatic tolerance about 15,000 centigrade.

17 DR. NAG: If you are injecting it into the tumor,
18 if you are selectively putting into one artery, you can give
19 it to that segment only.

20 DR. DIAMOND: That's very important. It's a
21 partial liver dose or tumor and immediate vicinity dose, but
22 you get 15,000 centigrade and it will not work.

23 DR. CASE: Okay.

24 Getting back to the question you had about why
25 this is important for all licensees, the patient comes in,

1 they have a catheter put into their hepatic artery, and the
2 therasphere administration kit is put together, assembled,
3 and you have the theraspheres in the vial, you put the
4 syringes in by hand, and then what you do is push saline
5 through. That puts the radioactivity or the itrium-90
6 microspheres into the hepatic artery.

7 The hepatic artery is the blood supply that goes
8 right to the tumorous tissues. Once the microspheres get in
9 there, they get stuck in there or embedded due to their
10 physical size, and once they're in the liver, they're not
11 metabolized and they're not biologically active.

12 Misadministration, you would say that
13 conventionally, you could say, brachytherapy, radiation
14 dose, involving the wrong individual, isotope wrong,
15 treatment site -- I tried to hide these other things, and I
16 thought, well, for --

17 DR. CERQUEIRA: We have a question.

18 DR. WILLIAMSON: I'm sorry, I'm really confused
19 about the legal basis of this, of what we're trying to do.
20 Is this a modification to the existing Part 35?

21 DR. PACE: No.

22 DR. WILLIAMSON: Is this something to go in the
23 new 35.1000?

24 DR. PACE: No, no. Can I answer that question?

25 DR. CERQUEIRA: Yes.

1 DR. PACE: At the beginning, I thought I described
2 that this is guidance for licensees who are going to be
3 using this therasphere device, and this guidance actually
4 came about or our discussion about providing guidance came
5 about due to licensees asking us how are we going to --

6 DR. WILLIAMSON: That's what I'm asking.

7 DR. PACE: So our reasons for doing this is,
8 again, not to increase regulatory burden, but for clarity.

9 DR. CERQUEIRA: Well, some of the background
10 information is useful, but I think some of us have already
11 read it. Maybe you could sort of get to the question.

12 DR. PACE: Sure, all right.

13 MS. HANEY: Jeff in a way this is similar to the
14 intravascular, and that is that unfortunately, in the
15 current 35, it falls between 35.300 and 35.400. But because
16 of definitions, the closest place we can put it is 400.

17 If we were in the new 35, maybe we could call it
18 an emerging technology, but in the meantime, we have people
19 that want to use it right now, and we're just really looking
20 for what are the best definitions for misadministration,
21 what are training requirements?

22 Should we require 35.300 users or a 35.400 user;
23 those are kind of some of it. So, I mean, Dan, I don't even
24 think you need to go through the licensee experiences. I
25 think that if you just -- do you have --

1 DR. PACE: I believe I have a question about that.

2 DR. CERQUEIRA: Now, what questions do you really
3 want us to answer? I think it would be --

4 DR. WILLIAMSON: Why don't we get to that.

5 DR. PACE: Okay, I understand that your patience
6 is running low here. I felt it was important to present
7 some of this information to make sure that everybody was
8 onboard, because this isn't just adding more regulations.

9 Again, I said, we're clarifying what makes this
10 device so unique is that the theraspheres are in here, but
11 this administration assembly has quite an impact on the
12 administration of this theraspheres to the liver.

13 The potential for human error, using this, is
14 high, and, in fact, one of the misadministrations that did
15 occur, did occur because of inserting -- having to manually
16 insert these syringes themselves.

17 So I won't go through any of this. I guess if you
18 want to get right to it, we'll just talk about the training
19 and experience requirements, potential authorized users.

20 I can tell you that the staff associated with this
21 -- not everybody, but the staff who are trying to formulate
22 this guidance, believe that the use of the microspheres for
23 brachytherapy should be performed by a team consisting of
24 the 35.200 authorized user and a 35.400, 35.200 being a
25 diagnostic nuclear medicine, and the 35.400 being the

1 brachytherapy physician.

2 The reasons for this? Maximize the palliative
3 effect, to decrease the adverse effects, which can be
4 actually quite detrimental. In fact, you can actually do
5 some good, perhaps with this.

6 But if you do it the wrong way, you could, in
7 fact, adversely affect the patient to prevent intolerable,
8 lethal effects, and to ensure radiation safety.

9 The --

10 MS. HANEY: Diane, I think you can stop there,
11 really. The question I would just pose to the Committee now
12 is, given what you've known from the package, what type of
13 user? Do you agree with the Staff approach?

14 DR. CERQUEIRA: No.

15 MS. HANEY: Or at least what's being talked about,
16 a 200, a 400 user, or what do you see it as? I think that
17 if we could just open that up for a couple-minute
18 discussion.

19 DR. CERQUEIRA: You need somebody to put the
20 catheter in; you don't need a cardiologist this time, but
21 you have an interventional radiologist who's there also;
22 don't you?

23 MS. HANEY: Yes, but again, do you need to go
24 there for radiation safety purposes?

25 DR. CERQUEIRA: No.

1 DR. WAGNER: Well, I don't know.

2 DR. PACE: Does everybody here understand the way
3 that a person -- it's determined whether or not an
4 individual can receive this?

5 DR. CERQUEIRA: Jeff?

6 DR. WILLIAMSON: I want to say something about
7 this whole approach. It really concerns me. It looks to me
8 like what you've done is, you've taken the sort of proposed
9 package insert, which are the instructions from the vendor,
10 and you're trying to turn it into a regulation.

11 And this seems wrong. I mean, why do you need to
12 legislate down to the nearest tenth of a millicurie, how
13 much dose a radiation oncologist can give to the lung?

14 DR. PACE: I think that perhaps you're
15 misunderstanding the intention here.

16 DR. WILLIAMSON: Well, no I'm not. Let me finish,
17 okay? I'm sorry.

18 DR. PACE: I think you are, but --

19 DR. WILLIAMSON: This is a general comment that it
20 seems to me that much of this could be accommodated by the
21 existing 35.400 regulation, which would require -- which
22 basically allows the radiation oncologist a fair amount of
23 latitude as to how the written directive is written.

24 DR. PACE: Is the 35.400 going to do the
25 localization studies?

1 DR. WILLIAMSON: I think that's an issue of
2 medical practice, you know. Why does NRC have to get
3 involved in legislating how and who does exactly these
4 studies? I think a radiation oncologist orders, you know,
5 the appropriate study from nuclear medicine, and in most
6 hospitals, only qualified nuclear medicine practitioners are
7 allowed to do localization imaging.

8 That's covered under existing training and
9 experience requirements. So why is it necessary to single
10 out this procedure for this much sort of regulatory
11 structure?

12 DR. PACE: It's actually the structure is not any
13 different than what exists right now. As I said before,
14 it's simply a clarification.

15 DR. WILLIAMSON: Well, I think it's too specific
16 and you've gone beyond safety into practice of medicine.

17 DR. CERQUEIRA: Dr. Nag?

18 DR. NAG: I'll give you my practical experience
19 with a very similar thing: And I'm glad that at that time,
20 the NRC was not overlooking, because we used Iodine-125
21 seeds into the vessel, and were putting them into renal
22 tumors.

23 Now, again, you are using the -- you are using the
24 -- that humans have a more -- and therefore the radioactive
25 material will go into the vascular tumor.

1 Before that, you perform a die study to see where
2 the vascularity is. And then there was no special
3 regulation required, other than the brachytherapy
4 regulations that were already there.

5 The brachytherapy regulations that you already
6 have are -- , except that the source is now smaller than the
7 Iodine-125 seeds.

8 You can put Iodine-125 seeds into the renal
9 vessel, and going into the tumor and can get stuck into the
10 tumor which is exactly the same thing you are having here,
11 except it's a smaller, a little smaller source, and in terms
12 of misadministration, you can use the same definition you
13 have now, that we prescribe I'm going to put X-number of
14 millicuries into the renal vessel. Here it will be the
15 liver vessel.

16 You know, all the other definitions can remain the
17 same. The other thing I would suggest is not by specifying
18 it only for liver, because then you are tying the hands of
19 the physician.

20 DR. PACE: I'm sorry, not what?

21 DR. NAG: Not specifying this to be only in the
22 liver.

23 DR. PACE: Well, that's what the FDA has done.

24 DR. WILLIAMSON: But you don't need to --

25 DR. NAG: You don't need to say that, because I

1 can foresee the similarity of this to be used in other
2 tumors. So why can't you put radiation safety issues --

3 DR. CERQUEIRA: Let's not deal with sort of
4 indications. I think that's an important point, but I think
5 the question they're asking, they're recommending that it
6 should be a team of a diagnostic authorized user, and
7 somebody.

8 Why do you need the 35.200 user?

9 MS. HANEY: That's the for the level set there.

10 DR. PACE: That would b for the tests for the --

11 DR. CERQUEIRA: Why does that person -- why isn't
12 that a routine clinical study? Why should you get into
13 that?

14 DR. PACE: Well, this is what -- actually, this is
15 why we're here today.

16 DR. CERQUEIRA: We're saying you don't need the --

17 Sally, you've been very patient.

18 MS. SCHWARTZ: Traditionally in nuclear medicine,
19 we do studies now, injecting technetium labeled MAA, and we
20 do something very similar to this. I mean, it's not
21 directly into the liver, but certainly it just -- and we do
22 it through different -- I mean, radioactive materials are
23 injected into the CSF fluid.

24 I mean, they're injected numerous ways.

25 DR. PACE: Right.

1 MS. SCHWARTZ: Not necessarily does the NRC
2 regulate anything, I mean, with regard to the specific
3 injection.

4 DR. PACE: What you have to do is, you have to
5 understand that this is not a radiopharmaceutical; it is a
6 sealed source.

7 MS. SCHWARTZ: The first portion where you're
8 injecting the technetium labeled MAA, that's a
9 radiopharmaceutical.

10 DR. PACE: Right, right, right, right.

11 MS. SCHWARTZ: And that's why it probably doesn't
12 need to be regulated.

13 DR. PACE: But the thing is, I don't think -- I
14 need to know where you say it's regulated, because I don't
15 know where you're saying we're regulating that.

16 DR. NAG: You don't want to include the authorized
17 user.

18 MS. SCHWARTZ: Technetium labeled MAA is a
19 currently-approved --

20 DR. WILLIAMSON: It's a clinically-indicated --

21 MS. SCHWARTZ: Radiopharmaceutical.

22 DR. PACE: They're saying if we use a 400, that
23 will cover everything.

24 DR. WILLIAMSON: Yes, it will.

25 DR. PACE: Okay, I appreciate that.

1 DR. WILLIAMSON: The other thing is that your
2 written directive is so specific. It's based on the package
3 insert which I think reflects a fairly preliminary and
4 probably primitive knowledge of how to use this device, and
5 I agree with you, it's a device.

6 But, you know, eventually, you know, newer and
7 more sophisticated methods of doing dosimetry will be
8 developed.

9 DR. PACE: This is --

10 DR. WILLIAMSON: Let me finish one more thing.
11 The other thing is, in many areas of brachytherapy, there
12 are constraints on normal tissue that we have, and that we
13 observe, and these do not have to be in the written
14 directive for any other brachytherapy procedure.

15 That's sort of up to the authorized user to go and
16 look at the balance of what is going to be accomplished and
17 be on behalf of the patient, versus damage to normal tissue,
18 and it's a clinical decision.

19 So I don't know why that needs to be coded into a
20 special, you know, definition of written directive and
21 misadministration for this kind of patient.

22 DR. CERQUEIRA: I agree. Let's hear Dr. Leedham.

23 MR. LEEDHAM: In this case, it's a little bit
24 different. There are other instances.

25 The other ones, they were approved devices. This

1 one is a humanitarian use device, and it's more analogous to
2 an IDE where they are actually collecting data and providing
3 that back.

4 So, in this case, the more that the package insert
5 or the labeling is followed, is very critical. There will
6 also be restricted distribution of who can participate in
7 this.

8 So I think that as far as protocols go,
9 participation will be according to the labeling, because it
10 is actual, ongoing studies; it's actually a trial.

11 DR. PACE: That's right, and that's what I wanted
12 to say, was that this is an interim guidance for those
13 licensees who want to use it right now in its current state,
14 in its current form, and given the information that we have,
15 as well as the licensee's experience.

16 DR. WILLIAMSON: So why is this needed for a broad
17 scope licensee anymore? You don't require this for a
18 participant in a intravascular brachytherapy trial that's
19 under the supervision of FDA through an IDE, so why does
20 this have to be so detailed? Why can't sort of FDA
21 supervise it?

22 DR. PACE: Simply because the definitions of the
23 misadministration written directive and prescribed dose, as
24 written, are written for devices -- are not written for this
25 device. This device just cannot meet those requirements

1 because that's a sealed source.

2 It cannot meet the definition of --

3 DR. WILLIAMSON: Sure it can. Why not?

4 DR. CERQUEIRA: It's covered under 35.400.

5 DR. WILLIAMSON: How are permanent implants
6 handled now?

7 DR. CERQUEIRA: I think all of us are missing the
8 question. So if you could please tell us the question.

9 MS. HANEY: Let me try. The issue, Jeff, is that
10 in the current 35, a written directive for all other
11 brachytherapy says the radioisotope, number, sources, and
12 source strengths, and after implementation but prior to
13 completion of procedure, the radioisotope site, total
14 source, strength, and exposure time, you can't do all those
15 things for this.

16 So we need to change, we need to have an
17 alternative for this. So the question that's on the table
18 is, for this use only, we need an alternative definition for
19 what needs to go in the written directive, and, then, of
20 course, it falls out from that, as far as when you get into
21 misadministrations. That's what on the table.

22 Because what is in here right now, doesn't fit.

23 DR. NAG: In a permanent implant, there is an
24 exception. In a permanent implant, the activity -- that's
25 how I do a permanent implant. I prescribe the number of

1 millicuries that I need to give, and it's called a permanent
2 implant.

3 This is a permanent implant, and it's going to
4 stay there all the time, and you prescribe the number of
5 millicuries. I mean, I have been doing this for many years
6 with I-125, rather than a microsphere, and I have been
7 putting it in the vessels.

8 And I prescribe X-number of millicuries that I
9 want to give to the site, which in this case indicates that
10 it will be delivered.

11 DR. PACE: But what we wanted to do is include
12 something as far as misadministration goes --

13 DR. NAG: Same definition of misadministration
14 would apply. If I'm putting X-number of millicuries into
15 here, I'm putting X-number of millicuries into the liver.
16 The same definition would apply.

17 DR. PACE: Right.

18 DR. NAG: You don't have to create anything.

19 DR. PACE: However, this is a different device,
20 and I'm sure that whatever you're doing now is one thing.

21 DR. WILLIAMSON: I think that technically it could
22 be handled by just modifying the existing definition to
23 delete number of sources and requiring total activity.

24 It has number of sources, too, so I think you're
25 right; you have to delete number of sources, but you could

1 have total activity.

2 DR. PACE: This is a very simple thing.

3 DR. WILLIAMSON: And/or absorbed dose, just as
4 it's stated now.

5 DR. PACE: All right, how about when the
6 calculated administered dose differs from the prescribed
7 dose by no more than 20 percent of the prescribed dose you
8 put to the liver?

9 DR. WILLIAMSON: Well, how do we handle the
10 situation in prostate brachytherapy where you do a permanent
11 implant, and you don't always have control over, for
12 example, what is the minimum dose.

13 So if you were prescribing the minimum dose for
14 implant and you notice it fell 25 percent short, you know,
15 then you would have a option to revise the written directive
16 to say what it is that you observed on the post-implant
17 dosimetry.

18 DR. PACE: But the permanent implant that you put
19 in does not necessarily have a probability of migrating to a
20 different site.

21 DR. WILLIAMSON: Yes, it does, to some extent, or
22 potentially being implanted to the wrong site in a subtle
23 way that you couldn't detect.

24 DR. PACE: Right.

25 DR. WILLIAMSON: But again, you know, you've put

1 inside here, you know, constraints that, you know, the FDA,
2 I guess, constrains physicians to observe. But, you know,
3 that's their law and they constrain it. I mean, in no other
4 site for brachytherapy, do you put normal tissue constraints
5 or require, you know, ancillary procedures.

6 I'll give you an example: If one were treating
7 Hodgkin's Disease with a Cobalt-60 teletherapy unit, if you
8 didn't put the lung blocks in, it would be a disaster.

9 The patient would have intractable pneumonitis,
10 but you do not require, you know, that the authorized user
11 specify that after 15 gray, I'm going to put the lung blocks
12 in, and that if you don't put the lung blocks in, it's a
13 misadministration. It's bad medical practice, but do you
14 see my point?

15 In many areas of brachytherapy and teletherapy,
16 there are important normal tissue constraints that the
17 radiation oncologist uses in defining the prescription, and
18 that is, I think, if you look at the medical policy
19 statement, you know, outside of your purview.

20 And maybe for this device, it's between the
21 physician and FDA, but why is it NRC's business?

22 DR. PACE: I don't think it's NRC's -- I think
23 it's NRC's business to ensure, you know, the safety of the
24 public, and also to -- but I don't think that -- I do not
25 think that anything that's been added, or anything that's

1 here -- but with your advice -- I don't see it as adding --
2 I mean, I don't know if you're sensitive to everything
3 becoming more constraints, more constraints, but I can
4 assure you, we don't want to have more constraints.

5 We're trying to clarify for the licensees who are
6 actually asking us for this.

7 DR. WILLIAMSON: Well, I think --

8 DR. CERQUEIRA: Dr. Ruth.

9 DR. MCBURNEY: My comment was on the authorized
10 users, and I agree with the Staff recommendation that the
11 diagnostic part of that should be under the 35.200, and the
12 other should be considered brachytherapy and under the
13 35.400.

14 MS. HANEY: There are no changes that are needed
15 there, so with -- so that moves us into the current
16 definition for written directive.

17 DR. DIAMOND: What's that page, please?

18 MS. HANEY: On page 10 -- oh, on 35-4 and 35-4;
19 that's the current regs.

20 But under 35-5 is the definition for written
21 directive. And where I was looking was Item 6, and for all
22 other brachytherapy.

23 And that does not work in this case.

24 DR. NAG: Now, there's an exception for I-125
25 permanent implants.

1 MS. HANEY: Where are you looking, Dr. Nag?

2 DR. NAG: I know that I have been dealing with
3 permanent iodine implants every day.

4 I'm trying to find it in here, but in the
5 permanent implant, the way we define permanent implant and
6 we prescribe, we say we want X-number of millicuries to be
7 implanted into the area, and then we implant and the
8 misadministration is not by dose, but by number of
9 millicuries.

10 So it's -- and I know you do have it in here. Let
11 me find the permanent implant area, exception for permanent
12 implants.

13 DR. WILLIAMSON: He wants the definition here.

14 MR. LEEDHAM: Can I ask a question: Kathy, where
15 in Number 6 does this not work?

16 MS. HANEY: In the number of sources.

17 DR. WILLIAMSON: You can't simply say that you
18 used a vial?

19 MS. HANEY: No.

20 DR. PACE: If also I can just say one thing, as
21 far as the administration device goes, there have been some
22 problems with it with the licensees. It doesn't seem to be
23 working as well as one might hope that it would.

24 And this is where also the part comes in about
25 misadministration. That is another thing that I had hoped

1 that we would talk about, but I'm actually -- I actually
2 don't want to get into it.

3 But how are we going to determine what a
4 misadministration is? It's a pure beta emitter; it's being
5 injected or administered through all these syringes and
6 through all these tubes, and we have found that licensees
7 have found pooling in the stopcocks, and they've found that
8 one only gave 38 percent of the intended dose.

9 Now, of course, an under-dose, well, you could say
10 that that's not so bad, but the question is, what happens if
11 the person is improperly pre-screened and anything goes to
12 the GI tract or a certain amount goes to the lungs and the
13 person does, in fact, die from pneumonitis or from GI tract
14 complications? And that is important.

15 DR. WAGNER: But to me, that situation, that's a
16 medical situation. I mean, those are medical conditions and
17 things that can occur in medicine. Patients are advised of
18 the risks and possibilities.

19 And in the practice of medicine, this applies to
20 anything in the practice of medicine. I mean, you go in for
21 surgery, see what they tell you.

22 I don't see why in this situation we have to worry
23 about misadministration with regard to this. This is a
24 matter of things that can go wrong.

25 They shouldn't, if you have really good control on

1 this, but I guess there is some chance that they might
2 happen, and it's the risk patients have to take.

3 DR. PACE: Right.

4 DR. CERQUEIRA: Jeff?

5 DR. PACE: I suppose there is a reason for
6 misadministration that -- we're not going to have that
7 definition anymore, but the pure definition of
8 misadministration is to find out whether or not the
9 intended dose or the intended activity was given.

10 So --

11 DR. WILLIAMSON: I'd like to make two points about
12 this, one general point and one specific suggestion for you
13 about this device:

14 I think the general point is, I would imagine at
15 some point, either this device is going to go away or the
16 conditions on its use are going to be liberalized, and maybe
17 other kinds of colloidal sources that are sealed sources
18 like this will appear.

19 So I would urge you to think generally, and try to
20 come up with a very flexible set of regulations.

21 DR. PACE: These aren't regulations; these are
22 guidances for the licensees using this material.

23 MS. HANEY: Well, be careful. They're not
24 regulations, but what you're looking to use these for are
25 license conditions.

1 DR. PACE: Yes.

2 MS. HANEY: For use --

3 DR. WILLIAMSON: They're de facto regulations.

4 MS. HANEY: Which in this situation, would

5 actually become a requirement that is a big deal.

6 DR. WILLIAMSON: Can I finish my comment? Okay,
7 so my general comment is, is to try to think a head a little
8 bit and not to be so special-cased and narrow that you can
9 only see the sort of one single device and the immediate
10 clinical indication that's before you, and be a little more
11 general.

12 And I would say, yes, probably -- now, to be
13 specific, I think probably both the written directive and
14 the misadministration definition need to be modified a
15 little bit.

16 And I would say it's reasonable for this case to
17 keep the existing definition, but delete the requirement to
18 report the number of sources, since that can't be done, and
19 consider certainly total activity and maybe total absorbed
20 dose.

21 Or I would suggest probably leaving that at the
22 discretion of the practitioner. So that's the specific
23 point.

24 For misadministration, I think -- thinking back,
25 what is the concept of misadministration? It's an error

1 that involves a technically-avoidable mistake on the part of
2 the caregiver, not something that happens because of the
3 patient's medical condition.

4 DR. PACE: Sure.

5 DR. WILLIAMSON: Or as a consequence of a medical
6 judgment by the practitioner that you may disagree with,
7 but, you know --

8 DR. PACE: No, I'm right there with you.

9 DR. WILLIAMSON: So I would say that in this
10 situation, a reasonable definition would be, you know,
11 defining it in terms of the percentage of activity that goes
12 from the vial into the catheter, since that's the sort of
13 one part that, you know, really is under technical control
14 of the practitioner, is how much of the activity goes from
15 the vial into the catheter, into the patient.

16 And I think to some extent, what happens to it, at
17 least in the general case, and in more general indications,
18 can't always be controlled with the level of rigidity that
19 you would like, and you shouldn't make a regulation.

20 DR. PACE: No, and that's why in the
21 misadministration, we put in here, that it says the wrong
22 treatment site, if preliminary shunt tests were not
23 performed, not performed properly, or the results were not
24 used.

25 DR. WILLIAMSON: But I would say that's going too

1 far. I would not agree with that.

2 DR. NAG: Okay, now, the present regulation -- I'm
3 just reading out from the present regulation, 35-4, and
4 brachytherapy misadministration is already in there,
5 involving wrong patient, et cetera, wrong isotope, excluding
6 for permanent implants seeds that were implanted in the
7 correct site, but migrated outside the treatment site, where
8 the migration has been taken care of already.

9 MS. HANEY: But that's only for the definition of
10 misadministration.

11 DR. NAG: Yes, right.

12 MS. HANEY: That doesn't help us with written
13 directives.

14 DR. NAG: Well, that's what I'm talking about
15 that, too, 35-5, under page 35-5, the prescribed dose that
16 the -- of radiopharmaceutical and brachytherapy, either the
17 total source strength -- and here you can give it in terms
18 of source strength -- and exposure time, here the exposure
19 time is permanent, or the total dose, and here you are not
20 talking about total dose.

21 So it is covered.

22 DR. CERQUEIRA: So it sounds like -- Diane, they
23 seem happy with the way -- there's enough written rules
24 already. The only problem is just the number of --

25 DR. WAGNER: Sources.

1 DR. CERQUEIRA: Sources. So it seems like it's an
2 easy fix that's already dealt with for the most part. Is
3 that not true?

4 DR. NAG: It will make your life a lot easier.

5 DR. WAGNER: It makes your life a lot easier if
6 you just say that all you need to do --

7 DR. PACE: Well, who is the person who said we
8 were looking at patient -- we have to remember the patients,
9 right? So we said that.

10 DR. WAGNER: This addresses the issue of, number
11 one, you've got everything and all you've got to do is take
12 out number of sources and tell the user that they don't have
13 to consider number of sources since that's not applicable in
14 this application.

15 And then use the definitions under permanent
16 implant for defining misadministration.

17 DR. DIAMOND: Excuse me, but just to follow up,
18 what you need, I think, from a rational basis, is to a total
19 administered activity and an estimated biouptake by the
20 organ of interest. That's it, an estimate biouptake of the
21 organ of interest, which in this case is the liver.

22 MS. HANEY: I would say that that might be true,
23 but I think you might want to consider the existing
24 definition and try to start with that and then back off,
25 rather than putting a whole new concept.

1 You're putting out a good idea, but then it starts
2 to become more and more inconsistent with the other
3 definitions, which is not -- if we don't have to go there, I
4 would say, not go there, but if you can get it by just
5 deleting one or two things from the current definition, it
6 might be an easier way to approach it.

7 I'm not --

8 DR. DIAMOND: I'm just saying that what you want
9 to know from a rational basis, is how much dose an organ is
10 getting; that's how you do it.

11 MS. HANEY: Okay.

12 DR. CERQUEIRA: But you're going to have to
13 calculate it, and I don't think we want to go into that
14 area. John?

15 MR. GRAHAM: As a lay person, I guess as the idiot
16 savant for this group, trying to translate all of the
17 technical discussion that takes place, can this be as simple
18 as the fact that the ACMUI recognizes that the Therasphere-7
19 device requires a license amendment under the current Part
20 35.400?

21 DR. CERQUEIRA: I heard that.

22 MR. GRAHAM: And that the ACMUI recommends no
23 restriction on condition of use beyond the FDA label,
24 because it does narrow this down to a very restrictive use,
25 correct?

1 DR. CERQUEIRA: Right.

2 MR. GRAHAM: And ACMUI recommends that the license
3 amendment include guidance that the written directive does
4 not require specification of the number of sources, and that
5 the license amendment will use the definitions under
6 misadministration for permanent implants?

7 MS. HOBSON: Correct.

8 DR. NAG: And I will just add one thing:

9 Everything else I agree with, but you said you take out the
10 number of sources, which is correct, but you have to have
11 total activity. You need to have the total activity.

12 MR. GRAHAM: I'll take a friendly amendment to
13 this proposed motion, that technically gets us where we need
14 to be.

15 DR. WILLIAMSON: I think it's already in there,
16 it's already inherent in what he said.

17 DR. CERQUEIRA: Do I hear a second on this motion?

18 DR. NAG: Yes.

19 MS. HANEY: I think we need more discussion.

20 DR. CERQUEIRA: More discussion? If we have a
21 second, then we can have discussion.

22 MS. HANEY: Okay, all right.

23 DR. CERQUEIRA: Okay, we have a second, okay.
24 Discussion?

25 MS. HANEY: Can I discuss?

1 DR. CERQUEIRA: Yes.

2 MS. HANEY: When you say the definition for a
3 permanent implant, that -- I think we need to be a little
4 bit more definitive in your statement, because if you look
5 at 35.4, it's under all brachytherapy, and the items that
6 Dr. Nag referred to is an exclusion for permanent implants.

7 But I want you to realize that Items II and III--
8 well, I guess, Roman Numerals II and IV still apply, so
9 there's no -- if I went and took your recommendation and
10 tried to look in the current Part 35 for the
11 misadministration criteria for permanent implants, I'm not
12 going to find it.

13 So, what I'm kind of asking for is a modification
14 of your statement that we would use the criteria for
15 misadministration that is in -- on page 35-4 under Item V,
16 Brachytherapy Radiation Dose.

17 DR. WILLIAMSON: Yes.

18 MS. HANEY: You have the exclusion in there for
19 the permanent implants if they do migrate. You have the
20 wrong patient and wrong treatment site and things like that.

21 Item II, involving a sealed source that is
22 leaking, I mean, that's not going to really apply in this
23 case.

24 Item III doesn't apply because it's a temporary
25 implant, but the bigger one is Item 4, are you in agreement

1 with the calculated administered dose differs from the
2 prescribed dose by more than 20 percent. And if you do,
3 then you're fine with going with what's in the current regs.
4 So we don't need a modification then to the
5 misadministration criteria.

6 DR. CERQUEIRA: So are you willing to take those
7 modifications, John?

8 MR. GRAHAM: Certainly.

9 DR. CERQUEIRA: All right, so we've modified his
10 original motion.

11 DR. DIAMOND: Please restate your motion.

12 MR. GRAHAM: We usually get this. The ACMUI
13 recognizes that the Therasphere-7 device requires a license
14 amendment under the current Part 35.400, and the ACMUI
15 recommends no restriction on condition of use beyond the FDA
16 label.

17 And ACMUI recommends that the license amendment
18 include guidance that the written directive does not require
19 specification of the number of sources -- you guys want an
20 amendment in here, so --

21 DR. CERQUEIRA: Just put activity, that you want a
22 total activity.

23 DR. NAG: Just the total activity.

24 MR. GRAHAM: -- will require specification of
25 total activity?

1 MS. HANEY: And radioisotopes and radionuclides.

2 MR. GRAHAM: Specification of total activity, and
3 radionuclides, and misadministration definition will be
4 applied using Item V for a brachytherapy radiation dose.

5 MS. HANEY: I could make it easier for you; that
6 the brachytherapy -- that the definition for a brachytherapy
7 misadministration as defined in the current Part 35, does
8 not need to be modified.

9 MR. GRAHAM: Fine.

10 DR. WILLIAMSON: One more friendly suggestion is
11 that you remove the clause referring to the conditions of
12 use being limited to FDA, because that's already covered
13 here by Section 814.110 of the Federal Code, which you can
14 see on page 22, Attachment 3.

15 There is already a law that says the conditions of
16 use for HUD are required to be in accord.

17 DR. CERQUEIRA: That's different than saying that
18 we're recommending that the NRC doesn't restrict it beyond
19 that point.

20 DR. WILLIAMSON: So I guess I'm saying that it
21 shouldn't comment on restriction of use at all. Because at
22 some point, no doubt, either this device will go away, or
23 FDA will liberalize it, and more general off-label uses will
24 be legal, and in that case, I don't think NRC wants to take
25 a position.

1 MR. GRAHAM: There was a discussion of potentially
2 restricting this use beyond what the FDA has discussed.
3 That's what I heard.

4 DR. WILLIAMSON: I guess that what I'm saying is
5 that it's unnecessary for NRC to reaffirm the restrictions
6 on the label because existing FDA regulations are adequate.

7 MR. GRAHAM: What you're not following, Jeff, is
8 that potentially, they can introduce restrictions beyond the
9 FDA label. You're looking at it from the other side of the
10 paradigm here.

11 DR. CERQUEIRA: I think it needs to be specified.

12 MR. GRAHAM: If the FDA opens this up later to
13 other uses, this covers it automatically. This just says
14 that the ACMUI recommends on restriction on condition of use
15 beyond the FDA label. If the FDA modifies the label, okay.

16 DR. WILLIAMSON: That would make it as a license
17 condition then, off-label uses are not possible; that would
18 be a violation of the license.

19 MR. GRAHAM: Actually, it does not. Listen to the
20 sentence.

21 DR. WILLIAMSON: All right.

22 MR. GRAHAM: The ACMUI recommends no restriction
23 on condition of use beyond the FDA label. So as long as I
24 stay within the guidelines and the law of what the FDA label
25 allows, we're not adding any restriction beyond that.

1 DR. WILLIAMSON: Okay, here's the scenario I'm
2 thinking of, John. I'm sorry.

3 At some point, the limitation on HUD may be
4 lifted. And then there will be no sort of special status
5 for this device, and the label will still say it's probably
6 indicated, you know, for X, Y, and Z liver diseases.

7 But now, as I read your amendment or as I
8 understand your amendment, it would now be -- would require
9 another license amendment for the -- to do a clinical study
10 in another site.

11 DR. WAGNER: I think he's right, Jeff's right
12 because we have many isotopes now where we have the FDA
13 label that comes with these isotopes to -- used to be used
14 to -- it wasn't used for heart at all, but many people are
15 using it for that for now. And that's an example that's
16 exactly what you're talking about.

17 DR. WILLIAMSON: Exactly.

18 DR. WAGNER: And so I would agree that Jeff is
19 right about the issue, because if you restrict it to the FDA
20 label, as the FDA moves in later, they'll make changes, but
21 the label will still say the old thing, because the
22 manufacturer doesn't want to change the label, because
23 they've got to go back to the FDA and get it all done.

24 DR. WILLIAMSON: So you'll preclude off-label uses
25 of the device after the HUD status is rescinded; that's my

1 point. And for the moment, there are existing federal laws
2 which require it. As long as it's an HUD device, as I read
3 this paragraph, it's got to be used according to what FDA
4 says.

5 MR. GRAHAM: We have a suggested friendly
6 amendment from our FDA representative. What if it was
7 changed to read beyond the FDA requirements?

8 DR. WILLIAMSON: That's fair. I like that.

9 DR. WAGNER: Cathy's got a friendly amendment.

10 MS. HANEY: Cathy only does friendly amendments.
11 Prescribed dose also needs to be modified, the definition of
12 prescribed dose, and why it needs to be modified is that it
13 keys off the misadministration definition, keys off of the
14 prescribed dose definition.

15 And I think it's, again, a very simple thing. It
16 says for brachytherapy, either the total source strength and
17 exposure time are the total doses documented in the written
18 directive.

19 Does total dose get it? Can we just rely on the
20 "or" in this?

21 DR. NAG: Not total dose, total activity. You
22 have to --

23 MS. HANEY: Okay, then we would have to modify --
24 the friendly amendment is modify the definition for
25 prescribed dose to allow for --

1 MR. GRAHAM: Change total dose to total activity?
2 DR. WILLIAMSON: No, total dose or activity.
3 MS. HANEY: Total dose or activity.
4 DR. WILLIAMSON: I think it could be different in
5 different techniques, that you would imagine in the future.
6 I think some flexibility for the authorized user to define
7 the prescription system is appropriate.
8 DR. CERQUEIRA: Excellent, excellent. Any further
9 discussion?
10 DR. PACE: Yes, I have one. So does this leave us
11 with -- if we're going to have some changes in the wording
12 for prescribed dosage, then I think written directive --
13 then, again, all licensees would come in for an amendment,
14 or no?
15 MS. HANEY: No, the specific licensees would have
16 to come in for an amendment.
17 DR. WILLIAMSON: It's just a one-time amendment.
18 DR. PACE: What about the broad-scope licensees?
19 MS. HANEY: Well, the broad-scope, I think, in
20 this case, given the definitions that we changed, they'd
21 also have to amend their procedure, because the broad-scopes
22 have to comply with 35, and these are the requirements.
23 So you're kind of stuck. I think the issue,
24 though, is that there are not that many licensees that are
25 going to be doing this, either broad scope or specific.

1 DR. PACE: But what we were trying to do is
2 accommodate those licensees who want to use it now, who are
3 trying to help patients now, and so that's why we're here
4 right now.

5 DR. NAG: Cathy, the way that it is written now,
6 for brachytherapy, either the total source strength would
7 include that activity, so it will cover it. Or the total
8 dose, so I don't see any reason to change it.

9 MS. HANEY: That's the question. If you're happy
10 with that as it reads, you think it fits in.

11 DR. NAG: No, total source strength. That entails
12 you have to match quite a number of sources for source
13 strength.

14 MS. HANEY: Okay.

15 DR. WILLIAMSON: Was suggesting total source
16 strength or total dose, whichever you choose.

17 MS. HANEY: Well, dose is just total dose. And
18 it's already in there.

19 DR. NAG: Both of them are there.

20 DR. CERQUEIRA: Total dose or total activity, you
21 want to keep it that way?

22 DR. NAG: The total activity and total source
23 strength is the same thing.

24 DR. CERQUEIRA: So you want to just replace that
25 with total source strength?

1 DR. NAG: It is there.
2 MS. HANEY: No, no.
3 DR. NAG: You don't need to change anything.
4 MS. HANEY: Okay, I remove my friendly amendment.
5 DR. CERQUEIRA: All right, any further discussion?
6 [No response.]
7 DR. CERQUEIRA: Do I hear a motion for a vote?
8 MS. HANEY: Also, did we clarify 35.400 physician,
9 authorized user?
10 DR. CERQUEIRA: Yes.
11 MR. GRAHAM: The entry of this says that ACMUI
12 recognizes that the Therasphere-7 device requires a license
13 amendment under the current Part 35.400.
14 DR. CERQUEIRA: Excellent, excellent.
15 DR. WILLIAMSON: I'm for a vote.
16 DR. CERQUEIRA: Second?
17 DR. NAG: Second.
18 DR. CERQUEIRA: All in favor?
19 [Show of hands.]
20 DR. CERQUEIRA: Opposed?
21 [No response.]
22 MS. HANEY: Did you vote, Ruth?
23 DR. CERQUEIRA: Abstentions?
24 [Show of hands.]
25 MS. HANEY: Okay, one abstention, and everyone

1 else is -- one, two, three, four, five, six, seven, eight,
2 nine, ten. Nine in favor, for the record.

3 DR. CERQUEIRA: Great. I think that worked very
4 well. I mean, John did a good job of keeping the amendment.

5 DR. PACE: If there is anybody in the audience who
6 would like -- who would be interested in learning about this
7 at all, just contact me, and I'll show you the slides.

8 MR. GRAHAM: If you'd like one last shot on how
9 that amendment was worded, you know, I'm open to -- I can be
10 bought.

11 DR. WILLIAMSON: I do want to say that your
12 handout was extremely well put together and very
13 informative, and you know, I read it, and I thought I really
14 understood a lot.

15 DR. PACE: Good.

16 MR. GRAHAM: I guess I'd want to echo that, that
17 the handout, having read it ahead of the meeting, allowed an
18 expedited discussion, and I'd hate to have you think that
19 we're just banging away after -- your handout answered a lot
20 of the issues.

21 DR. WILLIAMSON: If everyone did this, it would be
22 a lot smoother, I think.

23 DR. CERQUEIRA: All right, any other business?

24 [No response.]

25 DR. CERQUEIRA: In which case, who moves to

1 adjourn?

2 VOICES: So moved.

3 DR. CERQUEIRA: Tomorrow, we'll reconvene at 8:30.

4 [Whereupon, at 5:00 p.m., the meeting was

5 recessed, to reconvene at 8:30 a.m., Thursday, November 9,
6 2000.]

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