UNITED STATES
NUCLEAR REGULATORY COMMISSION
***
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Room T-2-B3
Rockville, Maryland

Wednesday, November 8, 2000

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Yes. Cathy Haney.

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

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

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

The function of the Advisory Committee is to

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Sure.

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

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

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

So I really want to congratulate you.

[Applause.]

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

DR. COOL: No.

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

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

So I think you guys deserve at pat on your back. So thank you.

DR. COOL: Thank you very much.

[Applause.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stakeholders range from our friends down on

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

Any questions for Mr. Cool?

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

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

also an important component of that public confidence.

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

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

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

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

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

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

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

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

DR. CERQUERIA: Tom?

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

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

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

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

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

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

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

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

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

MR. YOUNG: Go ahead.

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

MR. YOUNG: Sorry about that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

your questions there?

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

MS. HANEY: Okay.

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

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

MR. YOUNG: Pardon?

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

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

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

They do a very thorough review on the

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

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

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

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

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

MS. HANEY: Right.

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

April.

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

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

MS. HANEY: Roughly, right.

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

MR. YOUNG: Yes.

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

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

MS. HANEY: We can get some extra copies.

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

MS. HANEY: We'll get you copies.

DR. CERQUERIA: Okay. Tom?

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

We're focusing on the notification paragraph for

each of these. I'm going to show it to you on the next couple of slides. But these are -- if you look at the SRM, the attachment, these are items one and two of the attachment and we're incorporating these changes, and we want to show them to you here.

But we're deleting this record-keeping requirement out of 35.2045 and 2047, the companion record-keeping requirement, because we assume that if we get a report from the licensee, then we're responsible for keeping that as a record.

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

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

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

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

This is paragraph G. We're replacing it.

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

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

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

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

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

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

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

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

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

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

MS. HANEY: That has not changed.

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

MS. SCHWARZ: No.

DR. CERQUERIA: John?

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

this rule is going to go into effect.

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

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

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

DR. CERQUERIA: I'm sorry. What?

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: So additional rulemaking goes back --

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

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

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

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

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

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

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

DR. McBURNEY: Five rem?

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

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

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

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

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

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

DR. CERQUERIA: Ahead of the game.

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

MS. HANEY: No.

DR. WILLIAMSON: This will be a subsequent --

MS. HANEY: Yes.

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

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

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

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

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

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

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

DR. CERQUERIA: That's here.

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

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

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

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

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

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

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

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

We could put the training, the requirements, if

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

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

MS. HANEY: Right. Yes.

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

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

MS. HANEY: That's probably true.

MR. GRAHAM: Okay.

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

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

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

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

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

[Recess.]

DR. CERQUERIA: Mr. Torres?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. McBURNEY: I'm sure they will.

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

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

DR. NAG: The old.

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

DR. CERQUERIA: Jeff?

DR. WILLIAMSON: What document outlines the levels

of compatibility requirement by requirement?

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

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

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

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

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

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

or stakeholders to make comments.

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Is there an OAS contact person who

is sort of doing this?

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

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

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

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

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

straightened out.

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

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

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

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

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

And this is the --

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

DR. CERQUERIA: Cathy?

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

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

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

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

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

MS. HANEY: Oh, definitely.

DR. WILLIAMSON: -- to do a detailed

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

MS. HANEY: Exactly.

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

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

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

Thank you very much.

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

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

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

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

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

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

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

The radiation oncology community?

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

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

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

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

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

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

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

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

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

The credibility of this group long-term and the

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

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

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

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

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

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

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

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

Niki, from the perspective of the consumer?

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

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

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

MS. HOBSON: I think the support organizations,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: That definitely would be worthwhile.

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

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

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

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

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

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

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

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

Jeffrey?

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Good point.

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

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

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

DR. CERQUERIA: Those are very good points.

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

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

DR. CERQUERIA: Let's hear from --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. VETTER: That would be great.

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

mean to skip over you as we went around here.

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

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

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

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

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

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

Thank you very much.

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

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

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

DR. CERQUERIA: A tough issue.

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

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

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

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

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

DR. McBURNEY: Yes, there is. Paul?

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

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

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

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

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

wording of the regulation need to be identical.

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Training and experience for an

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

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

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

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

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

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

compatible.

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

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

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

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

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

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

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

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

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

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

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

you talking about more restrictive, also.
DR. McBURNEY: It depends on the level.
MR. LOHAUS: It depends on the level of compatibility.
DR. WILLIAMSON: The level.
MR. LOHAUS: Yes.
DR. WILLIAMSON: If it's A or B, it can't be more restrictive, isn't that correct?
DR. McBURNEY: That's correct.
MR. LOHAUS: That's correct, yes.
DR. WILLIAMSON: And just so everyone understands, the training and experience requirements are level B.
MR. LOHAUS: That's correct. They could not be more restrictive, under the designation that's been assigned.
DR. CERQUERIA: Is that true?
MS. HANEY: Under the -- yes, that's true.
DR. CERQUERIA: It cannot be more restrictive.
MS. HANEY: In training.
MR. LOHAUS: That's correct.
MS. HANEY: But realize there is that three-year gap where we could have differences.
MR. LOHAUS: I apologize. I talked about the category C, which is a different level, but some of the requirements are category C, but training and experience is

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

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

So if --

MR. LOHAUS: Neither. It can be neither.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

radionuclides.

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

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

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

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

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

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

Dr. Alazraki, did you have a comment?

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

DR. CERQUERIA: Good. Lou?

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

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

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

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

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

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

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

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

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

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

MR. GRAHAM: As is germane to radiation safety.

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

MR. AYRES: Or if they have a question.

DR. CERQUERIA: John?

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

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

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

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

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

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

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

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

DR. CERQUERIA: Dr. Diamond?

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

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

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

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

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

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

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

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

DR. CERQUERIA: Good point. Other comments?

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

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

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

different specialties and one of them is nuclear pharmacy.

DR. CERQUERIA: Okay.

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

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

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

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

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

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

nor through our General Counsel's office.

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

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

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

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

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

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

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

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

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

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

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

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

DR. McBURNEY: Yes.

DR. CERQUERIA: Okay. Good.

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

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

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

There really is a problem there with the board meeting the letter of the intent or letter of the requirements, NRC regulation, and the next one, slide, goes into some detail on that, as I recall.

We set forth the requirements, you have asked for this, so this is the requirements that are in question, which is one year of full-time radiation safety experience under the supervision of an individual identified as an RSO on a Commission or agreement state license.

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

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

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

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

DR. CERQUERIA: We have a question.

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

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

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

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

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

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

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

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

DR. AYRES: I think you're correct.

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

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

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

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

process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. CERQUERIA: Exactly. Yes.

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

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

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

I mean, they could do that, right?

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

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

Dick, do you have a comment?

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

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

DR. AYRES: We're not.

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

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

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

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

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

DR. AYRES: Missing component.

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

DR. CERQUERIA: That does. John?

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

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

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

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

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

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

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

We can go on to the next one.

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

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

DR. CERQUERIA: No.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. ALAZRAKI: Okay.

DR. AYRES: Or something like that.

DR. CERQUERIA: Dr. Nag?

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

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

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

I think if someone had three years of training as

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

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

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

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

DR. AYRES: Unfortunately, the rule says --

DR. WILLIAMSON: Can I finish?

DR. AYRES: -- what the rule says.

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

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

DR. AYRES: Jeff is raising a definition variance.

DR. WILLIAMSON: I think this hinges on the

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

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

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

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

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

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

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

require this.

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

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

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

That's where we're at.

DR. CERQUERIA: Dick?

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

anybody is going to meet this requirement.

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

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

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

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

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

DR. CERQUERIA: Niki?

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

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

DR. CERQUERIA: John?
MR. GRAHAM: I guess I just want to clarify what Cathy -- my understanding is that if somebody had the ABR and then someone is willing to sign the certification, they could -- they would meet all the requirements for RSO. That's how it's going to be written in the guidance. So the intent of what we hammered on for two years is still in here.
MS. HANEY: Yes.
MR. GRAHAM: It's just takes those two things together.
MS. HANEY: It's just how you get there.
DR. AYRES: The simple board certification, in and of itself, doesn't appear to work and the board is recognizing that and raising the issue.
Continuing on with the ABR letter --
DR. CERQUERIA: Bob, we're going to have to wrap up in about four or five minutes.
DR. AYRES: Okay. I will make it real simple. The issue, if a physicist certification for all the specialties and it applies across the board to authorized users, too, you can conceive -- I think it's fairly reasonable to recognize that if you sum together Parts 400 and 600, that not all medical physicists nor authorized users are going to get training in all of it, in manual

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

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

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

DR. CERQUERIA: Jeff, any comments?

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

user and authorized medical physicist or an RSO.

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

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

Let me finish, before you interrupt.

DR. AYRES: No, I was thinking.

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

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

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

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

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

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

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

If you have 700 hours of training and that 700

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

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

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

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

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

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

not have 500 hours of Cobalt-60.
So I think before this regulation goes out, we have to --
DR. CERQUERIA: Well we can't change the regulation.
DR. NAG: No, we are not changing. We have --
DR. CERQUERIA: The interpretation.
DR. NAG: The interpretation of that.
DR. CERQUERIA: Of how we deal with the boards.
DR. WILLIAMSON: I think something has to be done. This is very serious. I think this will all grind to a halt if something is not done about these interpretations.
MS. HANEY: Well, I think there are some things that we can still modify in the statements of consideration. I think what we need to do is make sure we keep a common sense approach to this and, as you said, not make it more difficult than what it needs to be.
But I think the issue that Dr. Nag is bringing up about it doesn't have to be 700 hours in everything, there is some overlap between the training, just as there is overlap between the training for a brachytherapy user, as well as one that's using an HDR.
So I think that common sense needs to be applied. The decay formula is the same decay formula whether you're in 100 or whether you're in 600. So you don't need to hear

that six different times.

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

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

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

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

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

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

Now, how it will s hake it out in the end, I don't know.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

learn about handling of Cobalt-60.

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

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

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

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

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

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

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

DR. CERQUERIA: I didn't --
DR. AYRES: Well, our general counsel has an awful lot to say about what the rule means exactly and it's only been discussed in a general way with them and exactly how to apply these requirements. There's no final -- I'm not presenting any NRC final position on this whatsoever, just some preliminary thinking.
DR. CERQUERIA: That's sort of -- maybe we should have had the counsel involved in all these meetings for the last three years, because we've spent time and come up with --
DR. AYRES: They have been.
DR. CERQUERIA: Well, not making direct comments and supplying direct information.
DR. McBURNEY: The guidance document still is to be written and although that doesn't carry the force of law the way the rule does, still, if those who are inspecting or interpreting what goes on in the real world use the guidance document, if that clarifies the intent --
MS. HANEY: We can always put out guidance that clarifies the intent and whether it goes into the statements of consideration or goes into the questions and answers that Roberto talked about maintaining on the web site, we can put the things in documentation.
The only issue right now is where it would exist

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

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

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

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

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

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

than at the time of implementation.

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

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

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

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

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

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

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

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

Thanks.

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

So it will just cut into our lunch break.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The sixth one, can startup and implementation

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

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

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

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

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

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

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

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

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

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

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

Commission office during some of the Part 35 deliberations.

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

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

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

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

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

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

I'd like to briefly mention training. We are

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

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

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

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

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

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

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

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

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

A couple of them, recently, Yucca Mountain project, DOE has suggested that they may do a graded approach for structures, systems and components, and we will review that, as well as a couple of other things.

The final thing I would mention is we are visiting a number of regulated entities to -- since we come from a variety of backgrounds, sort of inform our own group about some of the

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

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

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

DR. CERQUERIA: Cathy?

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

Risk management is another outgrowth entirely.

DR. CERQUERIA: I hope that answers your question,

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

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

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

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

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

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

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

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

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

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

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

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

DR. WILLIAMSON: Prioritization using NRC performance goals.

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

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

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

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

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

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

DR. CERQUERIA: We have a question.

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

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

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

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

to be in this discussion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

That's about it.

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

[Whereupon, at 12:20 p.m., the meeting was recessed, to reconvene at 1:16 p.m., this same day.]

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

schedule my time, how long do you think your presentation is going to take?

DR. AYRES: I'm going to try and speed through the first two. They're usually, I'd say, about five or ten minutes for the first one, and 15 for the second one, and god only knows for the third one.

DR. CERQUEIRA: For the discussion, okay. Well, that's good, because we do need to have discussion on this, and okay, great.

We do need to have discussion on this. Okay, great.

DR. AYRES: I envision most of the discussion occurring in the third, and that's where I've prepared, but I'm willing for anybody to interject into the first two and to have a question or something.

DR. CERQUEIRA: Sure. And then we have presentations from outside people as well, too.

DR. AYRES: Okay.

DR. CERQUEIRA: Good.

DR. AYRES: All right, I'll go ahead and get moving on this, then. Like I said, this first one is on what we're presently doing in license for the participation in trials.

We actually published our guidance in an FDA document which is now really outdated. I'll just note that.

It was also a later update to that that was done in a intravascular conference presentation abstract, which is not very well available.

As I said, it's become outdated, and if you have access to Advances in Radiation Therapy, that's where that was published in 1998.

Really, licensing is important on what class of licensee we have. And the two major classifications are, of course, Type A, broad scope licensees, medical licensees.

And they really, in most cases, don't even have to come into us to participate in these trials, because as standard license conditions, they have the necessary exemptions to our normal regulatory requirements to participate, that being the sealed source and device review that exempts them from 35.49(a), and they're exempted from the use requirements set forth in 35.400.

So, broad scopes can pretty well move on ahead, although we've had problems, and that was addressed with an IN awhile back, about we're delegating the responsibility for radiation safety to them by these exemptions, and they're not picking up the gauntlet and ensuring that these are using these in a safe manner.

For limited specific licensees, which are, of course, the larger number of ours and Agreement State licensees themselves -- and I should say that what I'm

talking about is the way that NRC does it.

The Agreement States, many of them follow very closely what they do; some are more restrictive; some are less.

So, you have to talk to your local friendly Agreement State to find out what differences there are.

Basically, we require all requests for authorization to participate in these trials that come into the Regions, that they be submitted to headquarters for review, and basically I looked at these with six criteria:

First, that it had undergone a sealed source and device evaluation and been registered in our registry. If it hadn't, we would not authorize it; we would not grant exemptions to this requirement.

The second one is that it had and FDA-approved protocol. FDA has classified this as a high-risk human trial, and therefore mandated the IDE process.

And so that was a regulatory checkoff that -- and that also satisfied our requirement in 35.6 for the conduct of human research, informed consent, IRB approval, all of those components.

And then the appropriately-qualified user physician: Essentially that boiled down to 35.400, a radiation oncologist qualified in manual brachytherapy, or remote afterloading brachytherapy. I'll mention one place

where we differed from that a little bit.

Then we also, in these IDE processes, which the FDA had reviewed quite thoroughly -- there was embedded in those, a number of radiation safety commitment. And so we asked our licensees to extract those and submit those to us in a separate document, because we could not incorporate by reference, radiation safety commitments that were contained within a confidential document, which an IDE is.

In some cases, these documents restricted access to confidential information, which we had the right for access to under the Atomic Energy Act, and just save a lot of wrangling. We made sure that we were included in the list of agencies that had access to that information, if we needed it.

And then the last one is not really a requirement, but a requirement on our part to issue an exemption to 10 CFR 35.400 for the use of whatever source or system was being used for intravascular brachytherapy, because all of our 35.400 uses are for the treatment cancer and none for benign disease.

With regard to the new Part 35, that will change it some, and that's been talked about quite a bit here. I'm not going to go into that in any detail.

The main thing is that it gives us a new way to write these authorizations, 35.1000, the emerging

technologies, and as intravascular brachytherapy is not addressed within the new Part 35, it will be viewed in most cases, if not all, as an emerging technology and handled under that section. We'll talk about that later, because that's certainly important to the routine use authorizations.

Under existing Part 35, the training and experience requirements for authorized users were pretty much established by 940, which is, under the new Part 35, is 35.400. It's training and experience for manual brachytherapy.

Under the new Part 35, clearly some of these systems will be classified as remote afterloaders, and so those that are manual afterloading devices would -- the training and experience would most likely come under 35.490, or be similar to those. Using 35.1000, we're no longer bound to those training and experience requirements, but if they're appropriate, then they're likely to be used, or if it's a remote afterloading device, 35.690.

One problem that comes up -- and I've got one on my desk now -- and we have not yet addressed this issue or made any decisions. Some of these new devices use unsealed sources or what I like to call contained. Generally, they are gas or liquid-filled balloons.

They neither meet our definition of a

radiopharmaceutical, nor do they meet our definition of a sealed source. They kind of fall in a space we didn't anticipate.

And, again, there, what is the most relevant training and experience? Is it 930? Radiopharmaceutical therapy, or 940, brachytherapy?

Handling the material is kind of the training and experience you would expect from handling radiopharmaceuticals; on the other hand, the dosimetry and the other issues are no different from traditional brachytherapy, so it's kind of a mixture of the two, and it could be a problem.

What we have authorized, to date, for participation in these trials is the Best/Cordis System, which is Radium 192 seeds and nylon ribbons, and nucletron Paris study, which is the traditional high-dose rate remote afterloader for treating re-stenosis and peripheral arteries, primarily the femoral and the popliteal arteries in the leg.

And early on, IN-implanted P-32 stents, it looks like the have -- well, they went away, and I think they're going to stay that way. It looks like there are some real technology problems there that to the best of my knowledge, are not solvable at this point.

Except for the stent systems, we used all the

presently authorized trials that we've authorized. There are plenty of other trials that FDA has authorized that we haven't, that use traditional photo emitters in the form of sealed sources.

The stents were authorized under 35.300, and have concerns related to leaching of the material and so forth. I think that was inappropriate and it's been discussed, and if they ever reappeared -- which seems unlikely -- we might revisit how we would authorize stents.

Clearly, the one thing you can say about stents is that it's unfortunate, I guess, that maybe the technology is not working out, because they probably have the least radiation safety hazard issues associated with them of any of these systems.

And that is all I had on how we're presently doing things for authorizing for trials. I'll bring up the other file, and if anybody has any questions about this, I'll be glad to answer them.

DR. CERQUEIRA: Does anybody have any questions for Bob at this point? This is mostly sort of historical in terms of what we've done to date.

DR. NAG: This may be historical, but the question I have is, the NRC is in the business of radiation safety aspect.

There are two aspects: One is the safety aspect

of intravascular brachytherapy, and the other is the efficacy and technique of doing intravascular.

Now, in terms of an emerging modality, in terms of -- a vessel, other than going into the issue, it is different. But in terms of the safety issue, why is this any different from the use of sealed sources or any other therapy that means under 35.490?

There are no issues that are any different from any of the manual brachytherapy sources. In terms of the use of the remote afterloader, the -- system, the radiation safety aspect is no different from 35.69 within the remote afterloader.

So why are we now trying to differentiate intravascular brachytherapy from any other brachy therapy?

DR. AYRES: Well, you take something like Best/Cordis system, the radium seeds and nylon ribbon, and I agree. There is very little difference.

But if you take something like the Nova system with the beta emitter, there is all kind of requirements that are inappropriate.

And there are additional considerations that maybe should be in, and we'll get to those when we start talking about what we should be doing.

DR. CERQUEIRA: Right.

DR. AYRES: So, like I say, they vary all over the

lot, particularly the liquid-contained systems.

DR. NAG: Yes, but that difference, we are saying about the sealed sources -- I mean, the liquid is entirely different, and that can come under the same category. But when we are talking about the high dose rates that we use for any other brachy therapy and the high dose rate you use in the vessel, the safety considerations, they are no different.

DR. AYRES: We get into some peculiar situations. For example, our definitions of new Part 35, all of the intravascular brachytherapy systems are high dose rates, so we'll have high dose rate manual afterloading systems, which we don't have now, for example.

And so there are a whole lot of new issues that pop up.

Well, let me go on and talk about the problems --

DR. CERQUEIRA: We'll come back to this during the discussion.

DR. AYRES: We'll talk about misadministration or event. Misadministration is just something that met our definition of plus or minus 20 percent or in the wrong site, and an event was something of a lower significance, but it was reported and of interest because it indicated some sort of problem with the delivery or the system.

To date, we've had 16 misadministrations or events

reported, and counting. The trials are still ongoing, and they will be ongoing for quite some time.

And I'll --

DR. CERQUEIRA: Bob, let me just ask one point of clarification: We're talking about intravascular brachytherapy?

DR. AYRES: This is purely intravascular brachytherapy.

DR. CERQUEIRA: If those trials that are currently being done -- I mean, are we still talking almost exclusively about the heart, or are we doing a lot of other organ systems? You did mention peripheral.

DR. AYRES: There's one trial that I'm aware of with the peripheral arteries. And there is also some work with the shunts for dialysis patients that also stenose or occlude.

But compared to the intravascular, it's very small amount.

DR. CERQUEIRA: To the intracoronary?

DR. WILLIAMSON: Yes, the cardiac intravascular.

DR. CERQUEIRA: Yes.

DR. AYRES: Yes, coronary, cardiac intravascular, yes.

DR. CERQUEIRA: In terms of the FDA, do you have any specific information in terms of the number of ongoing

trials and the different types of agents that are being used and the targets?

MR. LEEDHAM: We can't specifically comment on any applications that we have before us, however, I know for information that's been in public venues, that there are in heart, the renal system, and --

And a point of clarification just if I may: FDA has -- we have drugs, we have devices, medical devices, and we have drug/device combinations. Your example of the catheter with the radioactive material in a balloon, that's considered a device, however, it does have a radiopharmaceutical inside, but since it's intended use is not to be outside --

DR. AYRES: Exactly.

MR. LEEDHAM: It's considered fully a device.

DR. AYRES: I believe drugs does participate sometimes, jointly in these evaluations, particularly on the potential hazards, should a balloon rupture, on the materials.

MR. LEEDHAM: Very infrequently.

DR. AYRES: But it is classified as a device, and I'll talk some more about that issue later.

DR. CERQUEIRA: Okay.

DR. AYRES: We've had 16 misadministration events. There are several dozen of these trials underway, and not

only vendor-sponsored, but at larger research institutions.

There were seven misadministrations in one; four misadministration events in a second; three in a third; and I'll talk about those, and then we have one each in three additional ones, for a total of problems in five separate trials. Some were device-related; some were not.

We used this information. I go around to the various intravascular meetings and talk about this to alert other users of the potential problems and we published an information notice on a couple of these.

It is also why I am here, why I am presenting it now. It's good guidance on what is the appropriate level of regulation perhaps to govern these device approvals to prevent those that would be easily preventable and to provide feedback on ways to improve the device designs or study protocols.

I think there are some interesting lessons learned and I will try to point some of them out. The trials were the Novoste Beta-Cath trial. I got BERT but there are several trials there. There were seven there, three with the guidant. The guidant is a -- well, the Novoste Beta-Cath is a Strontium-90 hydraulically moved pellets, sealed sources. The guidant is a P-32, HDR-driven wire. The Angiorad was a hand-cracked radium wire. The Radiant is one of the Rhenium-188 filled balloons, the Nucletron pair

study I already mentioned and the Sabre trial was a chelated Rhenium-188 liquid filled balloon.

The first one that was reported to us was a patient receiving an unintended dose to the wrong treatment site by one of our licensee and in a very similar event less than a month later it was reported by the State of Washington with the same device.

This one was looked at quite extensively and determined a root cause and the possible source transport failure modes and this one was also one that was covered in considerable detail by an information notice.

We looked at the factors that contributed to the reported misadministration and the licensee prepared some quite reasonable corrective actions to prevent this sort of thing in the future.

DR. CERQUEIRA: So the device went out there but didn't get to where it was supposed to go?

DR. AYRES: That's what I am getting to right now, okay?

What the root cause was determined to be was over-tightening of the Touhy-Bourst valve, which is the valve that provides access to the femoral artery for doing the catheterization. If you tighten this anywhere near where an intravascular cardiologist would normally tighten this to prevent blood leakage, you crimp the transport

catheter for the sources and block the source path.

In fact, you can put a crimp in there that remains after you loosen the valve and it takes some time for it to expand -- for the elasticity to return back to normal. I suppose if you way overdid it, it never would.

Anyway, this blocked return of the sources to the storage position, left them in the patient and it did allow the saline flow. This system depends on two-way flow. That's been changed. It is no longer saline. It is now water.

A reversible flow in a triple lumen catheter to move the sources in and out of position from the storage safe, which is a hand-held device.

The second event more than likely had the same root cause but it wasn't investigated to the extent that the first one was, so we can't say with any certainty.

Like I said, there were identified and our licensee did an excellent job of analyzing the system after the event, and we pointed out that this is exactly the sort of thing we would prefer to have happen before they started using these new technologies -- in another information notice, and identified three modes of failure, one being the Touhy-Bourst valve over-tightening.

You can also -- the source movement and holding the sources in place depend on the physician, generally the

radiation oncologist, holding a constant amount of pressure on a device or there is an indicator to show that that is being done, but any inattention in it, it seems to not happen.

If you for example apply too much pressure you can deplete the transport fluid prematurely and then the sources float again, so that is another failure mode.

It was possible in our earlier design -- I think that has been corrected -- to over-tighten the syringe to the lure which supplied the transport fluid.

Like I said, we talked about the Touhy-Bourst. There was also issued related to the training and so on. It was felt that there was an excessive time interval between training and start of the clinical procedures.

The training itself was less than optimal for the didactic and practical training. There were limited and very limited opportunities for self-practice and rehearsal, which I think was certainly adverse and a contributing effect.

There was lack of detailed operational and emergency checklists, which is something we normally require for remote afterloaders. There may be some debate. I think this qualifies as a remote afterloader. I know not everyone agrees with me.

The proposed corrective actions was to improve the

radiation oncology training, and particularly a review of relevant interventional cardiology procedures. What you run into in these collaborative efforts between in this case an interventional cardiologist and radiation oncologist, they are not familiar with each other's procedures, equipment, and operations, and it is that lack of familiarity on the parts of a team that can cause problems.

That could be considerably aided by providing realistic training exercises in the Cath Lab environment, also be conscious of possible treatment catheter damage before and during treatment, develop a checklist of essential steps, checks, and there also should be emergency procedures checklist, and precautions to be followed in executing the treatment and develop an appropriately modified version of AAPM's device, called the assurance protocol.

There is a subcommittee of AAPM now expressly working on intravascular brachytherapy and I think there will be some useful guidance coming out of them, and a new Part 35 reference to industry standard documents and so forth. Hopefully more and better information will be coming in this kind of area -- daily testing of all the treatment units, testing of the treatment catheter before positioning, testing of the position catheter with dummy source train for unobstructed passage, verification of source strength and/or

prescription dose rate.

This latter one of one issue I'll talk about later is testing the catheter for unobstructed passage. That is now done laying out on a table, not in the torturous pathways into the coronary arteries. Maybe it might be better that the dummy source train be run in and out with the catheter in the treatment position rather than laying on a bench.

Verification of the source strength and/or prescription dose rate -- one of the things that one needs to keep in mind and we did this and didn't put much emphasis on dosimetry that we usually should, the important thing in clinical trials is that everything be done consistently even if the dosimetry is not optimal, because you invalidate the data if you decide that you know how to do something better than the trial protocol says.

FDA is acutely aware and reminds me of this and so you don't want to do better. Everybody wants to do the same, but once you go into normal use then the best dosimetry should be applied. We are out of the trial and into preparing data.

DR. CERQUEIRA: So in all three of these situations then basically the device is just pulled out inside the catheter, is that correct?

DR. AYRES: Well, this one, what happened --

DR. CERQUEIRA: I don't want, for the sake of time, so the problem was that the source was in the wrong position?

DR. AYRES: Yes, it was free-floating in an unknown position because these are hydraulic -- so you only know where the sources are at when it is in the safe or in the treatment position where it is in the fluoro field.

Anywhere else you have no idea where the source is.

Okay, continuing, to develop a mechanism for facilitating self-initiated practice procedure review, redesign a treatment to guide catheter interface to eliminate the possibility of catheter damage and there's been some of that done, and I will mention that when I go on to the routine licensing.

The issues are going to be there's been corrective actions. They are not now mandatory. Should they be? -- and this is some of the reason why I am presenting this information.

Comments from our licensee on the corrective action is that they could take care of the first three but the latter three required approval and support of the trial sponsor and was not in the hands of our license. For routine use I think everything important related to radiation safety needs to be in the hands of the licensee.

We wrote these up in the IN.

The AngioRAD ARTISTIC trial event, that one was a hand-cranked iridium source on a wire, so it was like your Nucletron HDR only it was a hand-crank, simpler. One of the problems is with all of the current HDR systems they drive the source with a pinch roller, not with the take-up drum. This hand-crank device used a take-up drum.

You got what you might expect. They encountered a blockage which was caused by over-tightening the connector to the catheter to the exit so when the wire hit that obstruction it acted just like a stiff rod and you got just what you would get with a fishing reel, a snarl, and not only snarls were bad, they couldn't move the source forward or backward. It bird-caged the wire so that it was jammed in the transport system, and this was a case that they didn't have the equipment readily available. They had to go to their HDR and get their wire cutters because this time they needed them.

Fortunately, this occurred on the exit from the machine and the patient got no real dose and they reacted fairly quickly and there was no real significant dose to the users either.

I got ahead of myself. It did have a clutch mechanism but again this one depended on you turning the crank at the right rate. If you turned it too rapidly the

clutch mechanism couldn't react in time to prevent the backlash.

There were a number of exactly similar failures. This is one that prompted the IN, including one identical to it during the demonstration to this licensee which the licensee never in turn reported to the Radiation Safety Committee when they applied for authorization to participate in the trials, which upset, rightfully so, the Radiation Safety Committee and prompted our IN to say, hey, you need to review the radiation safety issues before approving participation in these trials.

Since then we have learned of two more failures very similar to this, only with dummy sources. It didn't feel right when they kept trying to move it back and forth and finally gave up, and they couldn't verify the position with fluoroscopy.

Unlike electronically driven systems, really with most of these system you only know where the source is when it is in the safe or when it is in the treatment position.

I have pretty well covered most of this. One other thing they did, they had the wrong kind of survey meter. They had a GM survey meter anywhere in the room it was pegged so it didn't help them a bit in finding out where the source was jammed at, so they used scissors to cut the catheter until they found the source.

They went then with their HDR emergency procedures.

Like I said, there was fairly minimal exposures because they did react quickly to it, and it didn't, even though they fumbled around a bit, it didn't take them too long to isolate it and it was partially shielded because they hadn't fully exited from the machine.

This was a U.S. Surgical Corporation, which is now out of this business, sponsored device, and they did root cause analysis which found out they over-tightened the lure lock that connected the catheter to the device and that shaved off some plastic and blocked the source pathway.

The Rhenium-188 balloon, it was originally reported as broken and actually in further analysis it looked like it leaked, but anyway it dumped Rhenium-188 into the coronary arteries and it's been determined if the balloon ruptures, which has an order of a 10 percent probability on most balloons, angioplasty balloons, that the dosimetry has been calculated to show that there shouldn't be any real patient harm.

In both of these cases, whether it is the chelated version or the oxide or the perinate itself rather, most of the dose goes to the bladder, and it has a very short biological half-life.

The radiation dose here was 50 centigrade to the

bladder and like I said, it is an expected event with these liquid filled systems. They do take some extra precautions, sometimes double balloon, over-inflating the balloon with excessive pressure before actually using it and some tests for burst pressure.

That was what they proposed a corrective action, a pressure test before using the balloon.

The MAG, SABER trial was when they disconnected from the system they flopped the catheter around, contaminated the Cath Lab. Well, it there was a little message there that says if you are going to use a liquid contained system be prepared to give up the Cath Lab for the decay of the contamination. That is what they had to do. Poor Bill Bass worked till past 2:00 in the morning and could not get it cleaned up and they had to close the Cath Lab until it was decayed, so if you have only got one Cath Lab you might want to think about using such systems.

Like I said, contamination events can readily occur. If you can't tolerate the loss of lab, better not do it and although they can occur with sealed sources the probability is infinitely lower that they will happen with sealed sources.

The nuclear trials was mostly -- were not really device-related. They were mostly lack of thinking I guess you would say.

Originally the afterloader came with a 34 centimeter elbow, which made the transition from the non-sterile afterloader to the sterile field with the catheter connected. The vendor changed that and got rid of the elbow and went directly to the catheter connecting to the device, and they actually had the vendor's representative there and put the elbow in anyway on the new catheter which meant they treated 34 centimeters from the intended target position for the full course of it because they thought they saw the source when they didn't. They saw the guide wire.

One of the corrective actions when they got a dose of 70 to 108 gray to the wall there, they introduced with this new type of catheter, one of the problems was, one of the corrective actions is they made the radiographic markers on the source more visible. They were not particularly sharp.

So it was a new procedure and they used the old techniques and treated 34 centimeters away and they didn't confirm properly with fluoro and again it was a training issue and direction.

The two others were really kind of silly. Well, one was just an event. The source stuck out of the safe during a source exchange. It was just a failure during the source exchange. There was no real exposure to anybody.

The other one, the radiation oncologist or the medical physicist, I've forgotten which one, I think it was the radiation oncologist -- on these clinical trials they are double blind trials and he opened a randomization envelope to find out whether they get radiation or they don't, which he did, and then when he went into the treatment room he forgot which arm it was supposed to be and it was supposed to be receive radiation and he gave them the dummy source instead, so it was 100 percent radiation delivery error.

What is our perspective? Are they of unusually high frequency? Yes. I would say these are close to an order of magnitude higher misadministration rates in brachytherapy in these trials, which you might expect with new techniques and new technologies to a certain degree than they are in the traditional cancer therapies with ionizing radiation sources.

Can the frequency be reduced? Sure. Better review of the protocols and appropriate implementation and improved training, emergency procedures and checklists.

What else could we do? We already mentioned the IN, reminding our broad scope radiation safety folks of their responsibilities. That was IN-9924.

We expected them to do a better job and that covers the issue relating to the problems we have seen over

a couple of years of clinical trials, with a limited number of our licensees participating.

DR. NAG: Let me just say, we went 20 or 30 years back, all right? We had most of the radiation implants that were done with cesium in the cervix. Now, if you went and did interstitial implants, are you going to see that as an entirely new category, and therefore we have an entirely new mechanism of licensing?

Then we have an iodine implant, which is lower entity, and again you have a separate section. You know, that didn't make sense to me to categorize each of these like a section, because, you know, there is the broad category of high dose rate afterloader, or broad category of sealed source. Yes, that makes sense, because if you use the same reasoning, by now we should be having at least 20 different categories of sealed isotopes, because I can tell you the implication of iodine implant is entirely different from the implantation of iridium.

DR. CERQUEIRA: I think part of the thing that has come into this is the fact that obviously there are other people that could be using these devices and some of the discussions have been related to sort of more limited training which is specific for a particular type of treatment.

Similar to what you were discussing with the other

protocols this morning, there are some things to generalize and you don't need training on every specific device, but perhaps we have presentations from people. We have had discussions on this. I would also like to point out that a lot of the things that were misadministrations were sort of really mechanical failures of the system to some extent.

DR. AYRES: Right.

DR. CERQUEIRA: Resulting in radiation problems.

DR. AYRES: That was one objective. I said to catalogue them and determine what we could feed back to improve the system, whether it is the protocol or the training or the design of the device.

DR. CERQUEIRA: Right.

DR. AYRES: Or in some cases you compensate --

DR. CERQUEIRA: We will come back to your point but --

DR. NAG: The second point also is important. You said you would like to get and limit that application but as Bob has pointed out, the safety implications are just the same problem so even though it may be a low entity the safety issues are exactly the same. Therefore, I feel --

DR. CERQUEIRA: Well, again, we can discuss this when we get to it, but we have other presentations from the other people.

DR. AYRES: And there are some different safety

issues which are coming up.

DR. CERQUEIRA: Okay.

DR. AYRES: First off -- again we have the same situation. We have the broad scope and limited specific scope and the broad scope for routine use again don't have much of a problem, although some of the issues we want to talk about we probably want to provide some guidance to them, and I am looking for that guidance and then we will flow it on.

Darn. I think I modified a slide set and I think I goofed. I think I got the wrong one.

DR. CERQUEIRA: Maybe you could summarize it?

DR. AYRES: Yes. The main thing is I wanted to point out to you that we are really going to be -- and this is the second slide in your handout -- that we are going to be talking about two licensing issues, old Part 35 and new Part 35.

Really the relevant information I need at this time is for the old Part 35 because we are going to have to do licensing now.

The FDA has approved this technology and we have no choice. We are going to have to license it under old Part 35, which is far less flexible in many senses than new Part 35, and at the end I'll talk a little about new Part 35, but the important issue before us right now is licensing

this technology under old Part 35.

DR. CERQUEIRA: Bob, maybe perhaps we could -- you know, the FDA has approved use of devices, and have they made any --

DR. AYRES: That's coming up.

DR. CERQUEIRA: You're going to have that, okay.

DR. AYRES: Again, right now, I'd say the four criteria to look at for routine licensing, of course, always is the sealed source and device evaluation registration; that it's done and it's for the proper use.

Now, instead of an IDE, in order to be used for routine use, it needs an FDA PMA, Pre-Market Approval, which is at the successful conclusion of the IDE process, if you will.

An appropriately qualified physician as an authorized user, and I think under the old Part 35, there's just no question that it's 35.400, that's it. There's no discussion there.

And we'll need to grant the exemption to the requirements of 35.400 because it doesn't authorize this type of use. No problem; pretty straightforward there.

And I'd say there are really three levels of licensing complexity: Simple, the Best/Cordis system is really a traditional radiation oncology treatment system for a different use. That's about it.

There are some other issues that the Regions will have to be cautioned about, you know, using these non-shielded cath labs that could be radiation protection problems, and compliance with Part 20 issues. It's not all that simple, but it's pretty straightforward.

The monitor of pure beta-emitting sealed sources, there, we just have a lot of requirements in the current regulations that really are not applicable; in other words, all the shielding interlocks and that sort of thing are really not applicable to those kinds of sources.

And the more complex ones, which we haven't yet dealt with, are these unsealed sources.

DR. NAG: One question I have: You said -- why wouldn't it be less, less shielding.

DR. AYRES: The what?

DR. NAG: The -- sources.

DR. AYRES: No, they're not, because that means we've got a grant now, exemptions to all the requirements requiring the shielding, because we're under old Part 35 territories.

So from a licensing perspective, it's a heck of a lot more complex. From a use perspective, it's not. It's simpler. I'm talking licensing issues.

DR. WILLIAMSON: That may or may not be, actually.

DR. AYRES: Under new Part 35, when you start with

a clean sheet, you're -- it's easier.

And somehow I mixed up my files here, and this was supposed to go at the end. But as I said, 1000 is added to accommodate this sort of thing, and it allows a lot more flexibility, and applicable existing requirements are most likely the way to go.

Those things that are relevant would be applied, and then you write the new part.

DR. WILLIAMSON: Well, with regard to handling this under the old Part 35, why couldn't you do it by license conditions, just like you did for high-dose rate therapies?

DR. AYRES: That's what I think I'm going to do. And when -- in a just a minute, I'm getting to where I want feedback from the Committee on what license conditions are appropriate, okay?

Exactly, the mechanism isn't so important. We'll certainly try to do it the best and least burdensome way on the Staff here.

The present status of the FDA approvals: Like I said, there are numerous systems undergoing clinical trials, and two vendors have submitted trial results for the authorization, and they have both been approved.

The Best/Cordis Iridium-192 seeds and the Nova Strontium-90 seeds, and the hydraulically driven remote

afterloading device.

In both cases, the FDA circulatory systems device panels have recommended approval with conditions. And these conditions are varied, but in both cases, it's a mandated team of an interventional cardiologist, a radiation oncologist, and the medical physicist.

There are other things like tracking device problems, and in both of the trials, they wanted the patients followed out for further periods of time, because what is unknown is any long-term adverse health effects.

There's reason to expect from traditional radiation oncology that there might be problems five years or so down the road, and this patient population hasn't been followed out that far.

The Best/Cordis system, it was recommended -- the Committee recommended on June 19th, 2000, that they approve it with label changes, patient followup, and the team.

And it was recommended for approval for the treatment of in-stent re-stenosis only. It's the same thing for the Novoste system. On September 11th, it was restricted to a 30 mm. device. They have a larger device, and that's undergoing ongoing trials to establish its approval.

The labeling changes and that included the team, patient followup and post-market surveillance of the device,

failure and malfunction events.

In addition to the ones that I described to you where the source movement was blocked, with the Novoste system, there was a lot of source drift problem where if you don't hold that constant pressure, the train of seeds drift apart, and there are issues about whether that should be a misadministration, too, of course.

DR. McBURNEY: Have they made those labeling changes, or was that just a recommendation?

DR. AYRES: They had to comply with these requirements to FDA satisfaction before they would approve the PMA, which has been approved, and includes good manufacturing practice, inspections of the manufacturer, and there's a lot of procedures. I'm sure our FDA representative could address them in more detail than I.

Both these were approved simultaneously on Friday. Okay, now, we're at the meat of this. Conditions of use: I think it's important that we shouldn't approve them, license them for the treatment of stenosis or re-stenosis. I think we should restrict it to what the FDA has established as safe and effective use, which is the treatment of in-stent re-stenosis.

There are ongoing trials to try and establish safety and efficacy in other things. I've received numerous calls that we can do de novo lesions or it's good scientific

reasons why that might not be appropriate.

And the trials are ongoing to establish those uses. If we condition it this way, what does that mean?

Well, that means that our limited, specific scope licensees, that's the only thing they could do. Our broad scopes could conduct their own trials if they wanted to do something else, either under an IDE, if they are trying to establish FDA approval, or simply under 35.6, informed consent and their IRB approval for an inhouse trial. They have more flexibility.

But I think the condition of the use that we approve would be -- and limited specific could go with 35.6, too -- that the use which has been established as safe and effective should be what should be approved, and anything outside that would be a clinical trial. That's the way I think we should go with how we would approve the use of these devices.

DR. CERQUEIRA: Jeff, you had a comment?

DR. WILLIAMSON: Well, yes. I mean, I think perhaps that's certainly sound medical advice, and, no doubt, what people will do. But if you're going to sort of cast this into stone as the sole licensing criteria, at some point it could become an anchor or dead weight on clinical research.

So one could ask, FDA has its laws about following

the labeling, medical practice has its own internal control mechanisms, so what is NRC doing in the business of specifying by law, that this is the only clinical indication for this device?

DR. AYRES: Well, FDA's is not binding on the medical institutions, of course. That's called off-label and not binding on the vendor.

DR. NAG: I have a strong feeling about this. I think the job of the NRC is to deal with the radiation safety issue. In terms of the medical necessity or medical condition, NRC does not have any business to say about the medical requirement of that.

So we can say yes, you know, to use that, we license the use in intravascular and so forth. And it is the FDA or the medical community that would decide whether this is to be used, whether they are to be used for in-stent or --

Today we have shown in-stent re-stenosis; tomorrow is really possible that other uses can be possible, and FDA should license that.

DR. AYRES: And that could, in turn, be authorized fairly easily.

DR. CERQUEIRA: I think that's pretty much in line with everything else that we have done with the Part 35 revision. And you've got adequate approval process from the

FDA, and then you've got clinical indications, and reimbursement will obviously drive part of that.

So we really need to focus on the radiation safety aspects under the existing Part 35, which is what is out there right now.

DR. AYRES: Which I believe this to be one. I mean, this is the only indication that has shown to be safe.

DR. WILLIAMSON: I think you should apply the test of the medical policy statement to this suggestion.

DR. AYRES: Yes. I have, and I come out that we should license for in-stent re-stenosis.

[Laughter.]

MR. LEEDHAM: Just real quickly, we do have regulatory criteria for when an IND or NDA or IND or IDE is required.

DR. AYRES: Exactly.

MR. LEEDHAM: So it's not like you just approve something for one condition and then the world is out there and is using it under the practice of medicine. So there is clear criteria, regulatorily.

DR. AYRES: My understanding, talking with Bob Phillips -- and maybe you can correct me -- is if they wanted to go off-label and do it to establish clinical trial data to get authorization for other uses, then it needs to be under an IDE.

If they have no intent of using that data to establish with FDA, other uses, they could do it under our regulation with informed consent and their IRB approval and so forth to meet the federal requirement.

DR. CERQUEIRA: So there is still a mechanism out there.

DR. AYRES: There is still a mechanism.

DR. CERQUEIRA: And the radiation safety issues are going to be identical, regardless of whether it's being used in the context of a trial or for clinical applications.

DR. AYRES: Except that the advantage I see is that a patient would be informed that they are in an experimental or getting an experimental treatment, rather than one that has been proven to be safe and effective.

DR. ALAZRAKI: But that's what happens in the absence of any NRC involvement in these things.

DR. AYRES: Well, some places, that may happen.

DR. ALAZRAKI: That's exactly what happens, and I can give you some concrete examples.

DR. WILLIAMSON: Why do you want to put this additional requirement? You would prevent clinical studies like this from occurring, it seems to me, by licensing a specific scope.

DR. AYRES: The licensees of specific scope can perform research under 35.6, too. It's not restricted to

broad scope, 35.6 authorization.

DR. NAG: I think the other point is that the NRC has certain limits, and I think you are overstepping the limit by saying that under this condition only. I mean, so long as the radiation safety aspects are met, I don't think you can regulate the non-radiation safety portion.

Otherwise, you can say that you shouldn't use the I-131 for use of anything other than thyroid disease.

DR. AYRES: I guess the only thing I can say is that the FDA panel disagrees with you with being primarily radiation -- I mean, interventional cardiologists, and they deemed that this is the only safe and effective -- proven safe and effective use.

Now, that's not to say that there are not a lot of other uses that wouldn't be, but they're not proven.

DR. CERQUEIRA: But that's not really our issue. I mean, I think the FDA has been very clear on what the requirements are. It's a team approach. They've clearly specified who should be doing it.

Under the current existing Part 35, the training and experience requirements are fairly clearly spelled out.

DR. AYRES: That is only binding on the marketing; it's not binding on the use.

DR. ALAZRAKI: Yes, it is binding on the use.

DR. AYRES: No. The FDA does not -- if Washington

University gets one of the devices and decides that they wish to treat de novo lesions, the FDA has no issue with that.

DR. CERQUEIRA: But that shouldn't be the NRC's issue. As long as they're doing it in an efficient radiation safety arena --

DR. AYRES: It is a question of is it or is it not a radiation safety issue? I think it is, and obviously not everyone agrees here.

DR. ALAZRAKI: I think everyone disagrees.

DR. DIAMOND: Not me.

DR. NAG: If we had a vote here -- I think if we had a vote here, I think we'd all disagree.

DR. CERQUEIRA: Let's hear Dr. Diamond then.

DR. DIAMOND: I'd like this for the record as a point of dissent from what I'm hearing. I fully understand that the FDA has no statutory authority to regulate the off-label use of a drug or a medical device, and I fully understand that it's not the NRC's job to go and dictate what is good medical practice or not.

But let me just make a very clear practical point: If the NRC provides guidance that there will be no restriction on the off-FDA-label indication of this technology, then as soon, in the next two, three, four weeks, when the Agreement States and the NRC States are able

to get certain centers through on the final nuts and bolts of using these devices commercially, what you will have is, you will have individuals using these devices in the carotid arteries, for AV dialysis shunts, in the infrainguinal arterial system, perhaps in the great venous circulation for stenoses.

And we really need to ask ourselves, do we want to contribute into the death of any, in my opinion, reasonable clinical study of this technology, because I think that's what's going to happen.

I think what will happen is, this will become a device or a technology which is going to be used in a form without any proven safety and efficacy data. So we are now in a predicament.

We recognize the statutory restrictions that both parties hold, and we're in a gray zone. But from a clinician's standpoint, from my particular bias, I'm very concerned that in one month or two months from now, we start using this for a lot of different indications, with no efficacy and no safety data.

DR. ALAZRAKI: In my institution, if someone wanted to try something like this at a site which is not a recognized approved and validated therapy, they would have to go through the IRB, the Radiation Safety Committee, and get all the approvals, because it would clearly be

investigative work.
MS. SCHWARTZ: Right.
DR. ALAZRAKI: And this is an institutional prerogative to enforce that type of a practice and thinking when it comes to doing things which aren't clearly clinically proven.
DR. DIAMOND: And I think there is a mechanism in existence, as Dr. Ayres just mentioned, where that can be done.
DR. AYRES: Yes, that's what point was. If there are other uses to be allowed, they would have to go through the clinical trial process.
DR. ALAZRAKI: But the NRC doesn't have to be involved in that.
DR. AYRES: Well, I'll mention one other thing where we do exactly this now, and back historically, as I understand it, was that --
DR. CERQUEIRA: This is going to get controversial, so let's get everybody's input on this, and then, Ruth, you were next.
DR. McBURNEY: I think there are radiation safety issues when you start using the devices routinely. I mean, we're already looking at a big increase in the use of HDR for IVB.
And that's going to have operator implications,

the occupational dose and shielding, we're going to be looking at shielding.

And as you add to that, use of that device, even for other types of things, then you're going to add to the own time and there are radiation safety issues involved there.

DR. WAGNER: There are different radiation safety issues involved.

DR. WILLIAMSON: That can be handled by existing rules.

DR. AYRES: Well, one of the parallels where we do this is the Strontium-90 I applicator which is restricted to treatment of eye disease and is disallowed for further uses, and that was on at least several times, the recommendations of this Committee.

That's a parallel to this.

DR. CERQUEIRA: Jeff, you had a comment?

DR. WILLIAMSON: Well, I guess I have a question. It seems that you're saying, on the one hand, this doesn't mean anything because you could get around it by having a clinical trial, and on the other hand, you're reluctant to dispense with it.

So could you tell me, if we had this restriction as you wanted, what would be prevented, exactly?

DR. AYRES: The routine use without informing the

patient that they're receiving a therapy which has not been proven safe or effective and is experimental.

DR. WILLIAMSON: Outside of a clinical trial?

DR. CERQUEIRA: Let's try to keep the discussion going.

DR. WILLIAMSON: I'm trying to. This is a point of clarification. So you think that this could happen then without informed consent and without IRB approval?

DR. AYRES: If we don't restrict it to intravascular treatment of re-stenosis, yes. They could treat de novo lesions. If we said just stenosis, they could treat de novo lesions, they could treat any -- if we don't say intravascular, they could -- coronary intravascular, they could treat any location.

DR. WILLIAMSON: I really don't think that's true. I think there are institutional protections.

DR. CERQUEIRA: Well, we've got the FDA here. Let's perhaps --

MR. LEEDHAM: You're making some kind of comments, Dr. Ayres, that talks about the device has been through a review cycle once for another indication.

Now, practitioners want to use it in a different area. Now, that body of information on its safety and effectiveness is a building block.

Okay, so your statement that they're not safe and

not effective --

DR. AYRES: I was just saying that they're not proven as safe.

MR. LEEDHAM: They're not proven, but there is a basis for its safety and effectiveness for use in human subjects and patients in a certain patient population.

DR. AYRES: Partially.

MR. LEEDHAM: Now, no, the trial, when we say we approve a product that's been proven to be safe and effective, it's safe and effective for that indication.

Now, if you're going to use it, as Dr. Diamond said, in an off-label use, we can, in fact, and many times we do restrict the off-label use of items by very clear labeling.

We monitor the use of those devices and drugs in many other mechanisms so to give the impression that once it is approved and out there in clinical practice and it wants to be used for an off-label use outside the jurisdiction of the FDA is not true.

DR. AYRES: Well, I spoke yesterday with the cardiology group and I think it is but I will have to actually see the labeling, which I have not.

They seemed to indicate that they were hoping that we would take this approach because they couldn't prevent the off-label use.

DR. CERQUEIRA: Well, we have had these discussions before in the sense that when the FDA approves a drug physicians can use it, and these drugs potentially can be, you know, deadly, harmful, and we don't put any further restrictions on it.

I am not sure in this situation, you know, is it going to be limited applications to this particular in-stent re-stenosis and how much leeway does the cardiologist -- I mean this is not cardiologist. This is still a team approach that we are dealing with, so it is not a turf issue.

DR. AYRES: Well, that is one of the proposals.

DR. CERQUEIRA: Yes. John?

MR. GRAHAM: I guess I need to go back to your last comment.

You were talking to the group at FDA from cardiology that doesn't potentially have the legal ability to restrict this.

DR. AYRES: Well, he made an important point. I have not read the label and the label can -- and I need to do this as part of this. I mean this process is just occurring and I admit that all of the information is developing but I spoke with them the day before yesterday on the issue.

DR. CERQUEIRA: Have they submitted anything in

writing?
DR. AYRES: What?
DR. CERQUEIRA: Have they submitted anything in writing to you?
DR. AYRES: Well, certainly the labelling will be available.
Now I will get it for review, but --
DR. DIAMOND: But this is a very important point. This is directed towards Mr. Leedham.
Does the labelling that will accompany this product, does that labelling have any statutory authority to restrict the use of that product or not?
MR. LEEDHAM: In the sense that we could come out and say that it was used off-label that it would be misbranded, yes.
We could have that authority but we would have to have a compelling public health reason to do it.
DR. AYRES: And I don't think that was done, but I can't say for certain.
DR. DIAMOND: See, that is a very important point --
MR. LEEDHAM: And I can't make a comment on the labelling until I actually see it either.
There are a number of different things we can do as far as restricted distribution to who receives the

products that we approve, labelling restrictions.

Also there have been a number of cases about training programs required for physicians who will be receiving devices to be used.

So just to say that something was approved and then it just goes out there for general use without any kind of oversight or further follow-up by FDA is not true.

DR. AYRES: No.

My understanding is that restrictive labelling is not on this device but I don't know for certain one way or another.

MR. GRAHAM: But even if that restrictive labelling is not on there we spent two years reviewing a medical policy that specifically stated the NRC will not intrude into medical judgments affecting patients except as necessary to provide for radiation safety of the workers and the general public.

So if you are telling me if I use this for an in-stent re-stenosis and the FDA with input from the NRC you have decided that this is safe to the point of going into a PMA, then if an institution wants to define a clinical protocol which is within the FDA regulatory guidelines, which is going to be governed by IRB, which is setting up the parameters in which they want to do research on a different application, that sounds like pure medicine to me

and that is the piece --

DR. AYRES: I am saying this doesn't interfere with research aspects at all.

DR. CERQUEIRA: Let's -- let's hear from a couple of the other people.

I mean Sally, do you have any input on this, and we will come back to the other people.

DR. VETTER: I am speaking to this point though. Go ahead.

DR. CERQUEIRA: Well, we will come back.

MS. SCHWARTZ: I just feel that this issue at hand is really the practice of medicine and that essentially what you are trying to regulate through NRC regulations is infringing upon the practice of medicine, but if this device is out there and it is safe, essentially you are relying on physicians to appropriately use this device if they feel in their educational abilities that they can use it for another indication.

You are left with the basic situation that patients have to rely on the doctor to tell you, you know, this is what I believe is something that is good for you, and if for some reason that fails, what the physician has tried, I mean certainly the patient is dealing with malpractice, I mean possibly, and there are avenues to address this, but certainly I don't think this needs to be

regulated from the NRC's standpoint if the safety is addressed in terms of the workers who handle the device and the patients who are receiving the device.

DR. CERQUEIRA: Richard, do you have any thoughts?

DR. VETTER: No, I think I agree in general with the discussion.

Another disadvantage of specifying that this is approved only for in-stent re-stenosis, if FDA approves it for some other use then we have to go through a rulemaking to get that added on.

DR. AYRES: It's really not rulemaking since we are outside of it anyway. We are granting exemptions -- didn't authorize it at all under old Part 35. We have got to exempt the rules.

DR. CERQUEIRA: Let me get comments from Ruth and then Lou --

DR. McBURNEY: What we are doing in our IVB licensing is adding a license condition that clinical research of radioactive material for human use specified in -- whatever it -- where we list those isotopes and forms shall only be used by a licensed physician and other authorized users designated by the FDA through a current IDE, so it is just a license condition that authorizes them to use it under an IDE.

DR. CERQUEIRA: Neki, from a patient's

perspective, do you have any --

MS. HOBSON: Well, yes. From the patient's perspective, I think that we would very much favor the system that relies on the FDA and the hospital boards and institutional controls and the local level and our personal physician to make decisions that are not related to radiation safety.

NRC is the expert and has the responsibility for protecting us against undue radiation hazards and I think that it would be kind of over-stepping the bounds to begin to prescribe -- I mean basically it is a prescription here -- that the NRC would be issuing if this is put in.

DR. CERQUEIRA: Maybe -- we had comments from two different, three different groups.

DR. DIAMOND: Mr. Chairman, let me just speak to what you just said.

DR. CERQUEIRA: Yes, please.

DR. DIAMOND: I fully support the use of this in other sites with other indications on a clinical study, whether it be an individual hospital or individual university, institution, on a national or local scale. I have no problem with that. I encourage it. That is how medicine advances.

What I do not want to see is this being used for an indication that has no data to support it with no

requirement that the patient understand that this has no data to support it and with no trial being undertaken.

I can tell you there are many, many institutions in this country where the hospital would allow it to proceed without any IRB review.

I guarantee you that.

If I were a patient and this were being used in my renal artery or my superior vena cava or my graft or arteriovenous graft, I would want to know about it and I would want it to be done on a trial basis, so if we include any -- so if we had that understanding that it is on a clinical trial, I agree with you and everyone else here 100 percent but I don't want it in a month's time to be used -- this is just as a physician in general -- destroying the clinical science, so I wouldn't go and for conditions of use use the term "treatment of in-stent re-stenosis."

I would say "treatment of indications as approved by FDA plus other indications under study." Very simple.

DR. WILLIAMSON: Mr. Chairman, can I point out one thing?

DR. CERQUEIRA: Yes, Jeff.

DR. WILLIAMSON: Okay. Point number three of the medical policy statement, I just want to read it: "NRC will when justified by the risk to patients regulate the radiation safety of patients primarily to assure the use of

radionuclides in accordance with the physician's directions."

DR. CERQUEIRA: The physician's direction is still the key thing there. I understand your concerns but I just don't think that the NRC is necessarily the body to deal with that, and I think you have kind of heard the feelings of the people in the group that -- you know, your concerns are valid but they are handled by other areas within the practice of medicine.

One last comment and then let's hear from our speakers. Go ahead. Dr. Nag?

DR. NAG: Yes. I mean on a similar line, I mean quite simply brachytherapy is useful for cancer of the cervix.

If I want to use it on cancer of endometrium or any other cancer I don't need the NRC mechanism. I mean there are other mechanisms, FDA and IRB -- I certainly agree with you, Dave, but it is not the NRC's position to make that distinction. It is FDA and others and not the NRC's.

DR. CERQUEIRA: Okay. We have several groups who want to make comments related to the use of intravascular brachytherapy, and I am not exactly sure they were prepared in terms of what this discussion ended up eventually dealing with, but the first presentation will be by Dr. Albert Raizner, who is a cardiologist from Baylor College of

Medicine, and he is here representing the ACC and the Society of Catheterization, Angiography and Interventional Cardiology.

Isn't that it?

DR. RAIZNER: Well, thank you. I certainly am pleased to speak to the Committee. I hope you don't mind my reading some of my notes and comments.

My son is getting married this weekend, and the only thing freely floating in my brain is toasts to him, his wife to be, and my in-laws to be. So I'm going to stick to my comments on paper.

I'm an interventional cardiologist at Baylor College of Medicine. I've been involved in intravascular radiotherapy or brachytherapy since 1992 when we started our first studies in pigs, and have been active in this field since that time.

The purpose of my presentation is to enlist the support of the ACMUI to endorse the concept of changing the training and experience requirements, which would ultimately allow appropriately knowledgeable and trained interventionalists to be authorized users for the specific use of intravascular application to prevent re-stenosis.

By way of background with some clinical background, the most common cause of death among adults in the United States is coronary disease. Since 1979,

angioplasty has been performed to relieve the obstructions in coronary arteries by expanding balloons.

In the past six years, stents have been used to add internal support to the expanded artery. Currently, over a half of million of these procedures are performed in the United States.

The problem is that re-stenosis or re-narrowing of the artery occurs in approximately 40 percent of patients. Twenty-five percent of all patients require another repeat intervention to reopen the re-stenosed artery.

While stents have improved the safety and slightly reduced the re-stenosis, those who re-stenose within a stent have a particularly severe problem. While most can be reopened with balloons, the chance of repeat re-stenosis within a stent is higher, in the range of 50-60 percent. So it represents a very vexing and bothersome problem to the interventional community.

Intravascular radiotherapy has proven effective in significantly and clinically meaningfully reducing re-stenosis, and you've heard that two systems have recently received FDA approval.

Now, angioplasty or coronary intervention is performed as follows: First, a catheter is inserted into an artery, usually in the leg, and advanced to the coronary artery and dye is injected and pictures taken of the artery

and the lesion identified.

Then through this catheter, a soft wire is introduced into the artery and beyond the obstruction. This wire is used as a rail and remains in the artery from the beginning of the procedure till completion to allow bringing in and out, the different balloons and devices that are used to complete the procedure.

These devices include Roto-Rooters, lasers, stents, and now, the intravascular brachytherapy devices in these systems.

At the end of this, the angiogram is repeated. Sometimes other catheters are used, like intravascular ultrasound catheters to measure the effectiveness of the procedure.

And the procedure, in whole, takes from 30 minutes to two hours, in general, depending on the complexity.

The interventional cardiologist performs the procedure from the start to the finish. He or she alone is responsible for the safety of the procedure. In the cath lab, as in the operating room, the captain-of-the-ship concept rules. It is the cardiologist that's morally, ethically, and legally responsible for the standards of performance and safety of the entire procedure.

No matter what goes wrong, the medication or other, the cardiologist bears the primary responsibility for

that procedure.

During these procedures, speed is essential. It's an essential safety requirement. The longer wires are left in arteries, the more complications. The longer patients are exposed in these procedures, the greater the extent of anticoagulation, and the greater discomfort to the patient.

All technologies to date have attempted to speed up these procedures, and one of the major accomplishments of stents is to allow us to do fairly complex blockages in a much shorter period of time, because of the firm scaffolding effect.

So we're very much concerned about getting the procedure completed in the most reasonable amount of time.

Now, intravascular brachytherapy is performed as an add-on step to the interventional procedure, but it is part of the interventional procedure.

The difference is that the guide wire is left in place, that soft wire that remains in the artery. The patient is generally anticoagulated to an additional extent.

And the major treatment parameters are determined by the cardiologist. The location of where the radiotherapy is required, the dimensions of the artery, these are dimensions, the diameter of the artery, the length of the lesion, these are the dimensions that are necessary to establish the proper dose prescription.

What follows then depends on the system. The two systems that have been approved require insertion of a delivery catheter. This is essentially a hollow tube through which the source wire travels.

And positioning and assurance of the proper position of this delivery catheter, this is done entirely and solely by the cardiologist.

Then the delivery catheter is connected to a delivery unit or the source is delivered through the delivery catheter. In most beta procedures, the actual delivery is done by the cardiologist.

In others, the entire procedure, for example, radioactive stents, can solely be done by the cardiologist, despite the fact that its' a radioactive instrument.

After this is accomplished, the source is removed, and appropriately stored. Who removes it depends on the system. In some instances, it's a source delivery unit, and in others, it's hand removal or crank removal.

Finally, the delivery catheter is removed, and this is done by the cardiologist.

Arteriograms are done to assure that no injury has occurred by the catheters. If so, additional work is performed by the cardiologist to repair whatever affected the artery. Finally, the wire is removed and the final arteriograms are obtained.

Now, for intravascular brachytherapy we've heard much about the team, the team consisting of the radiation oncologist, medical physicist, and in some instances, radiation safety officers, and the cardiologist.

And we certainly support the concept of the team. There is redundancy in the safety features that the team performs. Many of these safety features can be performed by more than one member of the team.

Quality assurance, the medical physicist; room preparation, the medical physicist; measurement radiation in the room, medical physicist; after removal assurance of the removal, medical physicist, in addition to radiation oncologists.

So there is redundancy in the team. However, it's not a team but a single individual when it comes to the actual source measurement. Nobody in the team but the radiation oncologist, to date, can administer the therapeutic isotope.

And the team concept breaks down here. Picture a basketball team in which only one individual was authorized to shoot. The rest of the team would be passing the ball around, moving up court, would have to get it to that one individual who would shoot.

Let's say that individual was not on the court at the time. You'd have to stop, bring him onto the court, and

then get him the ball and he would shoot.

So the team breaks down. And this breaks down by the requirement that in all of these procedures only the radiation oncologist can deliver that therapeutic isotope.

Now, the cardiology community is concerned about safety, but a with broader definition: Safety of the overall procedure. This can be jeopardized in several ways:

One is manipulation of catheters within the coronary arteries. In some of these systems, this is done by others, and we have seen some instances where catheters were inadvertently pulled out, where catheters were advanced. The person most skilled at manipulation of the catheter, the cardiologist, may not be the one administering the radiation.

Time, as I mentioned, is of the essence. Despite the excellent intentions of our radiation oncology colleague -- and we work very closely with them -- they are not sitting around in our labs waiting for these procedures to reach a point where they come and do their thing. They're often busy in other areas, and often these other areas are at entirely opposite ends of the hospital.

We then have to sit with that patient, with the devices in these arteries, with the discomfort that the patient is experiencing, and with the extra anticoagulation needed, while we wait for the radiation oncologist to come.

Furthermore, some institutions have limited availability of radiation oncologists. We're fortunate in that we have a team of them involved in many projects, and we generally do not have great difficulty, but it's usually five to 15 minutes before one of them comes. This is added time to the procedure, and in some institutions, the radiation oncologist may not be available for hours, and you do not know when that procedure reaches that point that you need it.

Furthermore, some procedures occur as emergencies. Patients with in-stent re-stenosis often come in very unstable. The procedures have to be performed on weekends, middle of the night, and times when traditionally, the cardiologists are present, but some other members of the team may not be readily available.

Since we, the cardiologists, are responsible for the patient's life and safety, we're very uncomfortable about the logistic problems inherent in the requirement that only a radiation oncologist can prescribe and administer the therapeutic isotope.

We're urging the Committee to consider support and perhaps recommend to the NRC that training and experience requirements be modified to allow a properly-trained and experienced interventionalist, in addition to radiation oncologists, to co-captain the radiation team.

This entails a reconsideration of the current requirements for 200 hours of didactic teaching and 500 hours of practical experience currently needed to perform brachytherapy or to use therapeutic medical devices.

Let me expand a little bit: The specific use of isotopes for intravascular --

DR. CERQUEIRA: Dr. Raizner, you don't have too much longer, so if -- I'm going -- you may have to summarize, because we've got three other speakers.

DR. RAIZNER: Okay.

The interventional cardiology community has emphasized radiation safety in our training programs. An example is American College of Cardiology Consensus Document published in 1998, entitled Radiation Safety in the Practice of Cardiology.

There currently is a Board certification examination in interventional cardiology, a significant portion of which is dedicated to radiation safety. Joint committees of the ACC and SCNAI are developing a knowledge base and curriculum in intravascular radiotherapy.

We'd like to work with the members of the radiation oncology community to assure that such knowledge and training would assure the safe use of isotopes.

I will mention that there is no radiation oncologist and there is no track record in which

intravascular application of radiotherapy is an existing knowledge base. All has arise in the last several years in conjunction with the cardiology community. No prior brachytherapy is applied to intravascular brachytherapy.

In summary, we believe that appropriately trained, experienced, tested, and certified cardiologists should be allowed to administer therapeutic isotopes for the limited application of intravascular radiotherapy for re-stenosis prevention.

We believe that the logistics of the procedure dictate this, the logic is clear, and the safety of the patient enhanced, not diminished by such a policy. Thank you.

DR. CERQUEIRA: Thank you very much, Dr. Raizner. I think what I'm going to do is let all three of the presenters present, and then we'll take specific questions. Thank you.

Our next presentation will be by Dr. Tripuraneni, representing the American Board of Radiology and ASTRO.

DR. TRIPURANENI: Thank you, Mr. Chairman for giving me the opportunity. Just like Dr. Raizner, I'm going to use the slides instead of the paperwork, so that I make other points.

I'm representing the American College of Radiology and the American Society of Therapeutic Radiology and

Oncology. I'll also make one personal comment at the end regarding some of the indications.

The American College of Radiology is a organization that is representing --

DR. CERQUEIRA: We don't have your slides, and we'll stop the timer, so you can get ready.

[Pause.]

American College of Radiology is a professional organization representing both the diagnostic and the therapeutic radiologists and also medical physicists, with approximately 33,000 members.

American Society of Therapeutic Radiology and Oncology is an organization that's representing mostly radiation oncologists but also a broad spectrum of radiation biologists, hospital administrations, and radiation labs, and we have about 6,000 members.

I personally have an experience of vascular brachiotherapy of doing more than -- close to 400 cases in the past five-and-a-half years.

We have done the first case in March 1995 in La Jolla at our institution. I think we have done close to 600 to 700 cases.

And also, I take pride that we have experience in using multiple systems, with the multiple isotopes, just about all catheter-based systems, I think, at best count, in

looking at the broad spectroscopy of the vascular brachiotherapy rather than looking at one system only.

ASTRO would like to congratulate our Nuclear Regulatory Commission for successfully completing the process of the new CFR Part 35, and I think -- we think it actually was done in a really open and professional manner, and also, we appreciate the opportunity that was given to us several times to present our professional community involvement.

Intravascular brachiotherapy -- we feel that it's a temporary, sealed-source delivery of high dose rate, with therapeutic intent, and so, we feel that it's actually covered under the Part 35 training requirements, that there is no further need for any discussion to look at the training requirements.

On the other hand, if the NRC intends to include a separate section for IBV, both ACR and ASTRO recommends using the same rule-making process for establishing intravascular brachiotherapy requirements, and we would like to fully participate in that process, just like the last time.

The intravascular brachiotherapy requirements -- I think the focus should be not only on the safety of the patient, along with the efficacy, but also, we would like to be absolutely certain of the safety of the operators, not

only the radiation oncologists but the whole team and also the public at large, and as you know, the team approach has been used in clinical trials going back to March 1995, and also, just about all the clinical trials that have been conducted so far are right in there.

As you know and heard from several speakers this morning, the FDA has mandated the team approach, consisting of cardiologists, radiation oncologists, and medical physicists, in both the systems that they have given their approval, and I think Dr. Reizen has made several comments that are practical issues, and I think, having done close to 700 cases, the coordination of the team can be worked out and has been worked out with a relatively small group of three radiologist oncologists, and at no time patients wait no more than a few minutes on the cath lab table for the arrival of the radiation oncologist.

It's just a matter of working out the details.

Also, we radiation oncologists have a great deal of experience working with the urologists and the gynecologists and neuro-surgeons in the operating room, and we do work in the team setting, and we do understand that the urologist is the captain of the team in the operating room, as the cardiologist is the captain of the team in the cardio cath lab, but we have successfully worked with those other specialists for the optimal delivery of the radiation

and also the optimal treatments for whatever ailment that they have.

Likewise, the radiation oncologist is solely responsible for the safety of the public at large, and also the operator and the patient, for that particular delivery of radiation therapy in the cath lab.

I think there is a major source between the sealed-source delivery with the therapeutic intent, as opposed to the diagnostic delivery.

There are 16 misadministrations that are done so far, and I really want to emphasize that these 16 misadministrations -- I do know that they have happened for a variety of reasons.

They happened in the hands of the highly-trained, very focused and motivated, coordinated expert teams. I tried to use multiple adjectives so it actually comes across that these are the cream of the crop that you have in the United States, these 20 or 30 institutions that really want to do clinical trials.

In the best of the hands, actually 16 misadministrations happened out of 2,000 patients. That's one order of magnitude more than what is normally seen.

We are concerned that the potential for significantly higher rates of misadministration in the hands of a lesser-trained user can happen, so we strongly propose

that the training requirements be kept the same for the radiation authorized user.

Looking at the small practice where they do few angioplasties, I do not think that is the reason to relax the rules for the radiation delivery, especially considering the safety of the public at large and also the operators and the patients.

If there is enough volume, the medical practice is going to dictate that they will have a team in place to delivery the intravascular brachiotherapy. If they don't have enough volume, automatically the patients will be referred to the regional centers, like it happens in so many other medical procedures.

Emergencies -- we do not have any data what the radiation therapy is going to do when a patient has acute coronary syndrome.

Most of the patients -- just about all of the patients are actually schedule two to three weeks in advance, and I don't think that, actually, we need to do radiation therapy at this point in time for the approved indication of restenosis. So, really, that is not a reason to actually worry about that.

In conclusion, ACR and ASTRO recommend that the same training requirements be kept as we have at this point. On the other hand, if the NRC intends to look at them, we

would like to stand by and basically participate in any recommendations that we could provide.

On a personal basis -- this is the last slide, and this is not representing ACR or ASTRO, this is my personal recommendation.

I personally feel that I think the indication should be restenosis only; that is, routine clinical use. Any other use other than restenosis should be done under some sort of clinical usage protocol, whether it is FDA-approved doesn't matter, but I really think that actually it should be done under clinical usage protocol setting, whatever the mechanism may be.

I think I'll stop there. Thank you very much for your time.

DR. CERQUEIRA: Thank you. Very good presentation, and if we can get our next speaker to come up, it's going to be Dr. Peter Blitzer, representing the American Board of Radiation Oncology.

For those of you that are new to the board, we spend a lot of time trying to keep NRC out of the practice of medicine, and we adjudicate differences between different sub-specialty societies in terms of training and experience. So, this is a continuation of that.

DR. BLITZER: My name is Peter Blitzer.

Thank you very much.

I am here representing the American College of Radiation Oncology. I'm past president.

About 20 years ago, I did three years of radiation oncology residency at Mass. General Hospital.

Why did it take three years to do that?

We had extensive clinical experience, radiology biology, didactic and laboratory work, and extensive work in radiation physics.

We in radiation oncology walk a tightrope. When we treat a patient, we're exploiting a subtle and complex biologic principle, and that biologic principle is that radiation, in certain circumstances, damages pathologic tissue more than it damages normal tissue. But it's a very fine line.

If you give a little too much radiation, you damage the normal tissue beyond repair, and if you don't give enough, you don't accomplish what you're trying to help the patient with.

Let me reiterate that the job of the NRC, as I understand it in their charter, is to protect the public, and the public in this case is the patients, and if we have people who aren't adequately trained, if we somehow decide that there is now this one instance where we're using radiation to damage pathologic tissue and spare normal tissue and that this is a certain special instance where you

don't need as much training, I really think that's a dangerous precedent for the NRC to take, and I think it would be abrogating their responsibility to the public.

Let me mention, before the NRC was ever created, there is history of inappropriate use of radiation in treating benign disease by non-radiation oncologists. Dermatologists used radiation to treat acne. ENT doctors used radium sources to shrink lympho-proliferation in the nasopharynx. Gynecologists/obstetricians used radiation to treat post-partum mastitis, and if you're familiar with the literature in any of those, you'll know that there was dire adverse consequences.

The adverse consequences didn't happen right when they were administering the radiation but happened five to 20 years later, and I think that, to some extent, the cardiologists have kind of a cavalier attitude as to radiation.

They want to get in there, do their thing, and get out, but they don't realize what may happen five to 20 years later, and that's something that we're trained to deal with, and I think that we either need to be members of the team in there to protect the patients or the cardiologists need to undergo the full same training requirements that we have.

So, in summary, I support what Pravacar just said to you in the ASTRO and American Board of Radiology

recommendations.

Thank you.

DR. CERQUEIRA: Thank you, Dr. Blitzer.

We sort of have two -- we have Bob, who presented some questions that this panel needs to help address. We've also heard three comments really related to training and experience, and what's the panel's -- the committee's wish? Should we take questions to the training issue? Should we try to deal with Bob's problem first?

DR. ALAZRAKI: I thought we dealt with Bob's problem.

DR. CERQUEIRA: Okay. We're done with Bob's problem.

MS. HANEY: Maybe what we could do is, since we're dealing with these other nine issues -- and I think they're closer to radiation safety issues than medical issues -- maybe if we could try to go through them really quickly and at least maybe get some real quick preliminary views from the committee, because these are -- that's a real time issue for us right now as far as doing license amendments under the current Part 35, and then I think maybe spend a couple of minutes just on the training and experience, almost from the standpoint of maybe setting the stage for the next meeting, where I think each one of these meetings will be moving more and more into dealing with the intravascular

issues and with the training.

So, maybe if we just spend a couple of minutes setting the stage for where we would go from here but not trying to resolve anything, because I don't think we can do that, and then we'll move on to the next topic.

DR. DIAMOND: During our break, a couple of us were discussing a very important issue, which is, earlier, we were discussing some concerns, whether it be with the medical physicist training, the gamma knife training, and so forth, and there was some discussion of how we would give recommendation that there would be some guidance document that would reflect some of these wishes or concerns, and my question is very simple.

Does a guidance document or does a question-and-answer supplement that addresses some of the issues that were brought up -- there were three or four very important issues -- does that guidance document have any statutory bearing or not, because we're getting different perspectives here.

MS. HANEY: Any of the guidance documents do not carry the weight of the rule.

For the most part, they do carry a weight from the standpoint of explaining what was intended, and unless they fall into conflict with the rule, they're a tool, they're a benefit.

If you run into a -- we can't have a situation where a rule and a guidance document are conflicting, because the rule will always override any guidance document, and this is a non-lawyer's interpretation of what's going on, so when OCG sees these minutes.

So, I think, David, at least what was identified first thing this morning, there's nothing from my standpoint that puts us in conflict with the rule that's on the book.

So, I think a lot of these issues, maybe not all of them that came up this morning, but a lot of them I think can be resolved by adding either something to the statements of consideration or by adding something in a question-and-answer sort of format.

DR. DIAMOND: I understand.

DR. CERQUEIRA: And then, sort of, again, to follow up on David's question, I mean -- and what he proposed was actually going back and trying to revise what has already gone to the commissioners, so that it was more direct.

DR. DIAMOND: I hope we don't have to do that. I pray to God we don't have to do that.

MS. HANEY: I think, from this standpoint, we're in a situation where the document, as modified, with the items from the statements of consideration that the Commission approved -- if I change that any, I would need to

go back to the Commission.

I don't believe that, unless there was a fatal flaw, that the rule would get opened again, only because then we get back into a proposed stage, public comment stage, things like that.

I think if we went back to the Commission and suggested some minor changes or addition of a sentence here or there to the statements of consideration, I can do that in a less formal manner, as stepping into the Administrative Procedures Act, because it is just saying what was the intent in helpful guidance.

Now, I have to get all that cleared through Office of General Counsel and, you know, the powers that be here at NRC, but I believe that we can work some type of arrangement to get some of these issues into the document that goes out in the Federal Register, and if not, we would handle it as a separate document, as an addendum.

We're in a good position, because theoretically, we don't have implementation for a year from now. So, if it requires another Commission paper and another SRM, things like that, we have time to go through the more formal process, but the first things that I would attempt to work with would be, say, a less formal process and just say -- because I think, really, all we are doing is clarifying the intent of what was intended over the last three years.

We're not really changing anything.

DR. CERQUEIRA: And I think it was pretty much our understanding that, you know, in terms of the radiation therapy treatment, that if you didn't require everything -- but that it's only when we basically started the implementation by doing the boards that the issue came up.

I am certain there's other things where we had assumptions which, if you really question them, there may be some variability of interpretation and we have to basically do that for everything, and I think it's not worth this committee's time.

DR. DIAMOND: I understand.

DR. CERQUEIRA: Okay.

DR. AYRES: The specific safety precautions are addressing the issues I brought out in our misadministration presentation.

The most likely over-exposures to personnel with many of these devices is actually grabbing the catheter where the sources are.

So, I think one appropriate radiation safety precaution would be to wear extremity dosimeters when doing this kind of work. This would be, you know, a license condition type of requirement or proposed license condition type requirement.

The other one is, as I said, in the one device, we

identified two failure modes, which the vendor has supplied corrective actions. However, they're not required. The two corrective actions are a back-up already attached, a fluid supply, in case you have premature exhaustion of fluid, and the other is what's called an introducer sheath to prevent crimping in the catheter, and the issue is whether we should require those by license.

DR. WILLIAMSON: I'm sorry. These sound like they're very specific precautions for individual devices. Is it your intent to require a license amendment for every single device?

DR. AYRES: Well, we're going to have to do these individually by license amendment, because Part 35 -- we're talking -- I'm only talking old Part 35, that's what we've got to do now -- requires each one to be addressed individually, because they individually have to be exempted. There is no provision to licensees now.

DR. CERQUEIRA: The paperwork and costs and everything else associated with that is tremendous.

DR. WILLIAMSON: If one has the CORDIS system and then wants to go with one of the other iridium-based or photon-emitting systems, a separate license amendment is going to be required.

DR. AYRES: Yes.

DR. CERQUEIRA: Cathy has informed me that there's

no way of getting around that. So, that's a given.
MS. HANEY: But that's one of the reasons why we're trying to fix Part 35.
DR. AYRES: Right now, we've got to do it with the least flexible capability.
DR. ALAZRAKI: With the new Part 35, how would that be different?
MR. GRAHAM: This could be up to four years from now with states. So, we're not talking just a year.
DR. AYRES: There's also a lot of this that's not likely to be a compatibility requirement either with agreement states.
DR. ALAZRAKI: Cathy, with the new Part 35, how would that be any different?
MS. HANEY: Well, if we would make the decision once and for all that this is, in fact, 35.1000 and we have enough experience, we theoretically would move into a proposed rule stage that would deal with this type of use, and you'd almost set up a whole new set of regulations, so you're not dealing with it by license amendment.
The other way you can deal with it is 35.400 in the new rule says that you can use any source as long as it is approved in the sealed source and device registry for that type of use, and I'm not familiar enough with the SS&D sheets on these, but if the sealed source and device sheet

allow this type of use, then it actually does fall under 35.400 in the new world, in the new Part 35, and then you could go ahead and start using it.

Now, the one issue that would have to be addressed under that is there may be some requirements in 35.400 that do not apply to this type of use, and then you would need to be exempted from those couple of requirements, but that's -- a little bit of this is waiting to see when -- you know, how things all fall out with the uses and what's being used, but we're closer to not having to require an amendment for each one of these with the new 35.

I mean we're not completely there, but we're a lot closer than we are right now.

The problem with the current regulations is the 35.400 has specific sources tied to specific uses, and this is just not there.

DR. AYRES: The way we hope to go is issue some guidance to the regions and out through the agreement state programs and the way we think this out to go, and that would be the first thing, and ideally, later on, we could set conditions for classes of device, such as proton-emitting, beta-emitting, un-contained, but it's a little earlier right now.

DR. CERQUEIRA: So, I guess the feedback is we feel that this is burdensome, but there doesn't seem to be

any way out of it.

DR. WILLIAMSON: I think that we ought to be fairly parsimonious and not be more specific than is necessary for safety.

So, for example, the ALARA program requires badging and wearing of finger badges whenever there is a possibility of exceeding the MPD. It really does.

So, why is it necessary to have a specific regulation for that, because maybe you might have some system where, in fact, it's not necessary to touch it, like a high dose rate.

DR. AYRES: That's why I'm just putting it out for comment.

DR. WILLIAMSON: Well, I'm commenting, okay?

I don't think we -- I think you should really, really avoid narrow technical requirements that apply only to single systems and do your best to try and make them generic as you can be under the circumstances and realize this is going to propagate through the whole agreement state system, and we may, indeed, be saddled by these restrictive regulations, even in the 35.1000 area, because you know, that certainly happened with the temporary licensing guidance for high dose rate and remote after-loading. It was very difficult to undo some of that.

DR. AYRES: Well, I can give you one of the

reasons why it should be.

I can tell you from experience and very recent experience that, if we have mis-administrations that are device-oriented -- in other words, due to some weakness in the device -- they're always rapidly addressed and corrective actions are demanded, and if we can prevent those, we're way ahead of the game.

It can result in, you know, barring the use of the device till redesign or something. If we can take care of it administratively and prevent it, we may be ahead of the curve.

So, if we know there's a weakness and we don't address it and we start running into -- several misadministrations is all it takes.

DR. WILLIAMSON: I'm talking about, you know, finger dosimeters. It's certainly easy to punish somebody, and everybody will know that, and then they'll do the right thing. Why is it necessary to impose a big regulatory effort?

DR. AYRES: That's not a big issue.

DR. CERQUEIRA: Hold on for one second.

We have a representative from Novost who Cathy feels has some information that may help clarify a few of these issues, and I suggest we let them -- a very brief presentation, perhaps.

DR. REED: Thank you for giving me this opportunity to speak.

The first thing I'd like to say is -- well, I'm Craig Reed. I am a health physicist. I am also a former radioactive material license reviewer and a seal source and device evaluator with State of Illinois, and I'm currently the radiation regulatory manager with Novost Corporation and have been for several years, and let me say this up front. I have, you know, had the opportunity work around Dr. Ayres and see his work, and I have been very impressed with the level of detail and the tenacity at which he has taken this effort, and only a former regulator can appreciate that.

So, I would like to commend the effort that Dr. Ayres has done. I know he's done a lot of work on this, and there are a lot of devices and a lot of issues.

DR. CERQUEIRA: We need to be very focused, though, because of the time restraints.

DR. REED: Okay.

I think Dr. Ayres has presented a lot of information about devices, but let me say this right up front about the Novost Beta Cam System.

The device has been evaluated. There's a sealed source device registration certificate for the device. The State of Georgia has evaluated it and deemed it suitable for licensing, and that's typically acceptable by the states and

NRC systems.

It's also been through the FDA PMA process. We've treated a significant number of patients, and we can say the device is safe and effective, and I think to come to a committee meeting here and attempt to dissect the device design or, you know, present, you know, regulatory barriers to a treatment that might be very significant to the population of the United States is a mistake, and I think we need to focus on the big picture, on how we can accomplish getting this device into use.

Currently, everyone under limited scope needs an amendment to get this device because of the way the existing rules are written, and to the extent that that could be avoided in the future, that would be great.

I've read the proposed 1000, and it doesn't seem to preclude that, okay? It seems to suggest that anything you use that's not existing in the current regulations is going to need an amendment.

So, you know, I don't see that that's being resolved here.

You know, what I would like to see is the medical use committee focus on, you know, what it takes to get this new device into use.

So, I just want to say that.

Thank you.

DR. CERQUEIRA: Jeff, a quick comment?
DR. WILLIAMSON: I take that as supporting what I'm saying.
I think tiny little things that apply to individual systems should not be there, and I think there should be like a guideline that says the license amendment should address known mechanisms of the device that cause source retraction failure.
That would be a nice general requirement and would force all of the users to look into the sort of history of the use of the device and make individual precautions as necessary and in a flexible way, because what happens if they fix the catheter so you don't need an introducer sheath anywhere? Then you have to write a license amendment to get rid of that small technical provision.
So, I think this is not a reasonable approach.
DR. REED: From a risk-based perspective, the device has been evaluated safe and effective, and what else do we need to say here? The device design has been evaluated. It's safe and effective.
DR. AYRES: Well, of course, that's always subjective.
Now, understand, safe and effective means that, in risk-benefit, benefit outweighs risk. There are risks with all of these intravascular brachiotherapy systems.

DR. CERQUEIRA: So, you've got like nine things. Maybe we could -- why don't you just run through the list, and we can go back, perhaps?

DR. AYRES: These are just considerations, and part of them are based on, during the trials, observed problems and attempts to avoid them.

Others are just cautions to users. Clearly, they're going to need to amend their quality management plan, because this is a new modality.

What about written directives? There are certain things, one needs to review that, but there are known things that are done that are done differently in cancer therapy.

In other words, when a patient suffers ischemia, a non-fractionated treatment becomes fractionated. There's really no problem with that, but is there a problem with the language? We need to look at that. And clearly, treatment is terminated if medical complications necessitate it prematurely, and that shouldn't constitute a violation of a written directive or anything.

Those issues need to be looked at. I understand -- and if there's any others --

DR. CERQUEIRA: You don't have the list for us, but those are the items that you specifically need to make decisions on, right?

DR. AYRES: If anybody had any comments about

things that could run afoul of our regulatory requirements because of some requirement, new modality, we should try to remove that barrier, if it's reasonable to do so.

DR. CERQUEIRA: And I think you've heard the committee say that, you know, there's been testing with the device by the FDA. You've heard the manufacturer make some comments about approval in Georgia.

DR. AYRES: I understand all that.

DR. CERQUEIRA: And we should try to basically either, you know, make those requirements that you've listed, you know, a one-amendment thing that can be done for the license, rather than multiple, in the best way possible.

Some of the other issues, again, I think we can try to incorporate.

Some of those things are the practice of medicine, you know, the decision to stop a procedure.

DR. AYRES: What's I'm saying is we want to avoid realistic practice of medicine issues causing violations with our existing regulations, which it can happen if we don't write the licensing properly.

DR. CERQUEIRA: Okay.

Jeff?

DR. WILLIAMSON: I am sympathetic. These are certainly all problems, but they are all problems that exist with, you know, all existing brachiotherapy modalities.

The amendment to the QMP, if this falls, it's licensed under the existing 35.400. Why is the current QMP language not adequate?

Secondly, you know, a treatment -- any brachiotherapy treatment can be interrupted by the authorized user based on the medical condition of the patient, and that entails, you know, a verbal order to terminate the treatment and then a follow-up amendment or revision to the prescription within 24 hours.

So, why isn't that language okay?

DR. AYRES: Well, the unusual aspect that isn't covered is going from un-fractionated to fractionated just because of temporary ischemia, and then they retreat, and so on.

DR. CERQUEIRA: I guess what we're trying to do is keep it simple, and if you've got rules out there that may already be in place for other types of radiation therapy, then they should be applicable here, and so far, none of the things that you've identified are unique for this application.

DR. AYRES: Not entirely, no.

DR. NAG: As I'm listening to all of these points -- I've been doing brachiotherapy for a long, long time, and similar problems have come up with all the other kinds of brachiotherapy I have done.

So, why do we not make life a lot simpler for everyone, a lot easier for rulemaking? Place intravascular brachiotherapy in the same context as 35.400, and all the problems are the same.

DR. CERQUEIRA: That's where it is under the current rule.

DR. WILLIAMSON: It's not possible to do that under the existing framework. That's the answer.

DR. CERQUEIRA: This is for licensees of specific scope. That means anything that's not identified in Part 35, like iridium-192 for cancer, iodine-125 for cancer, requires a license amendment. There's no way around that.

We can't argue away the license amendment. So, what we're trying to do is decrease the amount of paperwork that's involved.

DR. WILLIAMSON: I'm mean there's just no question that this is a license amendment issue.

DR. CERQUEIRA: So, what other specific things have we not addressed? I would suggest, in the future, if you could give us a list, preferably ahead of time, people on the plane could at least begin to --

DR. AYRES: Well, there was a little mix-up on the distribution of the hand-outs which I had prepared a couple of weeks ago. The intention was there to do that. I made a deliberate effort to do that. There was an administrative

problem, so it didn't happen. My apologies.

DR. CERQUEIRA: So, what other specifics can we answer for you? I mean we've got this body of experts here.

DR. AYRES: I think everybody recognizes we've got specific licensees and exemptions for each and every one, and I just listed some sample issues, and if the committee has any, I'd be glad to hear them, but we're going to have to get some guidance to start down that path.

MS. HANEY: We'll also take e-mails after the meeting.

DR. CERQUEIRA: If you could send us the specific list of items in an e-mail, we could basically --

DR. AYRES: Well, I think the next thing that will happen will be the guidance getting out. We're kind of up against it right now.

DR. WILLIAMSON: I think the only thing on here that looks like it's unique -- number two, licensing issues, number two -- is the emergency procedures and response training. I think, indeed, that is specialized, and there's probably reason to expect a special plan, more like high-dose-rate brachiotherapy.

Use in un-shielded cath labs -- I mean that's covered by existing regulation. I don't see a problem.

DR. AYRES: My intent with that is -- I would caution our regions to be conscious of evaluating the 10 CFR

Part 20 requirements, because it could easily be exceeded.

DR. WILLIAMSON: But existing 35.400 and Part 20 covers that quite adequately. Everybody knows what they have to do.

DR. AYRES: Nothing new, just a caution.

I don't think we should get into new Part 35. It's too premature. We can talk about that after we get more experience and it gets closer.

DR. CERQUEIRA: Maybe we could bring our three speakers back. We'll take like 10 minutes of questions and we'll break at 3:30 for like 10 minutes and then we'll come back and finish the agenda.

DR. NAG: I have a question and comment.

One of the major problems in intravascular brachiotherapy was the fact that the radiologist had no idea that the radiation source -- you will not have the three-dimensional knowledge.

All of these require more than just a few hours of training in radiation oncology, because you have to have a three-dimensional radiation dosimetry that requires a few hundred hours, and when you have a radiation oncologist with all that background, it is to your benefit.

You want the procedure to go quickly. If you are administering the catheter in and out and you have someone else, that will be faster for your patient to have two

people rather than to have the same individual.

DR. CERQUEIRA: You're making a lot of statements. You need to ask some specific questions and give them a chance to respond. I don't mean to cut you off, but we have them sitting there, and let's not think of this as oncologists versus, you know, radiologists. We're dealing with patient safety issues.

DR. NAG: Having both together will help the patient safety.

DR. CERQUEIRA: Try to make the comments brief and ask specific questions rather than making more comments.

DR. NAG: In terms of the emergency issue, what happens in your hospital when a patient with a radiation implant needs an emergency to have the implant out? Don't you have a radiation oncologist who can come within the next 15, 20 minutes to remove an implant?

DR. RAIZNER: Well, I can't say, because we're not involved with the emergency implants in other departments, and yes, that is likely to be available in our hospital but not necessarily available in other institutions.

Now, I'm not advocating that every hospital in the United States or in the world have this resource available, but the availability of radiation oncologists is variable in different institutions.

DR. BLITZER: I would challenge that statement.

There are over 4,000 board-certified radiation oncologists in this country. If you care to look at the ASTRO directory, you'll find radiation oncologists in virtually every even small medical community.

DR. CERQUEIRA: Well, this isn't a fact-finding group here. We're not here to address those kind of issues.

We'll keep going. One question -- really, try to make it a question rather than a statement.

Dr. Diamond.

DR. DIAMOND: Dr. Raizner, at your institution, who provides the radiation consent for your vascular brachiotherapy procedures?

DR. RAIZNER: All of these patients are done on protocol. The protocol requires not only the cardiologist to explain the procedure but the radiation oncologist to meet with the patient beforehand and discuss the radiation specific issues.

DR. CERQUEIRA: Jeff?

DR. WILLIAMSON: Couldn't the conflict between the training and experience requirements requested by Dr. Raizner and the two radiation oncology representatives be dealt with by more flexible technical requirements that would, say, not necessarily require the physical presence of the radiation oncologist to actually load the source into the patient but be involved up front with the signing of the

written directive and the consenting of the patient?

DR. BLITZER: I'll take a stab at that.

Each patient -- we're walking that tightrope between delivering too much radiation and too little. There's decisions that have to be made based on the distribution of the radiation in an individual patient.

There's no way to do that in a a priori way. You've got to be there, and you've got to take an active decision-making role.

DR. TRIPURANENI: When things are going well, I think they do go well. I think the training and expertise really comes into practice when things go wrong, such as basically a misadministration or basically some sort of accident.

That's where I think the authorized user can really make a difference.

DR. RAIZNER: I would argue that all of the current use of radiation for restinosis in an artery is recent data and none of this is present in traditional radiation oncology literature or training prior to the introduction of this field five or six years ago.

DR. BLITZER: There's nothing unique in the way radiation affects the cells in coronary arteries. The radiation biology has been established for 20 or 30 years. That's not true. And there's nothing unique about the

physics of the way this brachiotherapy is done, as Dr. Nag, I'm sure, can tell.

DR. McBURNEY: If there were to be some other training and experience requirement for the specialized procedures, either for stents or for the remote after-loaders, what would you recommend?

DR. RAIZNER: I would recommend something more akin to the use of radio-pharmaceuticals, in which the same safety issues potentially prevail, perhaps some blend between the two requirements, but the requirement of 500 hours of didactic training and 200 hours of practical experience seems very excessive to us for this field of recent knowledge and very limited application.

It is not cancer. It is not cancer of other organs, and we agree that the radiation oncologists have vast knowledge in these other areas. This is a very limited and specific use.

DR. CERQUEIRA: I'm here as a cardiologist, as well, so I'm kind of in an awkward position, to some extent, but do you envision every cardiologist doing this, or what do you see as the requirements? Which cardiologist and what kind of training should they have to do this?

DR. RAIZNER: I certainly do not see every cardiologist doing this, and I believe that, if one sets training requirements at levels which require a full and

exhaustive knowledge of this specific field, that we will eliminate probably 80 percent of cardiologists from seeking that kind of training.

I'm not asking for a weekend course. I'm asking for a full in-depth training program covering the full body of knowledge that's needed and the experience, and not many cardiologists would have the wherewithal to achieve either that education or that experience.

So, it would not be thrown open to the cardiology public in general.

DR. CERQUEIRA: There is a fourth year, you know. Basically, people are doing three years of cardiology training, and there is an interventional cardiology program. Do you see that as the people who would be doing it, basically three years of medicine, three years of cardiology, and then an additional year of interventional cardiology?

DR. RAIZNER: I would see this as either incorporated into that year of the training or as an extension beyond that year of training.

I do not see the current training as adequate for this field.

MR. LEEDHAM: This question is for Mr. Reed.

Did your investigators in the clinical trials have training programs that they were required to go through?

DR. REED: Yes, there was proctoring required as part of the clinical trial for those positions.

MR. LEEDHAM: Okay. And criteria for who could participate in the trials?

DR. REED: Yes, cardiologists, oncologists, medical physicists, radiation safety officer, as a team, yes.

MR. LEEDHAM: It might be helpful if that kind of training program would be provided to the NRC staff, so they could see what training was provided or participated in.

DR. REED: Of course, that is part of our required FDA approval, and the training manual has been submitted to State of Georgia as part of our sealed source device registration.

DR. CERQUEIRA: Richard?

DR. VETTER: From the patient's perspective, I've heard various numbers, up to several hundred thousand people who are going to need this procedure. Will the radiation oncology community be able to assist the cardiology community in meeting that need?

DR. TRIPURANENI: We looked at the numbers, and I think it's estimated that there will be approximately 100,000 patients.

At this point, the current estimates are radiation oncologist time involvement would be approximately 60 to 90

minutes per patient, and if you look at the regional centers, relatively medium to large-volume centers, it is anticipated that it will be covered adequately, with some modifications in the personnel moving back and forth.

DR. WAGNER: I think the issue here is quite clear.

The issue just boils down to a matter of adequate radiation safety training in order to get these procedures done, and the question has been raised as to whether or not the 200 hours of classroom and the laboratory training is excessive and whether or not the 500 hours of work experience is excessive, and I think that's what Dr. Reizner is raising, this issue.

Do you have any recommendations, Dr. Reizner, as to specific changes that could take place that would adequate meet the radiation safety needs of these procedures?

MS. HANEY: I think when you're answer that question, though, I think you need to go beyond the 200 and the 500 and look at the three-year requirement, because I don't really think -- and that's in the current regulations, as well as the new Part 35, because I don't think -- at least over the last three years, the issue that I've heard is not so much whether someone has 200 hours of didactic and 500 of practical, it's the three years in radiation

oncology.

DR. CERQUEIRA: The last time we had heated discussions on this -- I mean the issue was the three clinical years.

I mean should a cardiologist have to do three clinical years?

DR. WAGNER: Yeah, I think that's the issue that really has to be addressed.

Dr. Reizner, did you have any specific recommendations as to how the current rules should be changed to meet those needs?

DR. RAIZNER: I'm not prepared to give specific hours, no.

I am prepared to say that I believe that some of the training and experience requirements that are in place for the use of radio-pharmaceuticals could provide a basis from which T&E requirements for intravascular brachiotherapy can be met.

DR. WAGNER: I guess I would have a comment with regard to that, and that would be this.

I've seen most of the training and recommendations that come out of the cardiology community, and they are mostly related to diagnostic.

They are not really specified for the higher intense and more risk higher doses that would come with this

kind of treatment, and they would have to be revised to meet those standards, because this is a risk-based type of policy now, and the question is what's the risk with regard to radiation, what are the levels that are being used, and what's the training that's really necessary to make sure delivery is adequate.

I think, right now, the FDA is requiring that the oncologist be part of that team. It's not us here. It's the FDA that is requiring part of that team, and it's for the purposes of meeting the needs of the radiation safety as it presently exists.

So, I think this committee has always been willing to review things on an as-need basis, but I think we would have to have some specifications and better recommendations with regard to specifics as to what is adequate to really meet the needs in this higher-risk situation.

DR. CERQUEIRA: I think that's probably what we'll end up going to at future meetings.

John, you had a comment.

I'd like to hear from sort of the non-medical people on the committee, because they have less of a vested interest in this.

MR. GRAHAM: Just a clarification of Dr. Reizner.

My understanding was that you thought this might be only 20 percent of the cardiologists that would propose

to take the additional training to be able to perform this procedure? I know that was a guesstimate.

DR. RAIZNER: Yes, that's a guesstimate based on the fact that this is essentially a sub-specialty within cardiology, that the numbers of patients are not all-inclusive.

That is, not every patient would be applicable to this, and so, the investment from the standpoint of a cardiologist to seek the additional training and experience would not pay for him in terms of the rewards in numbers of cases that he might do.

So, I believe that, probably across the board in the United States, no more than 20 percent of cardiologists would have the volume and the need and the referral base to justify getting the training and experience.

MR. GRAHAM: Just one other question to Dr. Blitzer.

Other than the 200 hours/500 hours that's enumerated as specific training related to radiation safety, what percentage would you estimate of the additional three years is tied to radiation safety versus learning the clinical knowledge base to function as a radiation oncologist?

DR. BLITZER: Well, maybe I'm naive, but I don't make a distinction between the radiation safety that's going

to happen right in the room and the radiation safety that's going to happen to the patient five years later, when his heart is damaged by excess radiation.

MR. GRAHAM: The FDA is requiring that these patients be followed for five years.

DR. BLITZER: Right. But I'm leading up to answering your question.

So, I think that three years of clinical experience are absolutely necessary. I think it's crazy to decrease the training requirement on a new technology which we don't even understand, as well as the more proven technology.

Why would we have a new technology and say you need less than three years of training?

DR. CERQUEIRA: Let me get comments from other members of the panel. I always want to hear the patient's perspective on this. And then we'll go to Dr. Diamond, who had a question.

MS. HOBSON: Well, this is kind of a tough one for me, because I'm not a technical person and I'm not trained in medicine.

Just sort of my common sense response to what you all have said is that, if it's a routine procedure, I don't see why a radiation oncologist could not be present in the room and ready to perform the procedure.

I mean I don't see why a patient should have to wait, if it's a routine procedure, as a matter of scheduling people to be there when they should be there.

I guess I'm ambivalent about what happens in an emergency procedure. I don't have any idea how often that happens, but perhaps there should be, you know, maybe some provision -- and I don't know what that would be -- where, in an emergent situation, someone other than a radiation oncologist could remove the stent or whatever would need to take place.

Is that practical?

DR. TRIPURANENI: With the experience we have in the beginning, we had difficulty coordinating schedules, but at this point in time, it actually flows very smoothly.

Some of the difficulties come because when Dr. Reizner is doing angioplasty, sometimes it doesn't go as planned. Sometimes they may require an additional half-an-hour or 45 minutes.

So, we time it such that it can be worked out within a particular institution, depending upon their particular needs.

Regarding the emergencies, again, at this point in time, having done close to 700 patients, at this point in time, they can be scheduled.

In other words, within one to two days of leeway,

they can be scheduled.

On the other hand, if they have to have a late-night angioplasty, I do expect it probably falls into the practice of medical practice and the radiation oncologist, whoever is working with the cardiologist, more than likely will end up coming to the cath laboratory and then basically provide the necessary service.

We do do this at this point for our patients with cancer. So, I see these patients no different.

MS. HOBSON: But you do see that there would be occasions when a radiation oncologist would not be available.

DR. TRIPURANENI: It is expected by the hospital medical staff that there is a radiation oncologist available 24 hours, seven days a week.

DR. BLITZER: We have cancer emergencies -- SVC obstructions, spinal cord compressions, some brain metastases. We're on-call 24 hours a day and we come in. We will be available. We are available.

DR. RAIZNER: I would just say that I have no doubts that, at Dr. Blitzer's institution and at Dr. Tripuraneni's institution, the radiation oncologists are top-notch, ready and available and more than willing to work with the cardiologist.

I don't think that's universal, nor can it be

expected to be universal. It essentially, therefore, ties the cardiologist's hands to perform these procedures only with the good grace of the radiation oncologist, something that realistically is not going to happen universally.

DR. CERQUEIRA: Dr. Diamond, you had a question?

DR. DIAMOND: Yeah, if I can ask my question for more than eight seconds without being cut off by the chair.

That has to do with the issue of consent, and I guess, if I can direct this to the members of the panel and to Nikita, as well, what's going to happen when a person suffers an untoward event, maybe because of the radiation or maybe not because of radiation, five or 10 years down the line, and what's going to happen if there's not an individual with very, very extensive radiation training and background when that comes in front of a jury?

I mean one great concern that I have is that there will be an untoward event one night and that this will be on the front page of the newspaper all across the country the next day and a potentially very important therapeutic modality may be destroyed, and in our practice of radiation oncology, our prejudices that we face every day about the use if ionizing radiation will be reinforced.

It's something that has to be considered, and I'd like the panelists' opinion and I'd also like to hear Ms. Hobson's opinion.

MS. HOBSON: I'll go first.

In a routine procedure, I don't think there would be any excuse for not using the best available person, who in this case appears to me to be the radiation oncologist.

In an emergency situation, as I say, I'm ambivalent. If I'm going to just lay on the table and die waiting for the radiation oncologist to get there or I could let someone else do the procedure and I'm going to die five years from now, I would probably elect to take the extra five years.

DR. CERQUEIRA: I don't think it's ever that kind of a situation.

DR. DIAMOND: It was more directed towards our medical/legal environment. What's going to happen if someone gets in front of a jury and a very clever prosecutor says, you know, Dr. So-and-So, can you tell me where you did your training in radiation oncology? Well, I really didn't do it. Or Dr. So-and-So, where did you do your training in nuclear medicine, and you say oh, do you intend to tell me that you're fully qualified to go and counsel these patients regarding informed witness consent, and that was the genesis of my question.

MS. HOBSON: I understand your concern, and it's sort of strikes a note with me, because today I have listened to regulatory people who are interested in

protecting the regulatory environment, and we have medical people, probably rightfully so, trying to protect themselves against malpractice suits and prosecution, but you know, the patient is the receiver of this, and the patient should be the focal point of all of our considerations.

DR. TRIPURANENI: I want to provide the best of care, whether the patient has cancer or whether the patient has heart disease.

My primary focus and goal is to provide the best of care, 24 hours, seven days a week, and I think most of my colleagues across the country, I think, basically operate on the same premise.

To answer Dr. Diamond's question, I think that's going to be a tough one. That's the reason why FDA mandated that patients be followed for at least five years, and in our practice, we like to follow them for life.

When I come to the cath lab, I am not coming there just with my expertise in radiation safety, but I bring in what I have acquired during my three years of radiation therapy training and lots of other things that actually I have learned in my practice of radiation therapy in cancer on other benign diseases.

So, I'm bringing actually a wealth of knowledge to the cath lab and actually applying that.

We have actually learned over the past three to

five years.

So, actually, we are using technology to actually welcome some of the problems.

So, I'm actually bringing more than radiation safety to the cath lab.

So, I think I still go back to, I think, three years of training, with the practice in radiation oncology that has a broad-based experience.

DR. RAIZNER: In response to your question, there is not a radiation oncologist in the world, including the very bright colleagues here, that can tell you what they should look for in five years after intravascular brachiotherapy. There is no track record, there is no literature, and there is no information.

We are all starting at the same stage and knowledge of this and we are all learning together.

The problems that were mentioned earlier with edge effects -- it was implied that our lack of knowledge of volume and mass created this phenomenon of edge narrow.

Bear in mind, all of these were done with radiation oncologists.

This is a field that's an infant field, and neither cardiologists nor radiation oncologists began this with any background knowledge of what happens when radiation is applied from within an artery in a radial manner.

It's non-existent in any field of radiation oncology to date.

DR. BLITZER: But we don't want have a lesser training requirement for a new field.

It seems like a new field -- I would challenge you that we can't extrapolate a lot of our current knowledge, but be that as it may, we don't want to have a lesser training requirement for a new and potentially very dangerous modality of treatment.

DR. CERQUEIRA: I think we should take a break. We're way past our break.

I'd like to thank our three presenters and the committee, and we'll reconvene in 10 minutes, five of 4:00.

[Recess.]

DR. CERQUEIRA: Diane Case is going to present.

DR. CASE: Unlike many of the people that you've seen today and you will see tomorrow, I haven't presented before this committee before.

I've been in the audience before many times, but I haven't actually participated myself, and I would really like to thank Dr. Ayres for setting up such a nice introduction for me, seeing that part of my presentation is somewhat similar in nature.

However, I'm going to preface my talk about theraspheres by saying what we want to do is come up with

some guidance for licensees to use this particular device, and the guidance is not based on our intentions of providing more regulations.

Actually, it's more of a point of providing clarity, providing clarity at the same time as providing safety to patient and safety to the personnel who are using the material, as well as fitting in with our NRC strategic plan and the NRC goals which Dr. Cool spoke of this morning, and that is to decrease regulatory burden, but at the same time still provide effective and quality radiation protection.

So, let me just quickly go through some slides. Hopefully you've all read my hand-out. I'm sure that you did. It's probably the first thing that you did. I don't know if you've War And Peace before, but if you have, you can certainly get through my document, and once again, I apologize if there were any typos, but the one that you received fixed those up. I'm sure that you found all those typos, as well, when you read it.

As you know, we have emerging technologies coming up, types of medical devices to deliver radioactive doses or radioactivity to treat patients for medical conditions, and one of the reasons for our new Part 35 is to try to capture the changes in technology that are occurring very rapidly.

This particular device that we have in front of us

now, therasphere device -- I'm using the word "therasphere." That just happens to be the manufacturer's name for the device that's out currently. However, the use of itrium-90 microspheres for this particular therapy -- the idea has been around -- and the clinical trials have been around for quite some time.

So, this is not necessarily to single out theraspheres itself.

Regulations are applicable to the current 10 CFR 35, are applicable to certain uses for radioactive material -- brachiotherapy, radiation therapy, diagnostic -- but if you look at the brachiotherapy regulations, they are very -- somewhat prescriptive, and we're starting to see these devices that don't meet a lot of the criteria, and the way that one would regulate them is going to have to change because of the particular unique characteristics of those devices, and this itrium-90 microsphere or therasphere is one such device.

I put the third bullet there, guidance necessary for unique modalities. Please take the word "necessary" with a grain of salt.

"Necessary" means we want to provide the licensees with the best possible guidance that we can give them. Licensees are actually asking us what do we do? So, we're trying to provide them with assistance and guidance.

Again, immediate examples of therasphere device and what is NRC's interest in this? It's not to over-regulate, but we want to maintain that the requirements and provisions of 35 are provided for, and that's the protection of the public health and safety, as well as the NRC mission and strategic plan.

Let me tell you quickly about the therasphere device. It's the itrium-90 which is embedded in a glass microsphere. The itrium-90 does not leach out. The half-life of itrium-90 is 64.2 hours. It's a pure beta emitter, and the average energy is .937 NEV.

So, contrary to external-beam therapy in which the -- you have tissues that's being irradiated, as well as the tumor tissue, the betas afford a short-range therapy to the liver tumors.

The therasphere use right now -- the FDA has -- is regulating it, if that's the right word, as a human use device, humanitarian use device, and the manufacture and distribution of this device is under an HDE, human device exemption, and what this means is that users of this device, the therasphere device, have to use it for a particular reason and only that reason, and that reason, right now, is radiation treatment or as an adjunct to surgery or transplantation in patients with un-receptable cellular carcinoma, and also, I just wanted you to notice that,

because of the status, you have the following sentence.

"The effectiveness of this device has not been demonstrated."

So, this statement has to be provided in the package insert of the therasphere device.

Again, the difference between a hard versus pre-market approval is somewhat of an abbreviated clinical trial prescription and an analysis that's required to use something, as opposed to use the pre-market approval.

One of those things is that it's going to treat a disease that is in a small fraction of the population, and it also provides an incentive to manufacturers to develop useful techniques that they may not do because of the financial constraints.

If it's only going to be helping 4,000 people and it's going to cost us a million dollars, two million dollars to manufacture, then what's in it for the manufacturers?

And later one -- or you can read in the notes -- there are some other constraints on HDEs that again kind of complicate the matter for us.

The glass microspheres come in a vial, and I'm going to get to that picture in a minute, but really, the therasphere device is a vial of itrium-90 microspheres, and they're supposed to come in unit doses, anywhere from 135 millicurie up to 450 millicuries.

At the time it was first approved as an HUD, they had three dosages that they came in.

So, you have a vial, and with this vial comes an administration kit.

So, again, we're going to see in a minute it's the administration kit that also causes this to be somewhat of a very unique modality.

It's also unique because it's a pure beta emitter, and we'll get into that in a minute, as well.

The glass microspheres remain in the liver permanently, even though the itrium-90 eventually decays away. There's no evidence that that causes any harm to the patient.

And I don't know if you can see this bottom bullet, but if you look at all the definitions that we have available to us in Part 35, staff -- or the staff concerned with this particular matter -- has determined that itrium-90 microspheres are, indeed, brachiotherapy sealed sources.

There's been a lot of discussion of why aren't they called radio-pharmaceuticals?

Well, if you look at the definitions of drugs and devices and you look at the radio-pharmaceuticals and sealed sources, you will find that this -- these micro-spheres, each one of them, individually, they meet all the definitions of a sealed source and a brachiotherapy source,

not as a radio-pharmaceutical.
They don't act biologically in the body.
DR. WAGNER: Because of the way they're delivered, do they get into the bloodstream and are eliminated through the bladder?
DR. CASE: No. We'll get to the administration, but I'll just say quickly it's administered by a catheter, hepatic artery, goes right to the liver.
DR. WAGNER: It's 100-percent trapped in the liver.
DR. CASE: If it goes to the liver -- whatever goes to the liver will be trapped in the liver.
DR. WAGNER: Well, what if it doesn't?
DR. CASE: Well, whatever goes to the liver will stay in the liver.
DR. CERQUEIRA: Is there any experience looking at other parts of the body?
DR. CASE: I'm going to be getting to that, and if I could go back, I would change it now and re-order my slides.
The reason I'm here today is because I've been tasked with coming up with some guidance that we can give to licensees on how they can use this material.
For example, licensees have come and asked us what is a mis-administration, what do we do for a written

directive, prescribed dose?

Also, the training and experience requirements, which you're going to love.

DR. WILLIAMSON: Why do broad-scope licensees have to submit license amendments?

DR. CASE: We're going to get to that, as well, and I'll tell you why, because the unique characteristics of the therasphere device, because it doesn't fall into the categories in Part 35 under brachiotherapy or under anything else, as a matter of fact --

DR. WILLIAMSON: For a broad-scope licensee, it doesn't have to.

DR. CASE: Well, broad-scope licensees also have to meet the definitions of a mis-administration, a written directive, and prescribed dose, and so, because the current Part 35 definitions are not applicable to this device, then all licensees are going to have to make some provisions for what a mis-administration is or a prescribed dose is based on the characteristics of this device.

DR. WILLIAMSON: Now, these two centers that are using it -- can you give me the number of total doses that have been administered to patients?

DR. CASE: We're going to get to that.

DR. WILLIAMSON: Okay. I think most of us have read this, probably.

DR. CASE: Have you? Okay.

Some of the adverse events -- elevated liver enzymes, gastro-intestinal toxicities, and this is important, because when you look at the ulcers, perforations, hemorrhages -- and there have been deaths attributed to GI or stomach toxicities, and actually, they are events that are -- that could be -- could have not occurred but did occur.

You put three to six millicuries of technetium-99 into the artery and you take a look at the lungs and the stomach and the GI tract to see if there's any shunting that goes there.

From this, you determine patient eligibility. You can determine the administration activity based on what kind of dose you want to give, and then, after administration, you're looking for any emergency, the efficacy, and also, any mis-administrations.

Here's the assembly. The theraspheres come in this vial right here, and the assembly kit, everything here, comes pre-packaged with the vial of theraspheres.

Now, if you read the package insert, the package insert advises that, to get the best administration, that you do, in fact, use all of the included lines and syringes.

Contra-indications -- any deposition to the GI tract which cannot be corrected or if there's any indication

that you could give more than 30 gray in a single treatment to the lungs.

Now, actually, every clinical test that I have looked up in any reference that I have -- in all of them, they have always not given this therapy to anybody whose shunt test did show that they were going to get more than 30 gray to the lungs, and also, they've never given it to -- or from what I can tell, they do not give to anybody who shows any deposition in the GI tract.

Administration is generally 5,000 to 15,000. Licensees that have been using it so far have been using approximately 3 gigabecquerel, about 80 millicuries or 15,000 centigray or 15,000 rem.

DR. DIAMOND: Hepatic tolerance is 15,000 centigrade to the whole liver? I'd like some clarification on that hepatic tolerance about 15,000 centigrade.

DR. NAG: If you are injecting it into the tumor, if you are selectively putting into one artery, you can give it to that segment only.

DR. DIAMOND: That's very important. It's a partial liver dose or tumor and immediate vicinity dose, but you get 15,000 centigrade and it will not work.

DR. CASE: Okay.

Getting back to the question you had about why this is important for all licensees, the patient comes in,

they have a catheter put into their hepatic artery, and the therasphere administration kit is put together, assembled, and you have the theraspheres in the vial, you put the syringes in by hand, and then what you do is push saline through. That puts the radioactivity or the itrium-90 microspheres into the hepatic artery.

The hepatic artery is the blood supply that goes right to the tumorous tissues. Once the microspheres get in there, they get stuck in there or embedded due to their physical size, and once they're in the liver, they're not metabolized and they're not biologically active.

Misadministration, you would say that conventionally, you could say, brachytherapy, radiation dose, involving the wrong individual, isotope wrong, treatment site -- I tried to hide these other things, and I thought, well, for --

DR. CERQUEIRA: We have a question.

DR. WILLIAMSON: I'm sorry, I'm really confused about the legal basis of this, of what we're trying to do.

Is this a modification to the existing Part 35?

DR. PACE: No.

DR. WILLIAMSON: Is this something to go in the new 35.1000?

DR. PACE: No, no. Can I answer that question?

DR. CERQUEIRA: Yes.

DR. PACE: At the beginning, I thought I described that this is guidance for licensees who are going to be using this therasphere device, and this guidance actually came about or our discussion about providing guidance came about due to licensees asking us how are we going to --

DR. WILLIAMSON: That's what I'm asking.

DR. PACE: So our reasons for doing this is, again, not to increase regulatory burden, but for clarity.

DR. CERQUEIRA: Well, some of the background information is useful, but I think some of us have already read it. Maybe you could sort of get to the question.

DR. PACE: Sure, all right.

MS. HANEY: Jeff in a way this is similar to the intravascular, and that is that unfortunately, in the current 35, it falls between 35.300 and 35.400. But because of definitions, the closest place we can put it is 400.

If we were in the new 35, maybe we could call it an emerging technology, but in the meantime, we have people that want to use it right now, and we're just really looking for what are the best definitions for misadministration, what are training requirements?

Should we require 35.300 users or a 35.400 user; those are kind of some of it. So, I mean, Dan, I don't even think you need to go through the licensee experiences. I think that if you just -- do you have --

DR. PACE: I believe I have a question about that.
DR. CERQUEIRA: Now, what questions do you really want us to answer? I think it would be --
DR. WILLIAMSON: Why don't we get to that.
DR. PACE: Okay, I understand that your patience is running low here. I felt it was important to present some of this information to make sure that everybody was onboard, because this isn't just adding more regulations.
Again, I said, we're clarifying what makes this device so unique is that the theraspheres are in here, but this administration assembly has quite an impact on the administration of this theraspheres to the liver.
The potential for human error, using this, is high, and, in fact, one of the misadministrations that did occur, did occur because of inserting -- having to manually insert these syringes themselves.
So I won't go through any of this. I guess if you want to get right to it, we'll just talk about the training and experience requirements, potential authorized users.
I can tell you that the staff associated with this -- not everybody, but the staff who are trying to formulate this guidance, believe that the use of the microspheres for brachytherapy should be performed by a team consisting of the 35.200 authorized user and a 35.400, 35.200 being a diagnostic nuclear medicine, and the 35.400 being the

brachytherapy physician.

The reasons for this? Maximize the palliative effect, to decrease the adverse effects, which can be actually quite detrimental. In fact, you can actually do some good, perhaps with this.

But if you do it the wrong way, you could, in fact, adversely affect the patient to prevent intolerable, lethal effects, and to ensure radiation safety.

The --

MS. HANEY: Diane, I think you can stop there, really. The question I would just pose to the Committee now is, given what you've known from the package, what type of user? Do you agree with the Staff approach?

DR. CERQUEIRA: No.

MS. HANEY: Or at least what's being talked about, a 200, a 400 user, or what do you see it as? I think that if we could just open that up for a couple-minute discussion.

DR. CERQUEIRA: You need somebody to put the catheter in; you don't need a cardiologist this time, but you have an interventional radiologist who's there also; don't you?

MS. HANEY: Yes, but again, do you need to go there for radiation safety purposes?

DR. CERQUEIRA: No.

DR. WAGNER: Well, I don't know.
DR. PACE: Does everybody here understand the way that a person -- it's determined whether or not an individual can receive this?
DR. CERQUEIRA: Jeff?
DR. WILLIAMSON: I want to say something about this whole approach. It really concerns me. It looks to me like what you've done is, you've taken the sort of proposed package insert, which are the instructions from the vendor, and you're trying to turn it into a regulation.
And this seems wrong. I mean, why do you need to legislate down to the nearest tenth of a millicurie, how much dose a radiation oncologist can give to the lung?
DR. PACE: I think that perhaps you're misunderstanding the intention here.
DR. WILLIAMSON: Well, no I'm not. Let me finish, okay? I'm sorry.
DR. PACE: I think you are, but --
DR. WILLIAMSON: This is a general comment that it seems to me that much of this could be accommodated by the existing 35.400 regulation, which would require -- which basically allows the radiation oncologist a fair amount of latitude as to how the written directive is written.
DR. PACE: Is the 35.400 going to do the localization studies?

DR. WILLIAMSON: I think that's an issue of medical practice, you know. Why does NRC have to get involved in legislating how and who does exactly these studies? I think a radiation oncologist orders, you know, the appropriate study from nuclear medicine, and in most hospitals, only qualified nuclear medicine practitioners are allowed to do localization imaging.

That's covered under existing training and experience requirements. So why is it necessary to single out this procedure for this much sort of regulatory structure?

DR. PACE: It's actually the structure is not any different than what exists right now. As I said before, it's simply a clarification.

DR. WILLIAMSON: Well, I think it's too specific and you've gone beyond safety into practice of medicine.

DR. CERQUEIRA: Dr. Nag?

DR. NAG: I'll give you my practical experience with a very similar thing: And I'm glad that at that time, the NRC was not overlooking, because we used Iodine-125 seeds into the vessel, and were putting them into renal tumors.

Now, again, you are using the -- you are using the -- that humans have a more -- and therefore the radioactive material will go into the vascular tumor.

Before that, you perform a die study to see where the vascularity is. And then there was no special regulation required, other than the brachytherapy regulations that were already there.

The brachytherapy regulations that you already have are -- , except that the source is now smaller than the Iodine-125 seeds.

You can put Iodine-125 seeds into the renal vessel, and going into the tumor and can get stuck into the tumor which is exactly the same thing you are having here, except it's a smaller, a little smaller source, and in terms of misadministration, you can use the same definition you have now, that we prescribe I'm going to put X-number of millicuries into the renal vessel. Here it will be the liver vessel.

You know, all the other definitions can remain the same. The other thing I would suggest is not by specifying it only for liver, because then you are tying the hands of the physician.

DR. PACE: I'm sorry, not what?

DR. NAG: Not specifying this to be only in the liver.

DR. PACE: Well, that's what the FDA has done.

DR. WILLIAMSON: But you don't need to --

DR. NAG: You don't need to say that, because I

can foresee the similarity of this to be used in other tumors. So why can't you put radiation safety issues --

DR. CERQUEIRA: Let's not deal with sort of indications. I think that's an important point, but I think the question they're asking, they're recommending that it should be a team of a diagnostic authorized user, and somebody.

Why do you need the 35.200 user?

MS. HANEY: That's the for the level set there.

DR. PACE: That would b for the tests for the --

DR. CERQUEIRA: Why does that person -- why isn't that a routine clinical study? Why should you get into that?

DR. PACE: Well, this is what -- actually, this is why we're here today.

DR. CERQUEIRA: We're saying you don't need the --

Sally, you've been very patient.

MS. SCHWARTZ: Traditionally in nuclear medicine, we do studies now, injecting technetium labeled MAA, and we do something very similar to this. I mean, it's not directly into the liver, but certainly it just -- and we do it through different -- I mean, radioactive materials are injected into the CSF fluid.

I mean, they're injected numerous ways.

DR. PACE: Right.

MS. SCHWARTZ: Not necessarily does the NRC regulate anything, I mean, with regard to the specific injection.

DR. PACE: What you have to do is, you have to understand that this is not a radiopharmaceutical; it is a sealed source.

MS. SCHWARTZ: The first portion where you're injecting the technetium labeled MAA, that's a radiopharmaceutical.

DR. PACE: Right, right, right, right.

MS. SCHWARTZ: And that's why it probably doesn't need to be regulated.

DR. PACE: But the thing is, I don't think -- I need to know where you say it's regulated, because I don't know where you're saying we're regulating that.

DR. NAG: You don't want to include the authorized user.

MS. SCHWARTZ: Technetium labeled MAA is a currently-approved --

DR. WILLIAMSON: It's a clinically-indicated --

MS. SCHWARTZ: Radiopharmaceutical.

DR. PACE: They're saying if we use a 400, that will cover everything.

DR. WILLIAMSON: Yes, it will.

DR. PACE: Okay, I appreciate that.

DR. WILLIAMSON: The other thing is that your written directive is so specific. It's based on the package insert which I think reflects a fairly preliminary and probably primitive knowledge of how to use this device, and I agree with you, it's a device.

But, you know, eventually, you know, newer and more sophisticated methods of doing dosimetry will be developed.

DR. PACE: This is --

DR. WILLIAMSON: Let me finish one more thing. The other thing is, in many areas of brachytherapy, there are constraints on normal tissue that we have, and that we observe, and these do not to have to be in the written directive for any other brachytherapy procedure.

That's sort of up to the authorized user to go and look at the balance of what is going to be accomplished and be on behalf of the patient, versus damage to normal tissue, and it's a clinical decision.

So I don't know why that needs to be coded into a special, you know, definition of written directive and misadministration for this kind of patient.

DR. CERQUEIRA: I agree. Let's hear Dr. Leedham.

MR. LEEDHAM: In this case, it's a little bit different. There are other instances.

The other ones, they were approved devices. This

one is a humanitarian use device, and it's more analogous to an IDE where they are actually collecting data and providing that back.

So, in this case, the more that the package insert or the labeling is followed, is very critical. There will also be restricted distribution of who can participate in this.

So I think that as far as protocols go, participation will be according to the labeling, because it is actual, ongoing studies; it's actually a trial.

DR. PACE: That's right, and that's what I wanted to say, was that this is an interim guidance for those licensees who want to use it right now in its current state, in its current form, and given the information that we have, as well as the licensee's experience.

DR. WILLIAMSON: So why is this needed for a broad scope licensee anymore? You don't require this for a participant in a intravascular brachytherapy trial that's under the supervision of FDA through an IDE, so why does this have to be so detailed? Why can't sort of FDA supervise it?

DR. PACE: Simply because the definitions of the misadministration written directive and prescribed dose, as written, are written for devices -- are not written for this device. This device just cannot meet those requirements

because that's a sealed source.
It cannot meet the definition of --
DR. WILLIAMSON: Sure it can. Why not?
DR. CERQUEIRA: It's covered under 35.400.
DR. WILLIAMSON: How are permanent implants handled now?
DR. CERQUEIRA: I think all of us are missing the question. So if you could please tell us the question.
MS. HANEY: Let me try. The issue, Jeff, is that in the current 35, a written directive for all other brachytherapy says the radioisotope, number, sources, and source strengths, and after implementation but prior to completion of procedure, the radioisotope site, total source, strength, and exposure time, you can't do all those things for this.
So we need to change, we need to have an alternative for this. So the question that's on the table is, for this use only, we need an alternative definition for what needs to go in the written directive, and, then, of course, it falls out from that, as far as when you get into misadministrations. That's what on the table.
Because what is in here right now, doesn't fit.
DR. NAG: In a permanent implant, there is an exception. In a permanent implant, the activity -- that's how I do a permanent implant. I prescribe the number of

millicuries that I need to give, and it's called a permanent implant.

This is a permanent implant, and it's going to stay there all the time, and you prescribe the number of millicuries. I mean, I have been doing this for many years with I-125, rather than a microsphere, and I have been putting it in the vessels.

And I prescribe X-number of millicuries that I want to give to the site, which in this case indicates that it will be delivered.

DR. PACE: But what we wanted to do is include something as far as misadministration goes --

DR. NAG: Same definition of misadministration would apply. If I'm putting X-number of millicuries into here, I'm putting X-number of millicuries into the liver. The same definition would apply.

DR. PACE: Right.

DR. NAG: You don't have to create anything.

DR. PACE: However, this is a different device, and I'm sure that whatever you're doing now is one thing.

DR. WILLIAMSON: I think that technically it could be handled by just modifying the existing definition to delete number of sources and requiring total activity.

It has number of sources, too, so I think you're right; you have to delete number of sources, but you could

have total activity.

DR. PACE: This is a very simple thing.

DR. WILLIAMSON: And/or absorbed dose, just as it's stated now.

DR. PACE: All right, how about when the calculated administered dose differs from the prescribed dose by no more than 20 percent of the prescribed dose you put to the liver?

DR. WILLIAMSON: Well, how do we handle the situation in prostate brachytherapy where you do a permanent implant, and you don't always have control over, for example, what is the minimum dose.

So if you were prescribing the minimum dose for implant and you notice it fell 25 percent short, you know, then you would have a option to revise the written directive to say what it is that you observed on the post-implant dosimetry.

DR. PACE: But the permanent implant that you put in does not necessarily have a probability of migrating to a different site.

DR. WILLIAMSON: Yes, it does, to some extent, or potentially being implanted to the wrong site in a subtle way that you couldn't detect.

DR. PACE: Right.

DR. WILLIAMSON: But again, you know, you've put

inside here, you know, constraints that, you know, the FDA, I guess, constrains physicians to observe. But, you know, that's their law and they constrain it. I mean, in no other site for brachytherapy, do you put normal tissue constraints or require, you know, ancillary procedures.

I'll give you an example: If one were treating Hodgkin's Disease with a Cobalt-60 teletherapy unit, if you didn't put the lung blocks in, it would be a disaster.

The patient would have intractable pneumonitis, but you do not require, you know, that the authorized user specify that after 15 gray, I'm going to put the lung blocks in, and that if you don't put the lung blocks in, it's a misadministration. It's bad medical practice, but do you see my point?

In many areas of brachytherapy and teletherapy, there are important normal tissue constraints that the radiation oncologist uses in defining the prescription, and that is, I think, if you look at the medical policy statement, you know, outside of your purview.

And maybe for this device, it's between the physician and FDA, but why is it NRC's business?

DR. PACE: I don't think it's NRC's -- I think it's NRC's business to ensure, you know, the safety of the public, and also to -- but I don't think that -- I do not think that anything that's been added, or anything that's

here -- but with your advice -- I don't see it as adding -- I mean, I don't know if you're sensitive to everything becoming more constraints, more constraints, but I can assure you, we don't want to have more constraints.

We're trying to clarify for the licensees who are actually asking us for this.

DR. WILLIAMSON: Well, I think --

DR. CERQUEIRA: Dr. Ruth.

DR. McBURNEY: My comment was on the authorized users, and I agree with the Staff recommendation that the diagnostic part of that should be under the 35.200, and the other should be considered brachytherapy and under the 35.400.

MS. HANEY: There are no changes that are needed there, so with -- so that moves us into the current definition for written directive.

DR. DIAMOND: What's that page, please?

MS. HANEY: On page 10 -- oh, on 35-4 and 35-4; that's the current regs.

But under 35-5 is the definition for written directive. And where I was looking was Item 6, and for all other brachytherapy.

And that does not work in this case.

DR. NAG: Now, there's an exception for I-125 permanent implants.

MS. HANEY: Where are you looking, Dr. Nag?
DR. NAG: I know that I have been dealing with permanent iodine implants every day.
I'm trying to find it in here, but in the permanent implant, the way we define permanent implant and we prescribe, we say we want X-number of millicuries to be implanted into the area, and then we implant and the misadministration is not by dose, but by number of millicuries.
So it's -- and I know you do have it in here. Let me find the permanent implant area, exception for permanent implants.
DR. WILLIAMSON: He wants the definition here.
MR. LEEDHAM: Can I ask a question: Kathy, where in Number 6 does this not work?
MS. HANEY: In the number of sources.
DR. WILLIAMSON: You can't simply say that you used a vial?
MS. HANEY: No.
DR. PACE: If also I can just say one thing, as far as the administration device goes, there have been some problems with it with the licensees. It doesn't seem to be working as well as one might hope that it would.
And this is where also the part comes in about misadministration. That is another thing that I had hoped

that we would talk about, but I'm actually -- I actually don't want to get into it.

But how are we going to determine what a misadministration is? It's a pure beta emitter; it's being injected or administered through all these syringes and through all these tubes, and we have found that licensees have found pooling in the stopcocks, and they've found that one only gave 38 percent of the intended dose.

Now, of course, an under-dose, well, you could say that that's not so bad, but the question is, what happens if the person is improperly pre-screened and anything goes to the GI tract or a certain amount goes to the lungs and the person does, in fact, die from pneumonitis or from GI tract complications? And that is important.

DR. WAGNER: But to me, that situation, that's a medical situation. I mean, those are medical conditions and things that can occur in medicine. Patients are advised of the risks and possibilities.

And in the practice of medicine, this applies to anything in the practice of medicine. I mean, you go in for surgery, see what they tell you.

I don't see why in this situation we have to worry about misadministration with regard to this. This is a matter of things that can go wrong.

They shouldn't, if you have really good control on

this, but I guess there is some chance that they might happen, and it's the risk patients have to take.

DR. PACE: Right.

DR. CERQUEIRA: Jeff?

DR. PACE: I suppose there is a reason for misadministration that -- we're not going to have that definition anymore, but the pure definition of misadministration is to find out whether out not the intended dose or the intended activity was given.

So --

DR. WILLIAMSON: I'd like to make two points about this, one general point and one specific suggestion for you about this device:

I think the general point is, I would imagine at some point, either this device is going to go away or the conditions on its use are going to be liberalized, and maybe other kinds of colloidal sources that are sealed sources like this will appear.

So I would urge you to think generally, and try to come up with a very flexible set of regulations.

DR. PACE: These aren't regulations; these are guidances for the licensees using this material.

MS. HANEY: Well, be careful. They're not regulations, but what you're looking to use these for are license conditions.

DR. PACE: Yes.
MS. HANEY: For use --
DR. WILLIAMSON: They're de facto regulations.
MS. HANEY: Which in this situation, would actually become a requirement that is a big deal.
DR. WILLIAMSON: Can I finish my comment? Okay, so my general comment is, is to try to think a head a little bit and not to be so special-cased and narrow that you can only see the sort of one single device and the immediate clinical indication that's before you, and be a little more general.
And I would say, yes, probably -- now, to be specific, I think probably both the written directive and the misadministration definition need to be modified a little bit.
And I would say it's reasonable for this case to keep the existing definition, but delete the requirement to report the number of sources, since that can't be done, and consider certainly total activity and maybe total absorbed dose.
Or I would suggest probably leaving that at the discretion of the practitioner. So that's the specific point.
For misadministration, I think -- thinking back, what is the concept of misadministration? It's an error

that involves a technically-avoidable mistake on the part of the caregiver, not something that happens because of the patient's medical condition.

DR. PACE: Sure.

DR. WILLIAMSON: Or as a consequence of a medical judgment by the practitioner that you may disagree with, but, you know --

DR. PACE: No, I'm right there with you.

DR. WILLIAMSON: So I would say that in this situation, a reasonable definition would be, you know, defining it in terms of the percentage of activity that goes from the vial into the catheter, since that's the sort of one part that, you know, really is under technical control of the practitioner, is how much of the activity goes from the vial into the catheter, into the patient.

And I think to some extent, what happens to it, at least in the general case, and in more general indications, can't always be controlled with the level of rigidity that you would like, and you shouldn't make a regulation.

DR. PACE: No, and that's why in the misadministration, we put in here, that it says the wrong treatment site, if preliminary shunt tests were not performed, not performed properly, or the results were not used.

DR. WILLIAMSON: But I would say that's going too

far. I would not agree with that.

DR. NAG: Okay, now, the present regulation -- I'm just reading out from the present regulation, 35-4, and brachytherapy misadministration is already in there, involving wrong patient, et cetera, wrong isotope, excluding for permanent implants seeds that were implanted in the correct site, but migrated outside the treatment site, where the migration has been taken care of already.

MS. HANEY: But that's only for the definition of misadministration.

DR. NAG: Yes, right.

MS. HANEY: That doesn't help us with written directives.

DR. NAG: Well, that's what I'm talking about that, too, 35-5, under page 35-5, the prescribed dose that the -- of radiopharmaceutical and brachytherapy, either the total source strength -- and here you can give it in terms of source strength -- and exposure time, here the exposure time is permanent, or the total dose, and here you are not talking about total dose.

So it is covered.

DR. CERQUEIRA: So it sounds like -- Diane, they seem happy with the way -- there's enough written rules already. The only problem is just the number of --

DR. WAGNER: Sources.

DR. CERQUEIRA: Sources. So it seems like it's an easy fix that's already dealt with for the most part. Is that not true?

DR. NAG: It will make your life a lot easier.

DR. WAGNER: It makes your life a lot easier if you just say that all you need to do --

DR. PACE: Well, who is the person who said we were looking at patient -- we have to remember the patients, right? So we said that.

DR. WAGNER: This addresses the issue of, number one, you've got everything and all you've got to do is take out number of sources and tell the user that they don't have to consider number of sources since that's not applicable in this application.

And then use the definitions under permanent implant for defining misadministration.

DR. DIAMOND: Excuse me, but just to follow up, what you need, I think, from a rational basis, is to a total administered activity and an estimated biouptake by the organ of interest. That's it, an estimate biouptake of the organ of interest, which in this case is the liver.

MS. HANEY: I would say that that might be true, but I think you might want to consider the existing definition and try to start with that and then back off, rather than putting a whole new concept.

You're putting out a good idea, but then it starts to become more and more inconsistent with the other definitions, which is not -- if we don't have to go there, I would say, not go there, but if you can get it by just deleting one or two things from the current definition, it might be an easier way to approach it.

I'm not --

DR. DIAMOND: I'm just saying that what you want to know from a rational basis, is how much dose an organ is getting; that's how you do it.

MS. HANEY: Okay.

DR. CERQUEIRA: But you're going to have to calculate it, and I don't think we want to go into that area. John?

MR. GRAHAM: As a lay person, I guess as the idiot savant for this group, trying to translate all of the technical discussion that takes place, can this be as simple as the fact that the ACMUI recognizes that the Therasphere-7 device requires a license amendment under the current Part 35.400?

DR. CERQUEIRA: I heard that.

MR. GRAHAM: And that the ACMUI recommends no restriction on condition of use beyond the FDA label, because it does narrow this down to a very restrictive use, correct?

DR. CERQUEIRA: Right.
MR. GRAHAM: And ACMUI recommends that the license amendment include guidance that the written directive does not require specification of the number of sources, and that the license amendment will use the definitions under misadministration for permanent implants?
MS. HOBSON: Correct.
DR. NAG: And I will just add one thing: Everything else I agree with, but you said you take out the number of sources, which is correct, but you have to have total activity. You need to have the total activity.
MR. GRAHAM: I'll take a friendly amendment to this proposed motion, that technically gets us where we need to be.
DR. WILLIAMSON: I think it's already in there, it's already inherent in what he said.
DR. CERQUEIRA: Do I hear a second on this motion?
DR. NAG: Yes.
MS. HANEY: I think we need more discussion.
DR. CERQUEIRA: More discussion? If we have a second, then we can have discussion.
MS. HANEY: Okay, all right.
DR. CERQUEIRA: Okay, we have a second, okay. Discussion?
MS. HANEY: Can I discuss?

DR. CERQUEIRA: Yes.
MS. HANEY: When you say the definition for a permanent implant, that -- I think we need to be a little bit more definitive in your statement, because if you look at 35.4, it's under all brachytherapy, and the items that Dr. Nag referred to is an exclusion for permanent implants.
But I want you to realize that Items II and III-- well, I guess, Roman Numerals II and IV still apply, so there's no -- if I went and took your recommendation and tried to look in the current Part 35 for the misadministration criteria for permanent implants, I'm not going to find it.
So, what I'm kind of asking for is a modification of your statement that we would use the criteria for misadministration that is in -- on page 35-4 under Item V, Brachytherapy Radiation Dose.
DR. WILLIAMSON: Yes.
MS. HANEY: You have the exclusion in there for the permanent implants if they do migrate. You have the wrong patient and wrong treatment site and things like that.
Item II, involving a sealed source that is leaking, I mean, that's not going to really apply in this case.
Item III doesn't apply because it's a temporary implant, but the bigger one is Item 4, are you in agreement

with the calculated administered dose differs from the prescribed dose by more than 20 percent. And if you do, then you're fine with going with what's in the current regs. So we don't need a modification then to the misadministration criteria.

DR. CERQUEIRA: So are you willing to take those modifications, John?

MR. GRAHAM: Certainly.

DR. CERQUEIRA: All right, so we've modified his original motion.

DR. DIAMOND: Please restate your motion.

MR. GRAHAM: We usually get this. The ACMUI recognizes that the Therasphere-7 device requires a license amendment under the current Part 35.400, and the ACMUI recommends no restriction on condition of use beyond the FDA label.

And ACMUI recommends that the license amendment include guidance that the written directive does not require specification of the number of sources -- you guys want an amendment in here, so --

DR. CERQUEIRA: Just put activity, that you want a total activity.

DR. NAG: Just the total activity.

MR. GRAHAM: -- will require specification of total activity?

MS. HANEY: And radioisotopes and radionuclides.
MR. GRAHAM: Specification of total activity, and radionuclides, and misadministration definition will be applied using Item V for a brachytherapy radiation dose.
MS. HANEY: I could make it easier for you; that the brachytherapy -- that the definition for a brachytherapy misadministration as defined in the current Part 35, does not need to be modified.
MR. GRAHAM: Fine.
DR. WILLIAMSON: One more friendly suggestion is that you remove the clause referring to the conditions of use being limited to FDA, because that's already covered here by Section 814.110 of the Federal Code, which you can see on page 22, Attachment 3.
There is already a law that says the conditions of use for HUD are required to be in accord.
DR. CERQUEIRA: That's different than saying that we're recommending that the NRC doesn't restrict it beyond that point.
DR. WILLIAMSON: So I guess I'm saying that it shouldn't comment on restriction of use at all. Because at some point, no doubt, either this device will go away, or FDA will liberalize it, and more general off-label uses will be legal, and in that case, I don't think NRC wants to take a position.

MR. GRAHAM: There was a discussion of potentially restricting this use beyond what the FDA has discussed. That's what I heard.

DR. WILLIAMSON: I guess that what I'm saying is that it's unnecessary for NRC to reaffirm the restrictions on the label because existing FDA regulations are adequate.

MR. GRAHAM: What you're not following, Jeff, is that potentially, they can introduce restrictions beyond the FDA label. You're looking at it from the other side of the paradigm here.

DR. CERQUEIRA: I think it needs to be specified.

MR. GRAHAM: If the FDA opens this up later to other uses, this covers it automatically. This just says that the ACMUI recommends on restriction on condition of use beyond the FDA label. If the FDA modifies the label, okay.

DR. WILLIAMSON: That would make it as a license condition then, off-label uses are not possible; that would be a violation of the license.

MR. GRAHAM: Actually, it does not. Listen to the sentence.

DR. WILLIAMSON: All right.

MR. GRAHAM: The ACMUI recommends no restriction on condition of use beyond the FDA label. So as long as I stay within the guidelines and the law of what the FDA label allows, we're not adding any restriction beyond that.

DR. WILLIAMSON: Okay, here's the scenario I'm thinking of, John. I'm sorry.

At some point, the limitation on HUD may be lifted. And then there will be no sort of special status for this device, and the label will still say it's probably indicated, you know, for X, Y, and Z liver diseases.

But now, as I read your amendment or as I understand your amendment, it would now be -- would require another license amendment for the -- to do a clinical study in another site.

DR. WAGNER: I think he's right, Jeff's right because we have many isotopes now where we have the FDA label that comes with these isotopes to -- used to be used to -- it wasn't used for heart at all, but many people are using it for that for now. And that's an example that's exactly what you're talking about.

DR. WILLIAMSON: Exactly.

DR. WAGNER: And so I would agree that Jeff is right about the issue, because if you restrict it to the FDA label, as the FDA moves in later, they'll make changes, but the label will still say the old thing, because the manufacturer doesn't want to change the label, because they've got to go back to the FDA and get it all done.

DR. WILLIAMSON: So you'll preclude off-label uses of the device after the HUD status is rescinded; that's my

point. And for the moment, there are existing federal laws which require it. As long as it's an HUD device, as I read this paragraph, it's got to be used according to what FDA says.

MR. GRAHAM: We have a suggested friendly amendment from our FDA representative. What if it was changed to read beyond the FDA requirements?

DR. WILLIAMSON: That's fair. I like that.

DR. WAGNER: Cathy's got a friendly amendment.

MS. HANEY: Cathy only does friendly amendments. Prescribed dose also needs to be modified, the definition of prescribed dose, and why it needs to be modified is that it keys off the misadministration definition, keys off of the prescribed dose definition.

And I think it's, again, a very simple thing. It says for brachytherapy, either the total source strength and exposure time are the total doses documented in the written directive.

Does total dose get it? Can we just rely on the "or" in this?

DR. NAG: Not total dose, total activity. You have to --

MS. HANEY: Okay, then we would have to modify -- the friendly amendment is modify the definition for prescribed dose to allow for --

MR. GRAHAM: Change total dose to total activity?
DR. WILLIAMSON: No, total dose or activity.
MS. HANEY: Total dose or activity.
DR. WILLIAMSON: I think it could be different in different techniques, that you would imagine in the future. I think some flexibility for the authorized user to define the prescription system is appropriate.
DR. CERQUEIRA: Excellent, excellent. Any further discussion?
DR. PACE: Yes, I have one. So does this leave us with -- if we're going to have some changes in the wording for prescribed dosage, then I think written directive -- then, again, all licensees would come in for an amendment, or no?
MS. HANEY: No, the specific licensees would have to come in for an amendment.
DR. WILLIAMSON: It's just a one-time amendment.
DR. PACE: What about the broad-scope licensees?
MS. HANEY: Well, the broad-scope, I think, in this case, given the definitions that we changed, they'd also have to amend their procedure, because the broad-scopes have to comply with 35, and these are the requirements.
So you're kind of stuck. I think the issue, though, is that there are not that many licensees that are going to be doing this, either broad scope or specific.

DR. PACE: But what we were trying to do is accommodate those licensees who want to use it now, who are trying to help patients now, and so that's why we're here right now.

DR. NAG: Cathy, the way that it is written now, for brachytherapy, either the total source strength would include that activity, so it will cover it. Or the total dose, so I don't see any reason to change it.

MS. HANEY: That's the question. If you're happy with that as it reads, you think it fits in.

DR. NAG: No, total source strength. That entails you have to match quite a number of sources for source strength.

MS. HANEY: Okay.

DR. WILLIAMSON: Was suggesting total source strength or total dose, whichever you choose.

MS. HANEY: Well, dose is just total dose. And it's already in there.

DR. NAG: Both of them are there.

DR. CERQUEIRA: Total dose or total activity, you want to keep it that way?

DR. NAG: The total activity and total source strength is the same thing.

DR. CERQUEIRA: So you want to just replace that with total source strength?

DR. NAG: It is there.
MS. HANEY: No, no.
DR. NAG: You don't need to change anything.
MS. HANEY: Okay, I remove my friendly amendment.
DR. CERQUEIRA: All right, any further discussion?
[No response.]
DR. CERQUEIRA: Do I hear a motion for a vote?
MS. HANEY: Also, did we clarify 35.400 physician, authorized user?
DR. CERQUEIRA: Yes.
MR. GRAHAM: The entry of this says that ACMUI recognizes that the Therasphere-7 device requires a license amendment under the current Part 35.400.
DR. CERQUEIRA: Excellent, excellent.
DR. WILLIAMSON: I'm for a vote.
DR. CERQUEIRA: Second?
DR. NAG: Second.
DR. CERQUEIRA: All in favor?
[Show of hands.]
DR. CERQUEIRA: Opposed?
[No response.]
MS. HANEY: Did you vote, Ruth?
DR. CERQUEIRA: Abstentions?
[Show of hands.]
MS. HANEY: Okay, one abstention, and everyone

else is -- one, two, three, four, five, six, seven, eight, nine, ten. Nine in favor, for the record.

DR. CERQUEIRA: Great. I think that worked very well. I mean, John did a good job of keeping the amendment.

DR. PACE: If there is anybody in the audience who would like -- who would be interested in learning about this at all, just contact me, and I'll show you the slides.

MR. GRAHAM: If you'd like one last shot on how that amendment was worded, you know, I'm open to -- I can be bought.

DR. WILLIAMSON: I do want to say that your handout was extremely well put together and very informative, and you know, I read it, and I thought I really understood a lot.

DR. PACE: Good.

MR. GRAHAM: I guess I'd want to echo that, that the handout, having read it ahead of the meeting, allowed an expedited discussion, and I'd hate to have you think that we're just banging away after -- your handout answered a lot of the issues.

DR. WILLIAMSON: If everyone did this, it would be a lot smoother, I think.

DR. CERQUEIRA: All right, any other business?

[No response.]

DR. CERQUEIRA: In which case, who moves to

adjourn?

VOICES: So moved.

DR. CERQUEIRA: Tomorrow, we'll reconvene at 8:30.

[Whereupon, at 5:00 p.m., the meeting was recessed, to reconvene at 8:30 a.m., Thursday, November 9, 2000.]