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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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OPEN SESSION

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WEDNESDAY,

NOVEMBER 12, 2003

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ROCKVILLE, MARYLAND

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The ACMUI met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 10:26 a.m., Manuel Cerqueira, M.D., Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

MANUEL CERQUEIRA, M.D., Chairman

DAVID A. DIAMOND, M.D., Member

NEKITA HOBSON, Member

RALPH P. LIETO, Member

COMMITTEE MEMBERS PRESENT (Continued):

LEON S. MALMUD, M.D., Member

RUTH McBURNEY, Member

SUBIR NAG, M.D., Member

SALLY WAGNER SCHWARTZ, Member

ORHAN H. SULEIMAN, Ph.D., Member, FDA Representative

RICHARD J. VETTER, Ph.D., Member

JEFFREY F. WILLIAMSON, Ph.D., Member

ACMUI STAFF PRESENT:

ANGELA WILLIAMSON

THOMAS H. ESSIG, Designated Federal Official

LINDA M. PSYK

ROBERTO J. TORRES

ALSO PRESENT:

John Szabo	NRC/OGC
Charles Miller	NRC/NMSS
Charles Cox	NRC/NMSS
Michael Layton	NRC/NSIR
Michael Markley	NRC/NMSS
Keith McDaniel	NRC/NMSS
Roger Broseus	NRC/NMSS
Patricia K. Holahan	NRC/NMSS
Bernard Stapleton	NRC/NSIR
Scott Moore	NRC/NMSS

ALSO PRESENT (Continued):

Paul Yurk	
Lynne Fairobent	ACRA
Nancy R. Paly	
James Boxall	
Tomas Herrera	
Angela Lee	
Bill Uffelman, Esq.	SNM General Counsel
William D. Nelligan	
Gerald A. White	AAPM
Susan Chidakel	OGC
Albert Raizner	ACC
Craig Reed	Novoste
Adam Lowe	Novoste
James E. Morris	
Andrew Kang	
David Tiktinky	
Donna-Beth Howe	
Hagar S. Bhaihu	

I N D E X

AGENDA ITEM	PAGE
Opening Remarks, Thomas Essig	5
Update on National Materials Program Pilot Project, Michael Markley	8
The Rulemaking Process, Keith McDaniel	21
Implementation of Proposed Revisions to Part 35, Recognition of Board Certifications, Roger Broseus, Ph.D.	53
Possible Licensee Implications Associated with Training and Experience Recommendations in SECY 03-0145, Richard Vetter, Ph.D. .	100
Novoste IVB Event Analysis, Jeffrey Williamson, Ph.D.	161

P-R-O-C-E-E-D-I-N-G-S

(10:26 a.m.)

CHAIRMAN CERQUEIRA: This meeting will officially come to order.

I request members speak into the microphones, and we will have all verbal votes on the voting actions.

The first item of business is the opening remarks from Thomas Essig.

MR. ESSIG: Thank you, Mr. Chairman.

As the Designated Federal Official for this meeting, I am pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Thomas Essig. I am Branch Chief of the Material Safety and Inspection Branch and have been designated as the federal official for this Advisory Committee in accordance with 10 CFR, Part 7.11.

This is an announced meeting of the committee. It is 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 September 22nd, 2003, edition of the Federal Register.

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

I request that whenever possible, we try to reach a consensus on the various issues that we will discuss today, but I also value minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

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 discussion that we're going to have today. I have not identified any items that would propose a conflict. Therefore, I see no need for an individual member of the committee to recuse themselves from the committee's decision making activities.

However, if during the course of our business you determine that you have some conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point I would like to introduce the members that are here today:

Dr. Manuel Cerqueira, Chairman, a cardiologist;

Dr. Leon Malmud, who is sitting at the right of Dr. Cerqueira, is our Vice Chair.

Ms. Nekita Hobson, patient advocate;

Ms. Ruth McBurney, our state representative;

Dr. David Diamond, who is temporarily absent, but is here, a radiation oncologist;

Dr. Subir Nag, a radiation oncologist;

Ms. Sally Schwartz, a nuclear pharmacist;

Dr. Richard Vetter, radiation safety officer;

Mr. Ralph Lieto, therapy physicist;

And Dr. Orhan --

MR. LIETO: I'm nuclear medicine.

MR. ESSIG: I'm sorry. Nuclear medicine physicist, and I missed Dr. Jeff Williamson, therapy physicist. He's being picked on today for being missed.

And Dr. Orhan Suleiman, who is the Senior Science Policy Advisor for the Center for

Drug Evaluation Research of the U.S. Food and Drug Administration.

And we have other FDA staff who are also with us today and are seated in the audience.

Committee member Dr. Douglas Eggli, a nuclear medicine physician, who was unable to attend this meeting of the committee due to a conflict in his schedule which could not be resolved.

Mr. Chairman.

CHAIRMAN CERQUEIRA: Thank you very much, Mr. Essig.

I think we'll move right along to the agenda, and the first item is an update on the national materials program pilot project on operating experience, and Michael Markley will be doing the presentation.

MR. MARKLEY: It's good to see you, one and all, again. Since we've last met, we've picked up a coach here to try to reinforce and strengthen the state participation in this. So Marcia Howard and the other members of the pilot were expected to be participating today, but it looks like they've abandoned me with the timing of the meeting and so forth. So it's just one of the unfortunate things; I have to make my way through it as we go.

One of the things that became pretty clear and was noted to us early on in the pilot is that there's not a real good understanding between us and the states as far as what do we mean by operating experience, and then at the OAS meeting I just kind of casually threw out a question. How many of you if I said "operating experience information" knew what we're talking about? Maybe a half a dozen people in the entire room raise their hands, and I think a lot of those were NRC staff.

(Laughter.)

MR. MARKLEY: So we shouldn't be surprised. I think if we talk about any of the individual items that we have here, domestic or foreign event data, special studies, risk analysis, performance indicators, we had common terms, but to talk about it as an integrated program I think we have a long way to go to establishing the kind of communication and relationship with the states that we would like to have.

We met in May last time, and one of the suggestions that the committee made was that we talk to the University of Texas about the work they had done, and we have done so. We had a teleconference a couple of weeks ago as well, and learning more

about what they had been doing for Texas as well as the State of Maine.

And it's interesting to look at the evolution of the work that they were doing and how those insights were adopted for the state programs and where he's currently working on products that really drove not necessarily serving the state regulating bodies, but now the licensees. That has transitioned to become their larger customer base.

And what they're providing in many respects are checklists of how to become compliant or how not to get in trouble with the regulator, which this is a pretty good service in and of itself. You know, the studies themselves were in many ways driven out of enforcement. That was the data that was readily available. So there's good information there.

And the pilot activities, we've revised our charter, issued the work product plan. We've been having bi-weekly teleconferences.

It's worthy to note that one of the problems we run into with these working groups with the states is the resource issue, and this pilot so far has been conducted entirely through teleconferences. We have given presentations at

CRCPD and OES, but for the most part we've done everything remotely.

The deliberations, we had the meeting with the University of Texas. We announced that as an open public meeting, as well, so that if people, members of the public or licensees, wanted to attend, we did not have them, but nevertheless, it was that way and done with a bridge line.

The kind of things we're looking at, you know, are what generic communications don't work, refining data, developing insights and trends. You know, we spend an awful lot of effort trying to get the data right to close the loop on particular events and information that go into the database, but one of the questions we raise is that how much time spent on that versus using those insights that you can derive or analyzing information that's within the databases.

And then how do you use those? From our view, some of the best impact areas are to apply them to the inspection and oversight processes and licensing, and then looking at risk studies and the prioritization of work and resource allocation, and how do you address human error?

If you look at these events, invariably

a majority of them have a lot of human error involved, and how do we treat that in a consistent manner.

The incident and working group reports, we're looking at a number of those, approximately ten, and looking at what the root causes of the events were, generic issues and how the information may have been communicated between states, between the NRC and states and so forth, looking at the trends and common themes, and the effectiveness of the initial regulatory actions and whatever follow-up may have been done.

And, again, looking for opportunities to expand the use of risk insights.

The pilot itself, we've been -- the working group, rather -- we've been conducting interviews. We've sent our surveys to managers, inspectors, reviewers. We've also done so with the states at the OAS meeting. We handed out a survey there, trying to gain information as far as their needs, the regulatory decisions that they're trying to make, and the communication practices, tools, and methods that we can use to enhance the process for both the NRC and the states, and using a couple of test cases.

The test cases that we've selected, one that's near and dear to the committee is intravascular brachytherapy. We selected this one because there is a need to gain some more information on training, the devices, and the data on the malfunctions.

The other one that we're using is portable gauges because there's information readily available, both in generic communications as well as data. There are a fair number of events, and this is one where we think we can gain a lot of insights from the states in terms of what are they doing and what are the impacts and benefits that regulatory actions have had.

And the endpoint that we're driving toward is to put together a set of recommendations for use by the NRC in agreement states on procedures and sources of information, criteria such that if the estates or the NRC were looking at a particular event or set of data that you would come up with similar regulatory response and decision making, and that the integrated decision-making process where you're using event data, inspection, and the other otherwise methods.

How can we better communicate it?

Really the communication part of it is extremely important. It seems that that's one of the real difficult areas that we have. Both the states and the NRC do a lot of things, but we don't necessarily communicate them very well with each other.

You know, the near payback I see coming out of the pilot is most likely to be some recommendations along the lines of the communications of these things. It's not just communication. It's really the relationship.

How do we invite the states to the table to participate in the decision-making process for things that affect us? And how do we become more involved in their decision making and sharing of things between the states?

So it really is a relationship as much as it is a communication process. There are opportunities we're not taking advantage of in many ways, I think, and those are some of the feedback we're getting.

We're doing interviews, you know, as I say, within the groups, and whether it's managers, inspectors or reviewers, and we haven't achieved that relationship that each one desires. That's the kind of feedback we're getting, I think, from both

sides of the fence.

Questions?

The members of the team, by the way, are Duncan White, who is a Region I person, who is also now Region II as well since they have both, and Debbie Gilley from Florida, and Marcia Howard from Ohio, who is a coach here.

CHAIRMAN CERQUEIRA: I guess I just have one question in terms of, you k now, the agreement states, you've delegated them the authority to regulate, but what sort of enforcement can the NRC impose if states are not compliant? I mean, once that authority has been delegated, what enforcement is available to the NRC for renegade states, as it were?

MR. ESSIG: I'll try to answer your question.

MS. McBURNEY: I can answer. Texas is not a renegade.

MR. ESSIG: The NRC has a process called the integrated materials performance evaluation program, or IMPEP, and we basically review a state's program on a nominal frequency of every four years or more often for cause, and the review consists of a team composed of NRC people and agreement state

people.

And ordinarily once the program is established and the agreement is set up with the state, it is pretty much NRC maintains oversight, but it's pretty much hands off. So the inspection, the licensing, the enforcement actions are all taken by the agreement state, and then we review that process every four years or more often for cause, but in order for us to find a particular -- if we find a particular element problematic, of course, we'll discuss that with the state during the IMPEP or at some other point in time, but typically we leave it up to the agreement state to regulate in accordance with the agreement the we have with it.

CHAIRMAN CERQUEIRA: So, in essence, you have no enforcement mechanism, and I think the Glenn Commission, you know, way back after the Plain Dealer incident, that was their conclusion as well, that the NRC does not have the ability to impose or enforce, you know, changes in rulemaking within the states that are self-regulated.

MS. McBURNEY: They do have the ability to take back the agreement.

MR. ESSIG: Do they?

MS. McBURNEY: Yeah, and just to

clarify, it's not a delegated program. It is they relinquish the authority to the state. There's a slight difference in how EPA does their delegated program versus NRC, which is actual relinquishment of authority over that, as long as they keep the program consistent and --

CHAIRMAN CERQUEIRA: As rigorous as the federal policy, but they can impose stricter regulation if they feel it's appropriate.

MS. McBURNEY: In certain cases. It depends on the compatibility level of the regulations and then the adequacy of their -- they're reviewed on the adequacy of the program and the compatibility of the regulations

DR. WILLIAMSON: I guess I probably asked the same thing previously. I guess I'm not completely clear what the problem is. You have the nuclear materials event database. Is it that all of this data is being collected and no one at NRC looks at it, or is the problem that the class of events that you formally analyze is too small or is the problem that you don't have access to the agreement state counterpart of NMED?

It's three questions really, but what is the problem?

MR. MARKLEY: Well, it's really more of the working group pilots themselves are really driven by the desire to have more of a partnering process with the states that we both function and operate better together and we derive more benefit from the state's experience, particularly considering there are as many agreement states as there are.

The pilot originally started as an event evaluation pilot to look at how we evaluate event states, NRC, and how we can make that process better, more consistent, more predictable, use more trending of information. We've had a few things that have happened since that time. So it was somewhat overtaken by events. Davis-Besse, for example, some of the cross-cutting threads of program features of operating experience and values, and that really took a lot of -- we derived a lot of influence and bearing as to where we are today and looking more broadly from that.

Let me back up and see if I have the third question.

DR. WILLIAMSON: Well, let me go back to my first one. I guess I'll ask more specifically. What is the level of compatibility assigned to the

medical event definition? Is it a B or a C?

MR. MARKLEY: I'm not sure I understand the question.

MS. McBURNEY: I think it's a B.

DR. WILLIAMSON: It's a B. So you know, at least that problem would be solved, is that there will be a uniform event definition around the nation. Is the --

DR. HOLAHAN: And the agreement states put the data into NMED. So we have access to all of the agreement states.

DR. WILLIAMSON: Okay, and that is working, and it's not broken.

DR. HOLAHAN: No.

MR. MARKLEY: No. If anything, we would look to find ways to enhance the use of NMED. That's the target. The working group and the pilot is driven by seeking opportunities to make things better. It's not to fix something that's broken .

CHAIRMAN CERQUEIRA: Other questions for Mr. Markley?

(No response.)

CHAIRMAN CERQUEIRA: If not, thank you very much for the presentation.

MR. MARKLEY: Thank you.

CHAIRMAN CERQUEIRA: Excellent. The next presentation which will take us up until the noon lunch break is the rulemaking process, and it's quite an extensive body of material in the book with both slides and other materials as well. And Keith McDaniel will be presenting the material.

Welcome, Keith.

MR. ESSIG: Let me just mention while Keith is getting set up this was totally our idea to present this to the committee, and it was really driven by the fact that we ask the committee from time to time and will continue in the future for you to comment on proposed rules in the early stages, and we felt to give you the benefit of a context here, we wanted to give you a good overview of what the rulemaking process is all about.

It's a very public process, and so you can feel or see where your activities fit into when we engage with you before it goes up to the Commission where that all fits together.

And we just felt based on some isolated comments that we're getting back from individual committee members that maybe there wasn't a good appreciation of how the rulemaking process works. So that's kind of what drove this to be placed on

the agenda today, and hopefully you'll find it instructional and useful.

MR. McDANIEL: Hi. Good morning. I'm Keith McDaniel. I'm with the Office of Nuclear Material Safety and Safeguards, NMSS, the Division of Industrial and Medical Nuclear Safety, IMNS, and in the Rulemaking and Guidance Branch, RGB.

The timing for this is really pretty good because I had developed this program for a pilot training class that we're giving to NRC staff actually tomorrow. So that's essentially what I'll be giving you this morning.

I'm here to give you an overview of the rulemaking process in NMSS. The Office of Nuclear Reactor Regulations has their own process, although there's a lot of similarities between the two.

Again, this is a presentation on the process. It really wasn't set up to discuss specific rulemaking issues, but of course, we'll try to answer whatever questions you might have. If I can't answer them, there's others in the room that might be able to.

Okay. The first two slides that I put in are just a list of acronyms, and I list these up front because even though I do try to limit my use

of acronyms, I do have some in here, and I thought if I put them up front you would have them to refer to.

I've got a feeling you know what most or all of them are anyway.

CHAIRMAN CERQUEIRA: Keith, can I just -- so this material is not in the handout that we have; is that correct?

DR. NAG: At the end.

CHAIRMAN CERQUEIRA: At the very end. Okay.

DR. NAG: Slide No. 27, 28.

MR. McDANIEL: Okay. Now, this is a revised -- I had given you guys a set of slides several weeks ago.

CHAIRMAN CERQUEIRA: Right.

MR. McDANIEL: And then several days ago I had provided a revised set of slides, and that's what I'm working off of, and did they get the revised set of slides?

MS. WILLIAMSON: I did not E-mail them any revised slides. Do you have a revised set we can give everybody.

PARTICIPANT: Keith, this is substantively different than what we have?

MR. McDANIEL: There's more in it, but essentially it's the same. I've just added some things to it.

CHAIRMAN CERQUEIRA: Yeah, I think for the sake of time it's probably better to just go forward.

MR. McDANIEL: Okay. I'll go through this, and I think we can make up some time in the schedule. It wasn't really set up for an hour and 40 minutes. So I apologize for what you have is different.

Okay. The next slide lists the discussion topics that I'd like to talk about, key documents. What is rulemaking? NRC's place in the government, types of rulemaking processes, organizations' responsibilities, working group responsibilities, and some Web sites.

Okay. First is the key documents, and I'm going to list four of them here. The Code of Federal Regulations, Title 10, Energy, this is where you'll find NRC's requirements. This is, of course, publicly available.

NRC's management directive 6.3, which is called the rulemaking process, this contains NRC's policies and objectives for rulemaking. It

describes organizational responsibilities. This is publicly available in NRC's public document room.

The third one is the regulations handbook. It's a NUREG, NUREG BR-0053, Rev. 5. This assists the staff in drafting rulemaking documents. It's a procedure for all of NMSS or all of NRC rulemaking, both NMSS and NRR. It is publicly available in Adams, and I list the Adams accession number.

The last document is more specific to NMSS. It contains detailed NMSS procedures. This is an internal document. However, I believe the ACMUI members have all been provided copies in their package of this document.

Those are the key documents. So what is rulemaking? Rulemaking is the process of developing regulations. So what are regulations? Regulations are like law. They're like administrative law. Regulations impose requirements that applicants and licensees must meet to obtain or retain a license or certificate to use nuclear material or operate a nuclear facility.

Also guidance is developed to aid licensees to meet the regulation. So the development of regulations is rulemaking.

All right. So one might ask where does NRC get the authority to develop regulations. Well, I have a flow diagram here, a tree diagram that shows the three branches of government, the legislative branch, which enacts laws, the executive branch which implements laws, and the judicial branch which interprets laws.

So you probably already can guess the NRC falls under the Executive Branch. The NRC is a federal agency that falls under the Executive Branch. Agencies either are independent agencies or dependent agencies. NRC is an independent agency. Dependent agencies are cabinet level agencies like the Environmental Protection Agency or Department of Energy.

Independent agencies are less affected by political influences, and they are the NRC, the Federal Communications Commission, the Federal Trade Commission, and the Securities and Exchange Commission, just as some examples.

The diagram here also shows the three main functions for NRC, rulemaking, licensing, and inspection and enforcement, and you can see rulemaking. Under there is where we do our regulations, make our regulations, and put them in

the Code of Federal Regulations.

So how is it when you look at this, how is it that NRC under the Executive Branch -- that it implements laws; what are we doing creating regulations?

Well, we're doing that because Congress had learned long ago that they weren't smart enough to make enough regulations for everybody. So they delegated the legislative authority to the NRC.

All right. So how did Congress delegate this authority, and what rules did they put in, what procedural rules did they put in to guide us?

Well, I'm going to mention some acts here. Congress passed these following acts to delegate the regulatory authority to us, and the delegated authority is under the Atomic Energy Act, AEA, as amended by the Energy Reorganization Act. That's what delegates the rulemaking authority to the Commission.

Let me speak to this for a minute. In 1954, the AEA established the Atomic Energy Commission. Section 161 provided the Commission the rulemaking authority.

Later in 1974, it's the Reorganization Act that split the functions of the AEC into

commercial licensing and into research and development and military functions, and it also created the NRC at that time to take care of the commercial licensing aspect of it.

All right. Congress also enacted the Administrative Procedures Act, and this was what gives us the procedural requirements to do rulemaking. This is Administrative Procedures Acts, APA, of 1946.

More specifically, APA-553 provides the basic requirements for what's called the notice and comment rulemaking. The primary goal was to insure that agencies observe the procedural due process for, in other words, fairness in conducting the rulemaking.

That essentially did two things. One, it required that the public is allowed to participate. The other thing that this Act requires is that the effective date of the regulation is not less than 30 days from the date of publication.

It's important to mention that if we don't follow the procedures of this act, we could be in trouble. The rule could be turned over in court later on.

All right. Before I get into the

rulemaking processes I want to mention how staff interacts with the Commission during the rulemaking process.

First, staff prepares a rulemaking package for the Commission. The rulemaking package would include a commission paper and is an attachment, could have the rulemaking plan or the proposed rule or the final rule.

Then the Commission votes on the rulemaking package. Then the Commission provides the staff with direction by issuing a staff requirements memorandum. They'll either approve or disapprove the rule and then give us further direction.

Sometimes the rulemaking authority is delegated by the Commission to the Executive Director of Operations, the EDO. The Commission mainly approves rulemakings that involve policy issues. So this is how we interact with the Commission.

Now, to mention several of the rulemaking types. The first one is the notice and comment rulemaking. It's our standard process. It's the one I'll spend the most time talking about.

The second one is enhanced public

participation rulemaking.

The third one is direct final rulemaking.

The fourth one is certificate of compliance rulemaking.

So let's discuss some of these. Yes, sir.

DR. WILLIAMSON: Just for maybe making this more real to us, which pathway did the Part 35 revision follow?

PARTICIPANT: Enhanced.

MR. McDANIEL: I'm sorry. I didn't hear that.

PARTICIPANT: The enhanced.

MR. McDANIEL: Okay. The enhanced.

DR. DIAMOND: Isn't there a component of the direct final rule?

PARTICIPANT: Talking about a major revision of Part 35.

DR. DIAMOND: The most recent change, wasn't that direct?

PARTICIPANT: Yes.

DR. HOLAHAN: And administrative corrections were made.

PARTICIPANT: There were two actually.

DR. HOLAHAN: There was an administrative rule and a direct final rule.

MR. McDANIEL: Okay. The notice and comment rulemaking, which is our standard process, essentially there are only four steps to this. The first is that there has to be a need for rulemaking.

The second is once there's a need, we have to prepare a rulemaking plan. Once the plan is approved, we prepare a proposed rule, and it goes out for comment in the Federal Register.

And then we collect the public comments, and then the fourth and final stage is to prepare the final rule.

So let's talk about each one of these steps.

The need for rulemaking. Well, the need for rulemaking comes to us -- I'm in the Rulemaking and Guidance Branch -- in different ways. Quite often we get a user need memo from the other divisions in NMSS or the Commission or the EDO can direct us to do rulemaking.

Now, from outside the agency we can get a petition for rulemaking under 10 CFR 2.802 or we can get a congressional mandate or an Executive Branch order that tells us to do rulemaking.

Those are the four ways that we get a need for rulemaking.

One thing to consider when developing the need is that a rulemaking should resolve its safety issue, a safeguards issue, or an environmental problem, although you can have rulemaking for administrative issues as well.

Also, one thing I'd like to point out regarding the need is that a technical basis should be developed early on in the process. We like to see the technical basis come with the user need memo if it can or, at the latest, maybe in the rulemaking plan. The earlier the better is the point I'm trying to make.

However, sometimes schedule doesn't allow for an early user need or an early technical basis.

DR. WILLIAMSON: Could you define technical basis, what you mean?

MR. McDANIEL: Technical basis is the reason why you're doing the rulemaking, and it's a reason that's based on some technical facts.

The step two is once the need is established, then a plan has to be developed. We call this the rulemaking plan.

The rulemaking plan should answer the following questions:

One, what is the regulatory problem?

Two, do any legal objections exits?

Will the rulemaking be cost effective?

Will it be a major rule, as defined by the Small Business Regulatory Enforcement Fairness Act?

Are there any agreement state issues?

Will we need supporting documents?

What resources are needed?

Who makes up the working group?

Angela, are those the --

MS. WILLIAMSON: Yes.

MR. McDANIEL: Thank you.

I'm on Slide 15, I believe. It should be halfway through.

PARTICIPANT: It's the fifth page.

MR. McDANIEL: Thank you.

Well, what else can be said about the rulemaking plan? One thing I should mention that is not on the slide is that the Administrative Procedures Act doesn't specifically mention the need to develop a rulemaking plan. This is something that agency does because they feel it's important to

get that information up to the Commission and upper level management early and get their buy-in on the process before we move further down the line.

Okay. The rulemaking plan also provides a preliminary outline of scope and impact. RGB, which is the Regulatory Guidance Branch I'm in, has the lead and assigns a task leader.

The task leader forms a working group. The task leader and working group together prepare the rulemaking plan. There can be agreement state participation.

The plan is provided to the appropriate advisory committees, and I'll talk more about that later.

The plan is approved by the EDO or the Commission, and developing the plan can take several months.

So we have a need. We've developed a plan. Up one more slide on the plan. I just simply list the references that have information on rulemaking plan, and I state in here where it can be found in these documents.

Then that takes us to the third step, which is the proposed rule. Again, RGB has overall responsibility. The proposed rule package includes

the Federal Register notice and other supporting documents. The Federal Register notice contains the proposed rule language and also has the statements of consideration.

Supporting documents that are included in the package include things like the environmental assessment or the environmental impact statement. Of course, NEPA, the National Environmental Policy Act, required NRC to review actions that had environmental impacts.

It also includes regulatory analysis, backfit analysis, OMB clearance package. OMB is the Office of Management and Budget. Congressional letters, press releases, and regulatory guidance. In other words, there's a lot that goes into the proposed rule package.

The package is provided to the appropriate advisory committees. This is before it goes to the Commission so that we can give them an opportunity to comment, and there can be agreement state participation.

The proposed rule is approved by the EDO or the Commission. As I had mentioned earlier, a Commission review would result in a staff requirements memorandum approving or disapproving

the rule and giving us direction.

A key element of the proposed rule is that it goes out for public comment. The public comment period is usually 75 days. The public can send in comments, either written or they can upload them onto our NRC Web site. I'm going to mention the Web sites on my last slide.

The advisory committees can also provide public comments.

A regulatory history is prepared. A regulatory history is necessary to insure that all documents of central relevance to the rulemaking are captured.

The proposed rule process takes about a year. This time varies greatly. It can be much shorter if the rule is simple. And as you know, it can be much longer for complex rules.

Question?

DR. VETTER: Relative to public comment, is there a threshold above which -- suppose you had some kind of overwhelming response, negative response towards a regulation or suggestion for a change in the regulation. Is there a threshold at which this has to go back to the Commission then before it continues in the process?

MR. McDANIEL: I think there have been times where if we've gotten enough comments that -- Trish can correct me if I'm wrong -- that we've actually maybe withdrawn the proposed rule and then rethought it and then resubmitted it. That doesn't happen very open, but it can certainly. It's at the discretion of management to do that.

DR. VETTER: Okay. So it's somewhat subjective, but you do look at them and if there's an overwhelming response, you do actually rethink the whole thing?

MR. McDANIEL: Right. Now, we do try to address those, as many as there are. We try to address them in the final rule. If the result of our review of the public comment is that we're not going to change a whole lot, then we can move forward.

However, if the result is that it really makes us rethink what we did, well, then we could take a step back.

DR. VETTER: I guess what I'm struggling with in my mind is that if this is the Commission's idea, you know, the staff are pretty much directed to carry this forward, make a rule, and our public comment is severely negative. What happens if --

DR. HOLAHAN: Well, in that case we'd go back to the Commission with either a paper or a briefing and say we've got negative comments. Do they still wish us to go forward?

MR. McDANIEL: And the whole purpose of putting it out for public comment is to get that feedback from the public. When we go through with this process at the beginning, it's not set in stone that we're going to end up with the final rule the way that it was in the proposed rule. We do take into consideration public comments, and it can change the way we initially plan to do things.

You know, I list here the references that have information on the proposed rule and indicate where in those documents that that information can be found.

That takes us to the final step. Step four is to prepare the final rule. Again, RGB has overall responsibility. This includes the FRN, preparing the FRN and supporting documents, very similarly to what we did for the proposed rule. This time the FRN contains responses to the public comments.

There may be agreement state participation. The final rule is provided to the

appropriate advisory committees before it goes to the Commission.

The final rule is approved by the Commission or EDO, and again, if it's a Commission review, that results in a staff requirements memorandum given to staff, providing them direction.

And this process can also take about one year. It's a lengthy process, a very deliberate process.

DR. HOLAHAN: But that, too, is variable.

MR. McDANIEL: Yes, it is.

This slide lists the references that have information on the final rule. I had mentioned earlier there were several rulemaking processes. One of them is the enhanced public participation rulemaking. NRC may designate certain rulemakings for the enhanced public participation. The advanced notice of proposed rulemaking, the ANPR is the most formal method.

There are other methods though that are available, most of which are less formal than the ANPR. For instance, there's a negotiated rulemaking, interactive rulemaking. There's a less formal request for comment, and there's meetings and

workshops.

I should note that the ANPR does not commit the NRC to issue a proposed or final rule. That remains a matter of agency discretion unless Congress mandates us to do it.

The public response in the enhanced participatory participation initiative is a factor in determining whether we will continue with the rulemaking or not.

Oh, and information on the enhanced public participation can be found in the regulation handbook, Section 3.7, Part 11.

DR. WILLIAMSON: I'm sorry to interrupt, but which flavor of enhanced participation rulemaking was used for Part 35?

MR. McDANIEL: Okay. I was not involved in Part 35, but there are people here that are that could answer that.

DR. HOLAHAN: Well, we had extensive public meetings, and we didn't issue an ANPR, but we built it on the NAS report and other things that had been done. So we held extensive public meetings, and we had -- we didn't have an issues paper. That's the other means we go through, but basically we did enhanced public meetings by having increased

stakeholder input.

MR. McDANIEL: Another rulemaking process is a direct final rule. It's a technique for expediting noncontroversial rules. This rulemaking is not explicitly mentioned in the APA. It is a relatively new method. I have heard that the EPA, the Environmental Protection Agency, invented this process. It is also used by other agencies.

Okay. For this process, the direct, final, and proposed rules are issued together. If adverse comments are received, NRC withdraws the final rule. If no adverse comments are received, then the NRC publishes a confirmation of the effective date.

Usually the direct final rule is effective 75 days after it is published. Information on the direct final rule can be found in the regulation handbook, Part 9.

That's all I was going to say about the rulemaking processes.

Next I'd like to talk about the involvement of the advisory committees. Rulemaking documents are forwarded to the appropriate advisory committees before going to the Commission. Usually

they're provided to the advisory committees when these packages go out for our office concurrence.

The packages that we provide the advisory committees can be the rulemaking plan or the proposed rule or the final rule, all three stages.

The committees review the rulemaking documents per their own procedures. The committee may request a meeting on a specific rulemaking or staff may recommend review by committee. If the committee provides the staff with comments, the staff should respond to those comments.

There's varying levels of participation with the advisory committees. I understand for the Part 35 rule, there was a lot of interaction between the staff and the ACMUI.

Next I'd like to talk about organizational responsibility. As I had mentioned before, RGB, which is in the Division of the Industrial Medical Nuclear Safety, has overall responsibility for rulemaking for NMSS. However, other divisions in NMSS have responsibilities for their programmatic and technical areas of expertise. They may be asked to provide a working group member for the working group.

Other offices outside of NMSS are also allowed to participate, and they may also provide working group members.

As I mentioned earlier, Management Directive 6.3 lays out the organizational responsibilities.

The next slide deals with the working group. An effective working group is essential for the rulemaking process to move forward. Let's talk about the membership of the working group. I'll mention these quickly.

Since RGB has the overall responsibility, RGB provides the task leader. There are members from other divisions in NMSS with programmatic responsibilities related to rulemaking.

There's a member from our legal group, which is the Office of General Counsel, OGC. They keep us out of trouble, try to; members from other divisions and offices as appropriate, and there can be a member representing the agreement states. That's typically the make-up of our working group.

Now, the task leader's responsibilities include developing schedules and resource estimates. The task leader forms the working group. They identify the need for contractor support. They

prepare the rulemaking documents and address comments. They prepare schedules, and they brief management.

The task leaders responsible for preparing the OMB clearance package, that's the package submitted to the Office of Management and Budget for their approval, and it contains changes in information collection requirements. And they also insure that the task is on schedule. Those are some of the things that the task leader does.

Let's quickly look at what the working group members do. Working group members work with the task leader to help prepare the rule package; to address comments, both management's and public's. They help estimate the public information burden, and they support briefings and public meetings. They review contractor reports.

The working group members, they keep their management apprised of the status and obtain their management's positions on the issues. When the working group gets together, they bring their management's views to the table, not necessarily their own. They do this to help grease the skid so that when the package goes out for concurrence, they already have management on board.

The working group members also help prepare associated guidance and develop milestones that complement the rulemaking schedule.

That's all I wanted to mention about the working group.

And last of all, I'd like to mention the Web sites that are available that contain rulemaking information. The first one is an external site. We call it the rulemaking forum. It's NRC's rulemaking Web site for the public. It contains proposed rules and petitions. The public comments can be uploaded to this site. Final rules are also available, but there are links to rulemaking documents on the site, and they are in what I call PDF format. I think it's portable document format, and I list the Web site link here.

Also, I'll mention that there is an internal Web site. It's called the NRC Rulemaker. It helps assist the NRC staff in developing rulemaking, and it is not available to the public. I've got a site listed there.

Okay. I hope that helps some. That's all that I had.

CHAIRMAN CERQUEIRA: Thank you very much, Keith.

Any questions? Jeff.

DR. WILLIAMSON: What does office concurrence involve? I mean, exactly what office is it?

MR. McDANIEL: Office concurrence involves offices like the Office of Research, NRR, OGC. It's a lot more offices than I'd like to have, but there's quite a number.

(Laughter.)

DR. HOLAHAN: And research is only involved when they do the technical basis for us, and NRR is only on concurrence when it applies to NRR. So we wouldn't send rules, medical rules over to NRR.

DR. WILLIAMSON: Yes, that's what I meant.

DR. HOLAHAN: Yes.

DR. WILLIAMSON: My context is related to the rules that are likely to involve science, like in medical licensees.

DR. HOLAHAN: And if I can take a moment, I'd like to introduce Scott Moore. He's the Chief of Rulemaking and Guidance Branch, and he can supplement what is being said here.

MR. MOORE: Thanks, Trish.

I guess I'd like to make two final points. One is to emphasize a point that Keith made on the role of agreement states in the rulemaking process. At each stage of the process the rulemaking plan, the proposed rule, and the final rule, we provide them to all of the agreement states for their review and comment in addition to having agreement states serve on the working groups themselves.

I guess the second point I'd like to make to the ACMUI is to emphasize the role of the staff requirements memorandum, the SRM to us. When the Commission gives us a staff requirements memorandum in final form, that's direction to us, and we don't go back and negotiate that direction with the Commission. It's direction for us to move forward and implement what the Commission tells us to do.

We get copies of the draft SRM for a very quick turnaround at the same time that all of the Commission offices are looking at them and finalizing them, but once the SRM is final for us, the Commission has voted, they made a decision, and we move forward on that.

That's it for me.

DR. HOLAHAN: And I'd like to add to that that sometimes we see multiple versions of a draft SRM, but you know, Scott is right. We have a very short turnaround time. We have to get comments back up in virtually two days.

DR. WILLIAMSON: Well, we have had some interesting situations arise over the years, you know, because of this, again, in connection with the Part 35 and particular training and experience. So when the staff gets an SRM to direct them to do something that the ACMUI and/or, you know, major segments of the community are in disagreement with or think is in error, what are the options at that point for effectively dealing with it within the committee?

Are we, you know, as special government employees, expected to just toe the line at that time?

CHAIRMAN CERQUEIRA: We are an Advisory Committee, which means we provide advice. Whether that advice is followed or not is really up to the Commission.

DR. HOLAHAN: Yes.

DR. WILLIAMSON: Of course. I understand that.

DR. HOLAHAN: And we get your views up to the Commission beforehand and try and solicit your views when we get the draft SRM, but as I said, we have to do it in a very short order.

And Charlie Miller was trying to look into getting the draft SRMs provided directly to the ACMUI, but he didn't have -- he has had minimal luck.

DR. WILLIAMSON: The reason I bring it up, you know, I think it's related to our discussions that we've had over the preceding months about whether we should, you know, -- whether there be value in the ACMUI being a Commission-level Advisory Committee. I think we have actually used the annual briefing of the Commission at least in one time as sort of an additional unofficial route of appeal to an unfavorable SRM.

And I am wondering if we were structurally a Commission-level Advisory Committee if we would have an additional -- whether there would be any, you know, advantage in that regard.

DR. HOLAHAN: Well, I can give you my personal opinion, but really I don't think it would influence the SRM directly because once the Commission has made up their mind, we have to -- and

the advisory committees, as Dr. Cerqueira mentioned, we're just considered as an advisory committee.

DR. WILLIAMSON: I understand that.

MR. MOORE: I agree with Trish's position. I think if you look at the role of the ACNW and ACRS, I don't think they have an additional step to intervene.

DR. HOLAHAN: Yes.

MR. MOORE: And so it's incumbent on us, the Rulemaking and Guidance Branch, in our packages that we provide to the Commission to correctly characterize and address the ACNS position on issues, and if the position is adverse to where the Commission has already directed us, we need to let the Commission know that.

But beyond that, once the Commission gives us direction, we go implement it.

Yes, sir.

DR. NAG: In that case, it's even more important that when the staff is making up the rules you have feedback from the ACMUI before the SRM is issued.

DR. HOLAHAN: Yes, and that's why --

DR. NAG: Once the SRM is issued, then there's not much we can do about it.

DR. HOLAHAN: That's why we send the rule out in various stages to the ACMUI before it goes up to the Commission, because we want your input before it goes up to the Commission, the rulemaking plan, the proposed rule, and the final rule.

MR. McDANIEL: Well, I thank you.

MR. LIETO: I just had a couple of questions on the Web sites. The internal site, is that accessible by ACMUI?

MR. McDANIEL: You know, I was wondering the same thing when I prepared this.

(Laughter.)

DR. HOLAHAN: I don't think you have access to the internal Web site.

MR. McDANIEL: I mention it more for the reason to let you know that the staff working on regulations has this as a resource to them, but I don't think you do have.

MR. LIETO: And my other question had to do with the external site. The Web site that you give is not an nrc.gov Web site. Is there something on the home page of nrc.gov or someplace? I guess I'm looking for another Web -- I mean, most people will go the nrc.gov Web site regarding a question of

rulemaking, and is there a Web page?

DR. HOLAHAN: If you go to the nrc.gov, there's a rulemaking site on --

MR. McDANIEL: There's a link to this.

DR. HOLAHAN: There's a link.

MR. McDANIEL: I thought it would -- I could have put nrc.gov, but I thought it would be more helpful if I linked you directly to the rulemaking site.

MR. LIETO: Is this the site that's listed in your slide, the lawrencelivermoreguide.gov site, is that the one that's given when things are published in the rulemaking?

DR. HOLAHAN: Yes.

MR. LIETO: Okay.

CHAIRMAN CERQUEIRA: Any other questions? It looks like we are ahead of schedule. I guess we get an additional half hour for lunch. I don't think we can do any additional business because people who want to comment would not be available.

So we'll adjourn for lunch, and we'll reconvene at one o'clock.

DR. NAG: Unless we want a closed session at the end of the day. Do you want that?

MR. LIETO: No. There's just a thing I do need to clarify with one of the slides. I think there's a typo, but other than that, I think my questions have been answered.

Thanks.

CHAIRMAN CERQUEIRA: Thank you.

(Whereupon, at 11:28 a.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:02 p.m.)

CHAIRMAN CERQUEIRA: This is the afternoon session, and I think we have Mr. Broseus up at the front ready to go.

And this first session is going to be "Implementation of Proposed Revisions to Part 35; Recognition of Board Certifications."

Roger, it's yours.

DR. BROSEUS: Thank you, Mr. Chairman.

This particular presentation relates to implementation of the rule in terms of how we go about the application process form.

I want to make a note here that there are slight changes to the slides that are in your briefing books. I passed out during the lunch break the revised slides. There are minor changes, and we just added an overview slide which I will proceed to now.

The presentation I plan to make today will talk about the implementation as directed by the Commission to the NRC staff and will talk about the basis for the approach to implementation, how we go about recognizing and maybe unrecognizing the board; application procedures; what I call

maintenance ore recognition; de-listing, if there's some reason to withdraw, and how we go about that; and some procedural things about listing on NRC's Web site and what our working group thought about in terms of information to put there on the Web site; and then the path froward from today.

I want to emphasize at the outset that we're dealing today with draft implementation procedures. This is the result of our working group process. We're providing them to the Advisory Committee, as well as to agreement states so they will have an opportunity to give us some input on the process, on the procedures as we move them forward.

The Commission directed the staff to prepare these procedures in SRM 02-0194, which was part of the direction going forward with the proposed rule. There was supplementary direction provided to the staff in the October 9th SRM 03-0145.

The direction to the staff is to provide for a regulatory determination that all boards meet relevant criteria and to develop procedures for adding or removing or de-listing so-called recognized boards.

I like to use the term "recognized certifications" because that's what we're really recognizing, is a certification as being adequate to meet the training and experience requirements in Part 35.

The process is to apply to both new and currently recognized boards. The Commission called them "new and existing," and the recognized boards now are listed in Subpart J, plus the certification board nuclear cardiology which has met the current requirements in the regulations.

Part of the process that we were charged with also was -- I'll put quotes around this. It came from the Commission -- to develop a process that involves due process. In other words, do things in a way that enables an orderly review of incoming application and provide for processes for making sure boards have input and so on. And we'll talk a little bit about that more.

Part of the charge that we have is not to inspect boards. That was in the first SRM, and in the last SRM issued October 9th, in addition to speaking of monitoring trends and medical events, using that as a basis for withdrawing recognition of a board certification, and if it's due to inadequacy

of radiation safety training; also, to assess the adequacy of the assessment of knowledge and skills by examinations administered by boards.

And I'd like to emphasize that there's a linkage here, and that is that if the staff has determined that there's trends in medical events that may be due to inadequacies in radiation safety training or processes, then the Commission has directed us to look at examinations and assess their adequacy.

DR. NAG: How are you going to do that? I mean that's really almost impossible to do.

DR. BROSEUS: That's a very good question, and in fact, I think that's an area that we would like to receive input from the Advisory Committee on.

I would expect, by the way, that these sorts of things would be rare events. However, that's an area that's of interest to us.

DR. WILLIAMSON: But, I mean, the inherent problem is that the events are really rare, and in most modalities the last reckoning I got from staff was that the risk per procedure of a medical event is on the order of ten to the minus fourth or ten to the minus fifth.

These are essentially random events, and so how can you make even intellectually, when even considering this, even hope to make some correlation between these events and the boards?

DR. BROSEUS: Yeah, for me to think about that, it would be pure speculation. Okay? I mean, one can speculate that during a review of trends, that there's a trace back to inadequacy of training, and if it's associated with board certification, then go the extra step.

And I would expect that as you'll see later in my presentation there would be involvement of the Advisory Committee. I sometimes say "ACMUI" instead of saying "A-C-M-U-I," but the Advisory Committee would be called on certainly also.

Let me move on to the procedural aspects of how would a board have its certification recognized. The staff in its current draft plans to issue a letter to the boards that we're aware of now who have an interest and invite them to apply and ask the Board's reply via letter and provide information about the type of use for which recognition is sought. And of course, that would apply to authorized users or obviously if it's for radiation safety officer, authorizing a nuclear

physicist or authorized medical pharmacist, they'd supply what they're after. Okay?

A description of certification procedures and their requirements, and then the staff review would compare that information, the procedures, to the requirements that we now are proposing and when they become final in Subparts D through H of Part 35.

D through H includes the training and experience requirements, as well as safety procedures for all the various categories that are under discussion: RSO, ANP, AMP, and the various types of use. For example, 190 and 290 have training and experience for typical diagnostic nuclear medicine procedures and so on.

The evaluation is to be process oriented, and I emphasize at this point not asking -- I shouldn't say "at this point." I shouldn't qualify it -- not asking for exams. Okay? Not a review examination. We're not inspecting. It's comparing the requirements of the boards to the requirements in the rule.

Going on in the process, if the staff finds they have questions with an application, staff in our draft procedures plans to notify the board

that has submitted the application, request clarification, re-review, and consult with this advisory committee as necessary with regard to the responses of the boards if staff feels there's inadequacy in their process, and they may not meet the requirements.

If the requirements are determined not to be met, draft procedures provide for notifying the board via letter. If they are mailed -- I'm sorry -- we'd advise the board via letter and ask them also in our approval letter to provide information to the NRC in the future if there are changes in the certification process that might affect the recognition.

If the requirements are not met, deny the application, notify the board of agreement states of the basis of this, as well as the Commission, and again, I emphasize this is after the consultation of the Advisory Committee and so on.

The agreement states are pulled into the process at this point. I shouldn't say "pulled in," but advised because the agreement states may also approve boards. They may also recognize boards. That's actually a provision of the current rule, and that is preserved in the proposed rule.

CHAIRMAN CERQUEIRA: If a board is recognized by the NRC, shouldn't it automatically be recognized by the agreement states?

DR. BROSEUS: Yes, yes.

CHAIRMAN CERQUEIRA: So these would be additional boards may not necessarily be recognized by the NRC, but could be recognized by agreement states then.

DR. BROSEUS: If a board is recognized by an agreement state, that's the same as recognition by the NRC. The rule says "recognized by the NRC or an agreement state."

CHAIRMAN CERQUEIRA: Okay.

DR. BROSEUS: And the reason, again, is for letting boards -- I'm sorry -- agreement states know about requirements not being met, and so they are aware of a disapproval of a board.

DR. WILLIAMSON: And this is covered by the fact that the whole training and experience requirement is a compatibility Level B.

DR. BROSEUS: It is a compatibility, yes.

MS. McBURNEY: The rules have to be the same.

DR. WILLIAMSON: They require the states

to adopt equivalent processes for vetting boards.

DR. BROSEUS: Yes.

MR. LIETO: Sort of the devil's advocate. Could you have a situation where the agreement state could approve a board and that the NRC would re -- that board might go to the NRC for NRC-regulated states and not be approved?

DR. BROSEUS: Well, if they're not NRC regulated states.

MR. LIETO: For agreement states.

DR. BROSEUS: If it's not an agreement state, then the NRC -- well, the NRC approval holds for everybody.

DR. HOLAHAN: Right.

DR. BROSEUS: I don't see that sort of pickle developing because once the board is approved by the NRC or an agreement state, that covers the whole country.

DR. HOLAHAN: Yeah.

DR. BROSEUS: That covers all types of medical licenses.

MR. MOORE: So the direct answer to the question is, yes, that could happen, although it's unlikely because once a board got approved by an agreement state, they wouldn't necessarily need to

go to any other agreement state or the NRC for approval.

MS. McBURNEY: Like the NRC, it would be approved for anyone applying for a license throughout the country.

DR. NAG: Right, but the thing is one agreement state may approve it, but it may not meet all of the criteria that the NRC sets. I mean, an agreement state --

DR. BROSEUS: the agreement states are bound because its compatibility --

DR. HOLAHAN: That's right.

DR. BROSEUS: -- to have the same requirements as in the rule.

DR. WILLIAMSON: They would, you know, use their enforcement against renegade agreement state programs if that --

(Laughter.)

DR. BROSEUS: The Office of State and Tribal Programs reviews agreement state rules to determine that they are compatible, et cetera.

MS. McBURNEY: That's right.

DR. BROSEUS: And so that should not be difficult. One more?

DR. WILLIAMSON: I do have one more

question. It is possible, I think, even maybe with compatibility level B that an agreement state could have more stringent criteria than Part 35?

DR. HOLAHAN: No.

DR. BROSEUS: They have to be essentially the same.

DR. WILLIAMSON: I guess I'd be more worried about the consequences of a particular state blackballing a certification, but that couldn't happen. If Vermont or some state -- I mean, if State X decided that they weren't comfortable with the American Board of Radiology, that doesn't preclude State Y or the NRC from recognizing that Board; is that correct?

DR. HOLAHAN: No.

MR. MOORE: That's correct.

DR. BROSEUS: You will see in our procedures that there are built in communications to try to make sure that there's a uniform approach to this, that people don't try end runs and that sort of thing.

CHAIRMAN CERQUEIRA: But technically, Jeff's question, if the NRC had recognized the ABR, Vermont would not have the option of rejecting the ABR because --

DR. WILLIAMSON: That's my question, correct.

CHAIRMAN CERQUEIRA: -- it's a Level B compatibility.

DR. WILLIAMSON: But if Vermont rejected ABR, that would not preclude Texas or NRC itself from recognizing --

DR. BROSEUS: From my understanding of the way processes work with the agreement state program, it's that there's communication between the states, and we would hope that if a state disapproves a board, that that's communicated so that somebody doesn't try to shop around.

DR. HOLAHAN: Yeah, I was going to say that same thing because if a state is going to not recognize a board, they'd let the NRC and all the other agreement states know first.

CHAIRMAN CERQUEIRA: But, again, to identify this issue before the physician move around, medical physicists and then the health survey and safety officers move around sa well, and if it has been recognized by the NRC, then those states should be compelled to recognize that board.

DR. HOLAHAN: And they will be.

DR. BROSEUS: Yes, that's right.

CHAIRMAN CERQUEIRA: Okay.

DR. HOLAHAN: Only if a board goes directly to an agreement state and they haven't come to NRC first, that the agreement state would be involved.

MS. McBURNEY: That we would even get involved in board recognition.

CHAIRMAN CERQUEIRA: Okay, okay.

DR. BROSEUS: What I'd like to do is try to keep that and see if you're satisfied with it and maybe come back to it later because we're going to be posing some questions, and you know, if our procedures don't cover these things adequately, that's where your advice back to us would be useful.

CHAIRMAN CERQUEIRA: Okay. Why don't you go on?

DR. BROSEUS: If I might move on, on the application, on the maintenance procedures here -- let's see. Where am I at? We've talked about the application. Now we're on two. Application for recognition.

DR. HOLAHAN: We did that.

DR. BROSEUS: Yeah, did that. We're on maintenance. Okay.

We're asking boards to notify the NRC of

changes to the procedures when they're approved, and that would be in the letter of approval, as I mentioned before. In our draft we're putting in to notify the NRC six months in advance of planned material changes in a certification process, those that would affect recognition.

The staff also plans under the draft procedures to request confirmation of certification procedures every five years from a recognized board. This is to verify that the information the NRC has on procedures is current and still meets the requirements in the rule.

If we see changes coming in, the draft procedures provide for using basically the same procedures for a new application to evaluate changes. Do they meet the requirements in the rule? Pretty simple and straightforward.

Finally, we're noting in our draft procedures that agreement states would be responsible for monitoring the status of the board they recognized. So if, in your example, State X were to recognize a board, our draft procedures say that state is responsible for continuing monitoring and recognition.

MR. LIETO: Question.

DR. BROSEUS: Yes.

MR. LIETO: Ralph, maybe it's the terminology I'm a little confused on. When you say changes in the board procedures --

DR. BROSEUS: The requirements for eligibility requirements.

MR. LIETO: So basically what you really mean, so you don't mean the procedures of how the board operates. You mean like the content.

DR. BROSEUS: The certification requirements. Did they require an examination, et cetera?

CHAIRMAN CERQUEIRA: Eligibility requirements for the people applying to take the board. That's --

MR. LIETO: Well, do you also mean the content of what is required?

MS. McBURNEY: Not the content of the exam.

DR. BROSEUS: No, no. We're not looking at examinations. We're comparing their requirements for certification under the proposal to what's required in the rule.

MR. LIETO: All right.

DR. BROSEUS: So you just go down and

tick them off.

MR. LIETO: It's not their procedures and how they go about it.

DR. BROSEUS: Well, and if in our draft procedures, implementation procedures, that seems a little bit fuzzy and leads to confusion, you know, make a note for us. That's good feedback.

I can't remember right now how we express it. I may be using terminology a little bit loosely in my presentation.

Okay. In the de-listing area, that is, withdrawal of recognition, we've identified a few potential reasons for withdrawal, and that would be changes so that the certification process wouldn't comport with the rule. Medical trends, we've talked about that due to inadequate training or if a board becomes inactive or disbands.

The evaluation --

DR. DIAMOND: Excuse me.

DR. BROSEUS: Yes.

DR. DIAMOND: So let's just talk about that last point for a second. The American Osteopathic Board of Radiology has residents go through training programs, all of whom are going through the diagnostic pathways. They currently are

also, I understand, -- trainees go through as radiation oncology, AU practitioners, although there has not been a radiation oncologist produced in any of their training programs for a number of years.

So in this case where there are no radiation oncology osteopathic training programs, but there are trained programs, I guess, for diagnostic or for maybe even nuclear medicine. I don't know.

Is that considered an inactive or an active board?

DR. BROSEUS: Well, the boards will have to reapply, okay, and meet the requirements in the rule when it becomes final.

DR. WILLIAMSON: I have a slightly different --

DR. BROSEUS: And so that would be -- you know, they would be measured against the requirements in the final rule.

DR. DIAMOND: We had a representative from the American Osteopathic Board of Radiology here some time ago saying they would like to retain the right to be listed for the AU pass, and I asked, you know, how many radiation oncologists are trained, certified by your boards, and he said zero.

DR. BROSEUS: So it seems like it's almost a non-problem, and since they would have to meet the new rule when it's published --

DR. DIAMOND: It's a real problem.

DR. BROSEUS: -- it's a real problem.

DR. DIAMOND: Because, you see, the board is not just doing a use. We're talking also about diagnostic and nuclear medicine trainees going through these osteopathic programs. So they are active in those two pathways, but they have no activity whatsoever in the AU pathway.

DR. WILLIAMSON: Here's another problem.

DR. BROSEUS: In order to have their certification recognized, for example, for 600 use, okay, which is the high dose stuff, their certification program, their requirements would be compared to the requirements in 690 -- 600 -- I'm sorry -- 690(a), the requirements for a board to be recognized.

DR. DIAMOND: So one of the requirements --

DR. BROSEUS: So to meet the requirements for a diagnostic, but not for the therapy area that they be recognized.

DR. DIAMOND: Right, but will the

requirements be that you actually have people sitting for these boards?

DR. BROSEUS: I'm sorry?

DR. DIAMOND: Will one of the requirements be that you actually have people sitting?

PARTICIPANTS: No.

MS. McBURNEY: No. They're just ready to have somebody come through.

DR. DIAMOND: It's silliness, of course, but --

DR. WILLIAMSON: I have a more substantive question. You know, it's not that this is unimportant, but this is a more real crisis because it would affect people.

The American Board of Medical Physics until recently certified physicists in radiation oncology physics. Now that pathway, you know, had ended and effectively that process has been merged with the American Board of Radiology. So henceforth everybody who does radiation oncology physics will come through ABR instead of ABR or ABMP.

But I think you should not de-list ABMP just because they've stopped offering that certificate. You have a responsibility to recognize

all diplomates of that organization who were boarded during a period of time during which that organization did comply with your requirements.

So I think, you know, you have an obligation actually to determine whether the American Board of Medical Physics certification, because there's many people out there who have that certificate --

DR. BROSEUS: That comes close to being, if not really, a Q&A for the current rule, but the American Board of Medical Physics is now recognized under Subpart J, I believe. So that may be something that should be addressed in comments on the --

DR. DIAMOND: Roger, but that's not the answer to the question. I think the answer is, Jeff, on page 6 it has evaluation of training and experience for outdated certifications, and it states that the certification will be considered valid if it was granted before the board's certification process is determined to be inadequate for recognition of the board certifications by NRC.

So once that certification was granted, even in the future if it's de-listed, that

MS. McBURNEY: If people were boarded

during that time, it was okay.

DR. WILLIAMSON: Your Web site needs to be a little more complicated. It needs to list the time period during which --

DR. BROSEUS: We'll talk about these issues later on when we talk about the information on the board and see if it solves the problem. I think it will.

Okay. We talked about some of the reasons we have identified that a board may have its recognition withdrawn. If this comes up, the procedures that we have drafted again call for reviewing against the contents of the rule, contacting the board, and ask them what changes they would make to avoid being de-listed, and also to consult with the advisory committee again of the circumstance should it arise in making a determination to withdraw recognition.

If the recognition is withdrawn, then we would communicate that to the Commission as well as agreement states. In the actual process of listing the recognized boards, what we provide on the Web site, what we're considering now is the name of the board, the type of use for which the certification is recognized, as well as noting if it is for AMP,

ANP, RSO, okay, the dates of recognition by the NRC or an agreement state with a "to" date if the recognition is withdrawn. People need to know for what period of time the recognition is valid.

CHAIRMAN CERQUEIRA: And, Roger, that answers Dr. Williamson's question. With respect to the American Board of Medical Physics, we would probably have a "from" and "to" date, and in the "to" date when the Board of Medical Physics stopped recognizing people.

So it would be recognized for the period that it was valid.

With respect to the American Osteopathic Board of Radiology, if they have a process in place but don't have any people going through it yet, then they could become certified if we agreed with their process. So, I mean, they could get advanced recognition to have the process in place as long as they met our conditions for recognition and we would put them on the board, whether or not they had people going through it.

CHAIRMAN CERQUEIRA: Roger.

DR. BROSEUS: I thought I was hearing another question.

One of the bits of information we would

plan to put on the Web site would be the period of time for which a certification is valid. Okay? For example, some of them are valid for four years. We have recency of training requirements for seven years, but if a certification has expired and a person has not renewed it, then their training and experience would no longer be current and recognized unless they could provide some other additional information, they may have to come in through the alternate pathway.

Where do we go from here? I think my bullets are kind of out of order. We're actually doing the second bullet right now, providing the Advisory Committee our draft procedures for review and comment.

We're also posting them to a closed state and tribal program Web site. The draft procedures are out there now for agreement state review and comment, and that comment period, the 30-day comment period will end in late November.

We will be looking for input from both you and the agreement states, pulling it together into a package for approval of our management. We seek your input on the procedures with questions we have generated. For example, are the draft

procedures effective measures for oversight of board activities? Do they place undue burden on boards?

If you see a need for improvement for the procedures, we would seek information on how you suggest a change to improvement, and realizing that we have bounds that we have to stay within directed by the SRM from the Commission, for example, on examinations.

Question?

DR. WILLIAMSON: Well, I think just one tricky point. The American Board of Medical Physics at this point does not offer certification as an active pathway for radiation oncology physics. So I think you don't want to say a reason for not listing or considering a process is that they must have an active process in place.

There is this group, probably hundreds of physicists, you know, that you're going to have to retroactively evaluate the process as it was during the certification granting period to determine whether those individuals meet the rules. So you, I think, need to refine the criteria just a little bit.

DR. BROSEUS: Future recognition of the boards.

DR. HOLAHAN: It's further.

DR. WILLIAMSON: This is past. This is recognition of certificates issued in the immediate past.

MR. MOORE: That would be a helpful comment for ACMUI to make back in the comments to us. I'm not sure that we have an answer yet on how to recognize boards in the past that certify people that are no longer certified, and if those individuals then want to apply to be in AU.

DR. WILLIAMSON: It would seem, you know, that it's an important problem for you to solve because you list ABMP radiation oncology physics certification in the Subpart J.

MR. MOORE: Right.

DR. WILLIAMSON: -- is appropriate, and so, you know, I think there is an existing organization to interact with, and I think this is just terminology and guidance you have full control of. So I don't see why it would be difficult to solve.

MR. MOORE: Right. I'd encourage the ACMUI to provide those comments back when you comment on the procedures.

DR. BROSEUS: Before we go on with more

questions, I think, Tom, are you going to suggest a mechanism by which we get collectively comments back?

MR. ESSIG: Yeah. Included in your packet was, and I think several have made reference to it already, is some draft procedures that we would very much like the committee's comment on, and it seems to me it would work best if you could identify, Mr. Chairman, if you would wish to identify a point of contact either now or at some near term date that will be the focal point, the integrator of the committee's comments and then relate it back to us.

CHAIRMAN CERQUEIRA: Well, I think, you know, Dr. Vetter did such a great job on this the first time we were --

(Laughter.)

CHAIRMAN CERQUEIRA: Due to training and experience, I mean, are you up for it?

DR. VETTER: Up for what specifically?

(Laughter.)

CHAIRMAN CERQUEIRA: You have to listen.

MS. McBURNEY: Being the collector of the comments for the --

MR. MOORE: Just to try, they would like

the ACMUI input, and as we talked about this morning sometimes it's better to funnel that through an individual or a subcommittee, and you know since you in your group, the subcommittee did such a great job of drafting a lot of this earlier, it would be good if you could continue to do that as well.

CHAIRMAN CERQUEIRA: I could do that.

MR. MOORE: Thank you.

The other thing, I guess this is --

DR. BROSEUS: And we'd like to get those by the middle of December. Do you think that's possible?

MR. MOORE: Yes.

DR. VETTER: Well, I can send you whatever I receive by the middle of December, yes.

MS. McBURNEY: Yes.

CHAIRMAN CERQUEIRA: You can make something up over Thanksgiving.

We have a question for the audience, but this would be for new boards, right? Now, I guess the Certification Board of Infant Cardiology was the only recognized board?

DR. BROSEUS: Well, the way the rule is written now, they need to be applied. Everybody, well, the procedures call for everybody applying

again.

CHAIRMAN CERQUEIRA: Okay.

MR. UFFELMAN: Bill Uffelman, Society of Nuclear Medicine.

I guess on behalf of the American Board of Science and Nuclear Medicine because we manage them, but then the American Board of Nuclear Medicine because I have a lot of members that are dependent upon them, you recall the reason we have Subpart J in Part 35 with this two-year window was because of the transition being I don't want to say not thought through, but was it thought through perhaps as well as it could have been that we had to have J to continue the process.

I want to strongly urge you that these newly recognized certifying boards, whatever the new rule is and the new requirements are and how you wind up wording the preceptor statement and how the board is coming into compliance with that, I think it needs to clearly state in the rule that the people who are subject to that new certification are the people who are entering these programs on or after, because I don't know what your effective date is going to be, whether it is going to be October, but certainly by June one would have a pretty clear

picture of what it ought to be, but perhaps those people who are entering residency programs or fellowships or whatever it is they're doing after June 30 of 2004. They are the people who are truly subject to the new certifying requirements.

If you've got a radiology resident out there that's in, you know, fourth year or whatever and somebody has decided that, in fact, you know, he needs a log book for all of the work he has performed during the past four years, you know, he did three of these and two of those and Dr. So-and-so, the attending, signed off or whatever so that in the end the program director, who may be the third person, you know, that he's done all of this under could look back at that log and say, "Yes, they've done it," and sign it; that, in fact, it would be very onerous to somebody who is almost finished with the program to suddenly, when they sit for the board exam and make their application to the NRC in June of 2005 -- where do they get that documentation from and how much of it is "well, you know, you were here, so you must have done it" as opposed to saying, "You know what the requirements are when you enter the program on July 1 of 2004 and this is how you're going to prove it up," so that you, in fact,

can sit for the board exam or you can sit for the exam if you want?

But the reality of getting the NRC approval is built upon having this track record that, in fact, is signed by the preceptor if that's going to be the requirement.

DR. BROSEUS: The Commission directed that the preceptor statement, requirement for that written certification be separated from. They accepted the Advisory Committee's recommendation. So we're following Commission direction. That will be separate.

But I think that part of the problem you have really relates to how will the NRC evaluate certifications granted by boards recognized under Subpart J after the rule is final.

MR. UFFELMAN: But the way the rule is written, it says specifically if you were certified during that window under J, at least my attorney's opinion of it is you're okay. I'm worried about the person who's in the middle of a training program at this point in time.

DR. BROSEUS: I would think that in most cases that would be a non-problem also because, first of all, we expect that most, if not all,

boards will meet the new criteria that the Advisory Committee established first, and secondly, they would be getting their certification after the rule applies, and it seems to me that the problem would evaporate that you're posing, but I think that that's a good thing.

MR. UFFELMAN: It would exacerbate it. It will exacerbate it because of the bifurcation, and I have no problem standing here saying -- I have no problem with having this bifurcated preceptor statement, but how does somebody who is in the fourth year of a four-year program or third year of a four-year program go back and get whatever it is somebody deems an appropriate preceptor statement for those first three years?

DR. BROSEUS: Make sure that you take a sharp look at the proposed rule so that we get comments back to make sure we cover these issues.

MR. UFFELMAN: I just wanted to in public air that.

CHAIRMAN CERQUEIRA: Okay. Thanks.

Leon.

DR. MALMUD: I think the issue that Mr. Uffelman is presenting is one that can be dealt with very simply, and that is that if a resident in

training or fellow in training is en route to completion but has not yet completed his or her program and there was no opportunity in the first -- let's say they're in the third year of a four-year program -- there was no opportunity because there was no requirement to document their experience case by case in the first two years, that that person will not be affected negatively by this new interpretation, which would require a retrospective analysis of data that wasn't kept.

Is that the point that you're trying to make?

MR. UFFELMAN: That's the point I'm trying to make.

DR. MALMUD: And all we need do is just put it in a statement that it's only for those who begin training, begin their training after the date of implementation, not for those who are already in training because there might be, but there wouldn't necessarily have been the opportunity to have documented the data from the first year of --

DR. BROSEUS: I think we'll have to look at this comment in the context of what is the proposed rule doing as well as the implementation procedures.

CHAIRMAN CERQUEIRA: Jeff and then Dick.

DR. WILLIAMSON: I think Mr. Uffelman has brought up a really important issue. I'm not a lawyer, but my reading of the regulation is as follows, and I'll give you a real case.

Subpart J currently recognizes American Board of Radiology Certification in radiation oncology as adequate for a radiation oncologist to become an authorized user for radiopharmaceutical therapy. Okay. Clearly, anybody who in this era of Subpart J applies and, you know, becomes an authorized user on a state or an NRC license is going to be okay for the future.

I believe the way the draft regulations are written now in future radiation oncologists, given current ABR practices, unless we change the rule, are not going to -- basically ABR certification in RAD AU will not be recognized for 35-300.

So it is my belief based on reading the regulation that individuals who become board certified in this Subpart J era but for some reason do not immediately apply to become authorized users for 35-300, when the new rule takes effect, they will be unable to become authorized users for 35-

300.

And you could, by extension, find any board which is currently recognized but for some reason fails to meet the new criteria in the revised training and experience regulation, I think unless those graduates who are in the middle of training or are completing their training now have already become authorized users before the effective date of implementation of the rule. They're just going to be out of luck.

DR. BROSEUS: It's something we need to look at before this is final.

CHAIRMAN CERQUEIRA: Yeah, Dick.

DR. VETTER: Yeah, right. I think a couple of comments. One is it has been over a year since we wrote our recommendations, and there have been some iterations of those words, and so when the final proposed regulations come out, I think we need to look at them carefully to make sure that our original intent is still there.

There is a possibility that words were added or deleted on purpose or not that have changed what we intended, and so Jeff's point is very important in that regard.

The second comment I'd like to make is

that relative to the documentation I'm a little confused there because that would refer to the need for the preceptor to be able to document that the individual had completed the program appropriately. The boards aren't requiring that. This has to do with the preceptor. And I don't think the NRC has prescribed what the preceptor must have in front of him or her in order to sign that preceptor statement.

I don't think that has been prescribed. In fact, I'm going to recommend in my comments that the preceptor statement be institutionalized and it be rather generic so that we have maybe a form that says this person completed the program, and you know, certainly there would be some sort of documentation that said the person completed the program without having to produce the abstract of every patient that that resident or fellow looked at.

DR. BROSEUS: I think if you read the proposed rule you'll find that it's a very general, nonprescriptive performance based rule, and that's sort of the starting point. I think we have to be careful about introducing prescriptiveness.

MR. MOORE: The proposed rule should be

issued in early December, and so you'll have it at that point to look at it. It's moving into concurrence now.

I guess when the ACMUI comments back to us, we would be interested in suggested fixes for the problem, too, if you have any. We've heard one which I'd characterize as grandfathering some of the people in the programs.

Another possible fix may be to review individuals' credentials and name them on licenses because that gets them into the process, but if you have suggested fixes, we would be interested in hearing those and the comments that come back.

DR. BROSEUS: I might just add in my development of where we're going with the proposed rule, and this was supposed to be implementation, but there's going to be additional opportunity for input to the Advisory Committee before the report becomes final.

Are there any other questions?

CHAIRMAN CERQUEIRA: Although we have to get this thing done by, you know -- we have until what, 2005?

DR. BROSEUS: October 2004

CHAIRMAN CERQUEIRA: Okay, and so we

basically need to get this thing done and published in the Federal Register six months before that date. Otherwise we're going to be an insane fix.

We have one comment from the audience and then Ralph and then --

MS. FAIROBENT: Lynne Fairobent, American College of Radiology.

Dr. Vetter, just to follow up on your point of what the preceptor or what form they have to sign, I think that we need to take a relook in light of what the final language is going to be in the draft rule we're anticipating in early December in light of what Form 313 and 313(a) say, which is already the form that requires the preceptor signature and what they're attesting to.

And I'm not sure that we don't have a disconnect or may have a disconnect with the proposed final language of the preceptor statements.

DR. BROSEUS: The current 313(a) staff recognizes that we will have to change it because it says right at the beginning if you're board certified stop here, and we'll have to change it to accommodate that a preceptor statement needs to come to the NRC at the --

MS. FAIROBENT: Well, I also think that

if you look at it, it's under the alternative pathway, and I'm stretching my memory back to when we looked at the form in the original draft stage of it before OMB approval.

Also though when a preceptor was signing it, there was clear indication of number of hours by subject matter delineated by each of the subparts of the regulation that they were attesting to that the individual had.

And so I think it is a much more detailed statement than perhaps Dr. Vetter was suggesting we might want to see in the future. So I do think that that needs to be looked at and perhaps thought about whether or not a revision to that form is going to appear at the same time for comment as the draft rule.

CHAIRMAN CERQUEIRA: I believe Dr. Vetter has a comment.

DR. VETTER: If I could just respond to that, the current 313 is meant for people to become authorized through the alternate pathway, and I would view a future form similar for the alternate pathway, but for those people who are board certified and need a preceptor statement, I would propose that the NRC institutionalize a very, very

simple form that the preceptor would sign, and it may have to be a different form for RSO, AMP. I don't know about that. We'd have to think about that.

But it certainly would not need to document case load or any of that. It is simply documenting that the individual has completed the training and is qualified to practice.

CHAIRMAN CERQUEIRA: Yeah, I think a standard form would be appropriate. You know, I have to write letters for fellows, and something simple and that would get at the language that the NRC wants would be very, very desirable.

Jeff, did you have a comment?

DR. WILLIAMSON: I guess during the next agenda item we're going to have an opportunity to discuss the time line for find tuning the language of the rule and hearing various concerns about the regulation a drafted, or is this the time to discuss that?

Is there a number at least of specific concerns I have about the proposed rule itself as distinguished from the mechanism for --

CHAIRMAN CERQUEIRA: I think we can probably discuss it in the next section.

Ralph.

MR. LIETO: Well, I guess that was one of my questions, was will a pre-decisional form of the rules in terms of old and new, in other words, what's being struck out, what's being replaced, be available to the advisory committee before it's published to be sure that, as Dick asked before, what we think is supposed -- our understanding of what's going to be in the rules turned out to be actually that just so that it doesn't get into the Federal Register, and then you have the Advisory Committee coming back and saying, "That's not what we said," or "that was not our intent."

And I just want to avoid that.

DR. BROSEUS: The process at this point is we're just about ready to publish, and it's not to come back to the Advisory Committee for review and approval. The staff took into account the Advisory Committee's recommendations, in particular, the one that was in Dr. Cerqueira's letter, and we are modifying the proposed rules directed in the SRM, and when we're done with that, we will publish it.

MR. LIETO: So we won't see it until it's published.

My second point --

CHAIRMAN CERQUEIRA: Is that an absolute or is it still possible to get it to the committee, especially to Dr. Vetter's subcommittee?

DR. BROSEUS: Well, we need to get this published so that we can get a 75-day comment and get it out, and we're planning on publishing hopefully the first week of December. So we're at the wire on getting it into the Federal Register for that.

And procedurally, our rulemaking process doesn't provide for this now because we're following what's laid down a instructions in the SRM.

The SECY paper that preceded that went up to the Commission with the draft proposed rule language and so on.

MR. LIETO: Right.

DR. BROSEUS: What we did and how we dealt with that.

DR. HOLAHAN: I was just going to say that because the rule is being approved by the Commission and we're following the SRM, then if you have any changes, we'd have to go back to the Commission again, and we would try to publish it and let you have your comments.

CHAIRMAN CERQUEIRA: So we would have an opportunity to make substantive comments or changes. So as long as that's understood.

Dr. Nag.

DR. NAG: Yeah. Many times it's just the wording and the details are sometimes more important than, you know, the overall view. I understand you have gotten the input of the ACMUI, but as we have seen before, it may be just the end and all and, you know, minor things like that that make a huge difference.

My request is that at least, although you have a short time, at least you allow Dr. Vetter or his subcommittee at least several days or one or two days. Once it goes out in the Federal Register, you can't change anything, while the day before, you know, that could be done much easier.

DR. HOLAHAN: Well, not necessarily because we'd have to go back to the Commission if we change it substantially, and even if an "and" or "or" we'd have to go back to the Commission, and it's better to -- you have a chance to comment on it publicly when it goes out to public comment.

MR. MOORE: Once it's issued for public comment -- this is Scott Moore -- once it's issued

for public comment in the Federal Register, the ACMUI members could either individually or collectively make comments on it at the same time the public is making comments on it, and we would have to consider all comments in creating the final.

I mean, what's being proposed in early December is the proposed. So any changes to the text, you know, could be considered in all of the comments, but the time schedule for this rule is key because to meet the October date for the final and address, you know, the quick schedule, we would need to get the proposed out now so that we could get the final out in mid-2004.

DR. BROSEUS: Well, thank you all for your attention.

CHAIRMAN CERQUEIRA: One final comment from Ralph.

MR. LIETO: Can I go to my point two?

CHAIRMAN CERQUEIRA: Yes.

MR. LIETO: Regarding communications with the specialty boards, I would like to suggest for the staff's consideration you have as a standing procedure a letter to the boards which I think as a standing procedure is fine, but this is such a new thing, a requirement. I mean, basically they

haven't had to do this in 30-plus years; that maybe it might not be a bad idea to provide or set up for some type of a conference, teleconference, video conference, that would include NRC staff, the board reps. Maybe you might want some ACMUI members so that there would be a question and answer two-way dialogue so that it would expedite what their understanding of what the requirements are to apply to the NRC for this recognition because this is going to be brand new to them.

And I think just sending them a letter is something that I think really needs to be supplemented in terms of that initial Board recognition process because, like I said, it's just going to be so new, and I think there's going to be a lot of questions that are going to come up.

DR. BROSEUS: I think as a suggestion you might want to incorporate into the feedback you give as a committee as a whole so that if the board has questions of the staff, they can call up that number. I have written into the procedures, but it seems like it's so obvious, a staff member they can contact so they can contact us, and I think there will be opportunity for the boards to interact.

MR. MOORE: I think that's a great idea,

and I think we'll take it as a recommendation to consider in between publication of the proposed rule and the final rule as we're receiving comments back. We can look at whether we could hold the workshop or a meeting with the boards so that we could answer questions about implementation, but I think it's a great idea.

DR. BROSEUS: Are you recommending a workshop for all boards or something that would be individualized so that a person coming in for a conference and then the application?

MR. LIETO: No, I'm just thinking of a one-shot deal where all of the boards come and you have this two-way dialogue and --

CHAIRMAN CERQUEIRA: Yeah, that was done before, I think for the initial process and so that could be redone.

MR. LIETO: The letter of contact, are you going to be sending that to all existing boards that are now currently listed in Subpart J?

CHAIRMAN CERQUEIRA: What's the time lines for when we're going to get comments to Dr. Vetter and then they're going to go to you?

DR. BROSEUS: I'd like to have comments back by mid-December. We can pick a date, December

15th.

MR. MOORE: And preferably we'd get integrated comments.

CHAIRMAN CERQUEIRA: So December 15th, which is a Monday, would be a good date. So in order for Dr. Vetter to basically get everything done, he's going to need to have them by December 1st, which is two weeks before.

DR. VETTER: No, I think one week before would be just fine. It will only take a few hours to look at your comments, integrate them into a single document and send them in. So if I had them by --

CHAIRMAN CERQUEIRA: December 8th?

DR. VETTER: -- December 8th, I do have a meeting that week in Washington, but you know, I'll have a couple of days. So if I get them by December 8th.

DR. BROSEUS: It would be nice if they were representative collectively of the Advisory Committee.

CHAIRMAN CERQUEIRA: Right. That's what our intent is, to get them to Dr. Vetter who has had the most experience and who will get them to you.

MR. MOORE: And to reiterate, we're

looking for comments on the procedure itself by that point. The rule then will still be in its open comment period, and you're certainly welcome to comment on it.

CHAIRMAN CERQUEIRA: Okay.

MR. UFFELMAN: The question was raised about having the boards come together, and on behalf of two boards I would heartily endorse that in early January you have that workshop for the boards so that me as a staff guy telling the physicians who are on the board that this is what you've got to do sometimes doesn't quite have the impact that if they came during that open comment period so they heard what you have to say, so that their comments are to the point of, you know, that there is a dialogue, I would heartily endorse it, you know, the first couple of weeks of January.

You know, we'll call t he snow off and all of that.

CHAIRMAN CERQUEIRA: Thank you, Roger.

And we now move on to the next item which is the discussion of possible licensee implications associated with the training and experience recommendations in SECY 03-0145. Dr. Vetter, you're going to lead the discussion.

DR. VETTER: Thank you.

Just to review briefly, you may recall that a year ago we worked on the process -- well, we originally objected to the fact that specialty boards would be recognized on the basis of their fulfilling the requirements of what we now call the alternate pathway, and we viewed that as being quite problematic, and in fact, only one board met those requirements.

So we proposed that boards be recognized separate from the alternate pathway and simply that. The alternate pathway, in fact, included a preceptor statement, as it does today. So we recommend that boards be recognized on the basis of their own separate set of criteria.

That was approved by the Commission with the exception of the preceptor statement. The Commission wanted a preceptor statement for everyone. So relative to SECY 03-0145, the primary issue was the preceptor statement.

So we went back. We worked with the staff. The staff agreed to take our position to the Commission saying that we still did not like the idea of a preceptor statement, and we had received a number of negative comments regarding the preceptor

statement. One of the issues was, well, boards actually determine that the individual has the knowledge and is qualified to practice. So we shouldn't have to have someone else testify to that.

The other was argument over the use of the word "competency," and once again the point was made that only one board met those requirements. So our recommendation, as I mentioned, was to eliminate the requirement for a preceptor statement to condition the board.

We did propose in the event that the Commission simply would not agree to that; we proposed an alternative or alternate proposal, which was the decouple the preceptor requirement from criteria for recognition of boards, as well as the alternate pathway, and simply place the responsibility for a preceptor statement on the individual who was applying to become authorized as RSO, AMP, AU, whatever it was.

The staff then took that to the Commission, and the Commission approved the alternate recommendation. So now we have a situation where we are today, which will be written into the proposed rule that boards will be recognized on the basis of that separate list of

qualifications or criteria that we have developed. They do not have to meet the alternate pathway requirements, and they do not have to have a preceptor statement. They do not have to require a preceptor statement on behalf of anyone applying to become certified.

But any individual, when he or she applies to the licensee to become an authorized user or RSO, whatever it is, either the broad scope licensee or the NRC will require that individual to provide a preceptor statement, regardless of whether they're board certified or use the alternate pathway.

To try to assess the community's response to that, I summarized that and sent that to, had that out to the radiation safety community and medical physics community on three different list servers, and I also contacted simply three boards. I'm not trying to get everyone's input here, but three boards, American Board of Health Physics, American Board of Medical Physics, and American Board of Radiology.

So hundreds of people received that E-mail, and I got back about two dozen responses. Perhaps that's because people don't take a real

interest in these things until it hits them in the face. I think we saw that before with Part 35, or perhaps because they think the issue is pretty much resolved.

But I made a few notes on the feedback that I received here, possible implications. There are some who had philosophical points of view that I think are arguable. About ten percent thought the preceptor is, in fact, needed. Ten percent were not convinced that being able to pass a board demonstrates that you are able to practice, and so they thought the preceptor statement was a very valuable thing.

About ten percent were neutral. These 20 percent were very well established people, people who had been practicing. In other words, they're old like me.

(Laughter.)

DR. VETTER: They're well established people. The other 80 percent had numerous complaints about the requirement for a preceptor statement for someone who is board certified. They basically feel that if someone is board certified, they've already gone through the equivalent of a preceptor statement and getting letters of

recommendation done and all of that sort of thing. Supervisors have to sign. A fellow has to get his supervisor to sign before he can take the boards. You know, the equivalent has already occurred.

So they don't see much point in it and do not think that the process of obtaining a preceptor statement for someone who's board certified will improve safety.

One person, in fact, one very well established person thought that we should go back to the original proposal where the NRC would issue an exam to all authorized users. I don't think we'll be doing that, but that person --

(Laughter.)

DR. VETTER: In fact, that's what the boards are for, but that person thought that that's the only way to guarantee that an individual understands radiation safety, whether it's in the practice of medicine or implementation of programs, and some other comments here that may be somewhat arguable.

There are some pragmatic issues that were raised that are less arguable, I think. One is that a licensee cannot allow a new board certified physician to practice until the preceptor statement

is received.

Currently, for example, our broad scope license, a new physician will simply provide a copy of their certificate from the board that says, "I want to do nuclear medicine," and the committee says, "Okay. I mean, you're board certified. The regulation says we can approve you. We will."

Now that individual will have to get a preceptor statement, as well, and if there is any difficulty in getting that, that's going to delay the process. So that's a pragmatic issue.

Preceptors. Some preceptors may perceive additional liability. A number of people mentioned that. Perhaps that needs to be addressed in guidance, in guidance space, the issue of liability on this preceptor statement. I don't know, but a number of people still perceive that it's a liability issue.

If I sign that this individual is capable of practicing and that individual makes a mistake, then I might be liable. That's what they're concerned about.

What to do if the preceptor is not available, the physician has died or whatever? Who will now sign? What if the preceptor simply refuses

to sign because of personality issues?

I think this is a rather -- we're down into the noise level now, but it's still issues that people are raising.

Questions. As I thought about this, then I came up with questions that I think that the staff may want to consider for guidance space. One is there's a lot of confusion about who the preceptor either is or may be and how many preceptors we might need: an authorized medical physicist who has passed the boards, and he did the bulk of training, or let's say a radiation oncology physician did the bulk of the training at University Medical School X, but he had to go to University Y to get the gamma knife training and University Z to get the HDR training.

Does he need three preceptor statements? Perhaps he does, but I think guidance needs to specify that so that it's very clear to individuals who the expectations are and in order to keep up with new users. If we get a new HDR, is the vendor the preceptor? The vendor who installs it and trains the staff in the use of the device, is that the preceptor?

Those I think have to be clarified for

individuals.

There's also a lot of confusion about the preceptor relative to 3557, the grandfathering paragraph. Someone who moves, an RSO who moves, a nuclear cardiologist moves. His or her name was on the old license. That should be adequate to qualify them for the new license, but under the old license it didn't need a preceptor. Does he now need one?

In my opinion, no, because he is already qualified, but there is some confusion out there about that. So that's another question that might need to be addressed in guidance space.

Define requirements for individuals to become reauthorized if they left their practice more than seven years ago. Do they need a new preceptor statement? If they never had one in the first place, like if I were to leave, if I were to become RSO at a land grant college and eight years from now decided to go back to medical, I guess I would need a preceptor statement from somebody or have to get retraining or what?

I mean, there's some confusion about what exactly would be required for an individual, and one of the commenters is, in fact, in that position. He was an RSO for 20 years. He's now

gone into medical physics. If he wants to go back to become an RSO -- and that was about ten years ago that he went into medical physics, what would he have to do to become the RSO?

He's board certified. So he would qualify with respect to that, but he doesn't have a preceptor statement, and his training is now 30 years old, the training for RSO. He has certainly kept up to date, and he has kept his board certification up to date, but what about the preceptor?

Define options for individuals who cannot get a preceptor statement, especially people like people whose training is a number of years old, whose original training is a number of years old, and now they want to go back into a specialty. A radiologist, for instance, who practiced nuclear medicine left and went into radiology and now wants to come back into nuclear medicine. He's board certified, but he doesn't have the preceptor statement, and his training, the preceptor is no longer at the institution where he trained. How will that work?

So there are a number of issues like that. I've given a few examples.

And then relative to the preceptor, we haven't really talked about this. I don't know if the staff has talked about this. What are we expecting that preceptor statement to be or to say? Is this simple a letter that Dr. Cerqueira writes, the same letter he writes on behalf of the fellows who go to take the board and you'll get 1,001 different varieties of letters, or is this going to be an institutionalized form that basically says what you want it to say and the physician or preceptor signs that form?

I personally would vote for something that's institutionalized so that we all are playing the same game, but that's a question, I think, that needs to be thought about and perhaps addressed in guidance space.

And then relative to the issue about logs as well, what are we expecting? I don't know if the NRC has thought about doing this, but if you wanted to go check up on a preceptor, what would you expect that preceptor to be able to produce to demonstrate that the individual had completed the program, had completed the training?

So if we need to provide some sort of logs, at least define what that is. Define what we

want that person to be able to produce.

I gave a few examples here which basically don't review anything new, but for instance, an RSO who left under disagreeable circumstances, wants to come back, wants to now get back into radiation safety, he's board certified, but he needs a preceptor, and that's probably going to have to come from his previous supervisor, and his previous supervisor is not going to sign it, is simply not going to.

What can you do? Some other examples like that. The death of a preceptor, I mean, what can we do in that circumstances?

I don't think anybody wants to be so unreasonable or so prescriptive that that person can't get authorized. It's just a matter of what needs to be said, put in guidance space, and what that individual can do to get a preceptor statement.

Now, I only focused on the issue of the preceptor statement, and maybe the initial discussion should just be around that. There may be other questions relative to the whole training and education issue that we want to vent here as well.

CHAIRMAN CERQUEIRA: Thanks for the good summary.

Now, Leon, you wanted to make a comment?

DR. MALMUD: Yes. Under your summary, Dr. Vetter, which is splendidly presented, you indicate that the ACMUI recommendation was for the elimination of the requirement of the preceptor statement.

DR. VETTER: For the boards.

DR. MALMUD: Correct, as a condition, to condition the boards.

When we pass the boards, when each of us pass the boards, we have demonstrated that we have been exposed to a body of knowledge and that we understand that body of knowledge at that time. The day after board certification, the assumption is that we are qualified to perform in our specialty.

It may be that that is not so. For example, I'll take my own area. We may have finished complete training in nuclear medicine with therapy, with exposure to all of the isotopes then in use, at an institution which has no PET imaging capability, and yet the next day take a job in an institution which has a PET facility in which we've had no experience.

That's just the way a body of knowledge expands beyond the point of what which we have

learned when we trained, and most of us that have been in medicine for a while recognize that most of what we do today we didn't even learn when we were in training. So it is correct to assume that a certification simply certifies exposure to a body of knowledge which was then current at that time, and that we as individuals who have been certified, that is, who have received board certification, have that body of knowledge from that time.

The requirement for a preceptor statement suggests, it implies and we infer, that the preceptor will have indicated some degree of competence. Well, the preceptor really did that or does that currently when signing off for the trainee to sit for the boards.

So it's probably best if we eliminate the requirement for a preceptor statement in toto and not get too prescriptive. What our concern is is radiation safety. We are the NRC. We're not the American Board of whatever, and the question is: does the individual have the competence to handle radiation of whatever type he or she is handling or supervising at that time?

I don't see how a preceptor statement covers that even currently, and therefore would

suggest that we recommend that the preceptor statement not be a part of the certification if the individual is board certified.

Now, there then comes the issue of the alternative pathway, the alternate pathway. There, again, one would have to find alternative ways of identifying competence, and those already exist and will exist into the future.

If we become too prescriptive, we are going to create problems. We will create unintended consequences which will come back to haunt the NRC and us as each individual case requires a review. I suggest that we not be that specific.

DR. VETTER: May I respond?

CHAIRMAN CERQUEIRA: Yeah, go ahead.

DR. VETTER: That's exactly the position that we took and presented to the Commissioners and the NRC took that on our behalf. The Commissioner said, "We don't care. We want a preceptor statement," period, and they directed the staff to implement that.

DR. MALMUD: And it may be that this is where we say board certification does not require a preceptor statement, and we do not support the NRC and do not recommend that the NRC continue with this

policy of requiring a preceptor statement.

I trained in 1973. Am I to get a preceptor statement from 1973 as if it had any application in 2003?

DR. VETTER: Well, you don't need one, of course, because you will qualify under the grandfather clause.

(Laughter.)

DR. MALMUD: Let's make it 1993.

DR. VETTER: No, anyone who is currently an authorized user will not require preceptor statement unless they leave the profession for more than seven years and come back. Then, as I understand the current rule, they would need a preceptor statement and that's where some of the issues, pragmatic issues like, you know, how would they obtain one.

CHAIRMAN CERQUEIRA: And I think your suggestion if we can't deal with it in the rule, can we deal with it in a guidance document and some way to accommodate those people, and I think Lynne did an excellent job of summarizing what we told the Commissioners on multiple occasions, and the answer has come back no.

You know, so the committee has two

choices. Either, you know, make some recommendations as Dr. Vetter has suggested to put it into guidance space in some way, which doesn't give any guarantees, or you know, if you want to take a firm stance and give the message to the Commissioners again, despite their recommendation that the committee still advises that this not be included.

DR. VETTER: Just one more comment and then I'll be quiet.

DR. MALMUD: Excuse me.

DR. VETTER: You will have 75 days for you and all of your colleagues to make that point.

DR. MALMUD: The other way to deal with it is to redefine what a preceptor is, and that is the way toward compromise, and that is for us to say fine. We will acquiesce to the NRC's strong recommendation that a preceptor statement be required and that a preceptor may be any of the following individuals: the current radiation safety officer at the institution at which the applicant is applying may give a short RSO course in three or four days, certify the person that's now able to handle radionuclides or radioisotopes to the degree that individual is required to do so in his or her

particular subspecialty, specialty or practice.

The second one is that it may be the individual who trained the applicant. It may be someone who has had contact with the applicant.

Make up a list of individuals, any of whom we would accept honestly as having the qualifications to certify that the individual who was seeking approval is adequate to the job. That way we have not come in conflict with the need to have a, quote, preceptor, but have redefined the preceptor in terms which are acceptable both to the NRC leadership and to ourselves.

Is that a fair compromise?

CHAIRMAN CERQUEIRA: I think maybe, Charlie or Patricia, if you could comment on whether the Commissioners would find, you know, whether that's something that would be acceptable.

DR. MILLER: I think that the Commission got, as you articulated two shots at this from you, and I think that in the last round the staff went out of its way to make sure that the Commission heard ACMUI issues.

As Dr. Vetter pointed out, at this point in time, they don't want to budget from the position. However, they did compromise some, I

think, with regard to separating it from the board certification, and I think my reading of it is at this point in time that's as far as they're to go.

There could possibly be a third avenue, which would take more time, and that would be go through the public comment period, develop the final rule. If the public comments come back very strong in this area, that would be included in the final package that went to the Commission for their deliberations. If they continued to want to continue to make the same stance that they have, the next best thing that the staff has done over time is go out and gather information over a period of time after implementation to see if it really does or does not make a difference and if the rule needs to be modified.

We're talking about probably at least a few years, and that's not a short term thing.

I don't see the Commission, quite honestly, changing their view on this. I think they clearly understand it, and I think they're entrenched in their position, and, Roger, they're unified, right? We didn't get dissenting votes on this, did we?

DR. BROSEUS: That's true. No.

DR. MILLER: At least with the three Commissioners that are currently standing.

DR. MALMUD: Often when well meaning people take a very strong position, there is still an opportunity for compromise.

DR. MILLER: Yes.

DR. MALMUD: And in this case it would be have they defined the term "preceptor."

DR. MILLER: Yes.

DR. MALMUD: They have. What's the wording for the term "preceptor"? Often when you see a legal document you'll see definitions of each term. What is the term for "preceptor"?

DR. BROSEUS: The term "preceptor" is actually defined in 35.2. I don't have the current rule with me.

DR. MILLER: What does it say, Roger?

DR. BROSEUS: I'm reading from the rule. "Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer."

Now, I might add that during the working group's deliberations, we looked closely at this and

also at what the Commission said with regard to preceptor statements, and they said, "Don't change the wording."

And so you read in 190, for example, that the person who may serve as a preceptor is an RSO, et cetera, and so it would take rewriting of the rule under the direction of the Commission to really change the total definition of a preceptor.

CHAIRMAN CERQUEIRA: Leon.

DR. MALMUD: The definition that you read before you made your comment is a definition which allows for enormous flexibility in the definition of a preceptor. It does not say that that was the individual who had originally trained and certified the applicant.

DR. BROSEUS: That's why I added the qualifier, and that is that it says in the rule now and we were instructed to retain the current wording in the preceptor statements, and so it really effectively further defines for a particular type of use or for RSO or ANP or AMP who may sign, who may certify, and that's written into the rule.

CHAIRMAN CERQUEIRA: But it doesn't state that preceptor trained that individual. So somebody who qualifies as a preceptor who has the

appropriate training and recognition could sign a letter for somebody that they didn't necessarily train if they were willing to. Would that --

DR. MALMUD: That's what I would say.

Roger, it seems to me that if an applicant comes to our institution and has the necessary hours with RSO, that our RSO can play the role of preceptor there in certifying that that individual has now been exposed to the requisite number of hours or has demonstrated competence in the area in which he or she is applying to practice.

What I just said I do not believe is in conflict with either of the two statements that you just quoted from the current regs., either the definition of preceptor or the content of the preceptor statement.

DR. DIAMOND: The key is preceptor means an individual who provides or directs. We had all been operating under the assumption that it was going to use individual who directs the training, but when you say who provides or directs, that does not -- that does not denote that that person is the same person that provided your training back five years ago. It does not denote that the person that provided your HDR training for this new device is

the same person as you may have received training years ago.

That's the key, provides or directs. So I think that the flexibility that you want is actually in here.

DR. NAG: Can you read the next one?

DR. DIAMOND: I'll read it again. Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an AMP, an authorized nuclear pharmacist, or an RSO, who provides and directs the training and experience.

CHAIRMAN CERQUEIRA: So it does sound like it gives us the leeway.

Patricia, you were waiting.

DR. HOLAHAN: I would just like to build on what Dr. Vetter said because currently the Commission believes that the definition of preceptor is as they've defined it, but if you comment on the rule and you can comment and provide different alternatives, compromises, that would be included in the final rule package, and the more people that comment on the rule when it goes out is because they're not always influenced by number of comments, but number of, you know, significant comments.

CHAIRMAN CERQUEIRA: All right, but we have one member of the audience who has been waiting patiently for a while.

MR. WHITE: Actually I have been listening to almost everything that I had intended to say.

CHAIRMAN CERQUEIRA: Can you introduce yourself?

MR. WHITE: I'm sorry. I'm Jerry White. I'm chair of the Professional Council from AAPM, although I'm speaking for myself and not AAPM.

When we look for wisdom in regards regulations, the first thing we always do is reach for the Federal Register, and I think the language is clear in most of the training paragraphs here, that the preceptor needs to testify, describe the level of competency that the person has achieved, and not necessarily that they have done particular training steps. It's the level of the competency that the actual regulation wants the preceptor to speak to.

And I agree with what has been said that there seems to be a disconnect between the definition of preceptor, at least in the case of the board certified individual and what the actual

regulation asks the preceptor to do.

And there's clearly two different preceptor requirements, one for people who are on the board certification path and one for those who are not, and I think that it's appropriate that there be two separate definitions for preceptor as well.

And in the case of the board certified individual, the preceptor might be any authorized user or RSO who is familiar or willing to attest that the individual has achieved this level of competency that the regulation asks for. That's what the regulation seems to want. It's common in medicine for other individuals to attest to the competency of their peers and the staff credentialing process and things like that, and there's a lot of parallels in medicine already for this that I think we could draw upon as a basis for this decision.

CHAIRMAN CERQUEIRA: They are very good comments.

Leon.

DR. MALMUD: I think that that which I think is important for us to remember is that the Commission for its own reasons wants those

definitions. Its goal is the same as this ACMUI's goal is, which is to assure the public safety and the training and competence to the degree possible of those who provide the service.

What we must do is find a means of satisfying the Commission's requirement, which is that we use the term or that we have the term "preceptor," and to define the preceptor in a way which is acceptable to the Commission and which is practical for those who will have been trained or have already been trained.

And it seems to me that the flexibility exists within the definition of the term "preceptor" and within the other definitions that have been quoted today from the existing documentation, and I think that we have a flexibility to achieve our goal without there appearing to be any conflict in the public eye between what the Commission wants and what this committee wants to achieve.

DR. DIAMOND: Leon, I think that just with a little bit of creativity, all four examples that Richard outlined could be satisfied by that language.

CHAIRMAN CERQUEIRA: Do we have counsel here? Because they always have a different twist on

this now.

(Laughter.)

MS. CHIDAKEL: Counsel is here, and I think you're raising some very --

CHAIRMAN CERQUEIRA: Can you go to the microphone for the recording? Thank you.

Because I think you gather the sense that the committee feels that the way that it's written it would allow us to, as Dr. Malmud said, to achieve the Commission's request as well as make it doable and practical from our perspective.

MS. CHIDAKEL: My name is Susan Chidakel, and I'm attorney for the Office of General Counsel with the Nuclear Regulatory Commission. I'm also a member of the Working Group, this rulemaking.

And I think you've raised some interesting issues. I don't think that we have actually discussed the definition of preceptor itself other than as it is in the rule, and correct me if I'm wrong, Roger. We have focused on the definition within the rule. What the Commission initially instructed us to do in the first SRM was that the preceptor statement must remain as written.

I don't read that saying that the preceptor definition must remain as written because

we never really reached that issue with what we sent up to the Commission.

So I think that, you know, you're raising an interesting point. Can I give you an answer off the top of my head? Of course not. You know, I understand the nature of the problem. Again, I don't think that it's something that we really focused on. Correct me if you disagree, Roger.

At this point, I think my advice would be as has been also advised by other people here that I think these are encompassing the comment period on the proposed rule. We're pretty much there with regard to, you know, noticing the proposed rule in the Federal Register notice, and I guess that's, you know -- if you wanted an immediate answer, I can't give you one. You know, I certainly can tell you it would require us going to the Commission and saying, you know, what exactly did you mean? What exactly are the bounds of not changing the definition of a preceptor because it's something that we have not raised, and you disagree with me.

DR. MALMUD: No. I'm shaking my head back and forth, but I'm in full agreement with you.

I don't think we should go to the Commission and ask for more definition. What we should say to the Commission is we agree with the wisdom of your recommendation and we agree that the existing definition of a preceptor as it appears in the Federal Register or the documentation is more than adequate to cover your concerns and ours.

MS. CHIDAKEL: And also let me add now within each section, within each section of the proposed rule, of course, we have specified who is a preceptor. I mean, when I'm saying definition of a preceptor, I'm talking about the definition in the definition section, and I presume that's what you're talking about.

DR. MALMUD: That's what I believe was --

MS. CHIDAKEL: Because the position of who can be a preceptor, which type of person can be a preceptor, of course, is specified within in the rule as well. So I just want to make sure we're talking on the same wave length.

CHAIRMAN CERQUEIRA: But I guess telling "don't ask, don't tell" could --

(Laughter.)

CHAIRMAN CERQUEIRA: -- could help.

MS. CHIDAKEL: I didn't say that. You did.

CHAIRMAN CERQUEIRA: Could help, but at the same time I think some of us would like a little bit more assurance that our interpretation is going to be the interpretation that's going to be used once this gets implemented, and whether this is in the rule or in the regs. in some way would be important to figure out how to clarify, codify, make certain that our interpretation that this preceptor has to be someone who would attest to the competency of the individual or the training of the individual, but doesn't necessarily have to be the one who physically was involved in the original --

MS. CHIDAKEL: Let me just make one statement, and of course, what you're saying is the way it is worded in the rule. There is nothing in the rule at this point that says the preceptor must be the person who did the training.

And, Roger, please take over.

CHAIRMAN CERQUEIRA: Roger, and then Jeff wants to make a comment.

DR. BROSEUS: I want to offer my comment as a constructive comment and my personal view and sort of a reflection of what I've heard over the

last, oh, say, year or two, and a little bit of what I hear and the way I hear it is that the same arguments that were made to the Commission some time ago are resurfacing, and that is who may serve as a preceptor.

And at one time there was an argument that it's okay if it was a person who directs the training program, and that didn't fly, and so there have been, I think, actually a lot of discussion of this point in different clothes, and we are at the point now that the Commission has said, "Keep a preceptor statement and don't change the wording," but it has not said --

MS. CHIDAKEL: Of the preceptor statement, Roger.

DR. BROSEUS: Well, and for me it extends to the definition which is sort of inherent in the whole thing, not that the Commission specifically talked about the words in 35.2, but I consciously and some working group members thought about what is the definition and does it need to be changed in light of the direction that we have received in the SRMs and so on, and we didn't change them.

And so my observation is that, again, a

personal comment and observation, that thought be given very closely to are the arguments that are coming up now the same ones in different --

MS. CHIDAKEL: Let me please make sure I understand that they are not the same arguments because I understand what you're saying, and though I haven't been involved in the whole process as long as Roger, of course, I know what the issues as I understood them were, and I'm seeing you raise a different issue.

As I understand the issue you're raising now, and please correct me if I'm wrong, is does the person who is the preceptor have to be the exact individual who did the training, and that you're seeing a disconnect between the definition of the preceptor and the rule, and that your feeling is that it doesn't have to be the exact person as long as this person can certify to the competency.

DR. BROSEUS: Correct, according to --

MS. CHIDAKEL: And that's why I think the issue that's being raised, Roger, if that's a correct interpretation, is not the same thing that you are raising that you're concerned about.

So, frankly, I think this is a little bit of a new twist, and --

CHAIRMAN CERQUEIRA: But it's a twist that could get us out of a dilemma which I think would meet everybody's needs, but I would like a little bit more assurance that our interpretation is the way it's going to be implemented.

David?

DR. DIAMOND: According to the definitions, 35.2, that I just read, to me it is very, very clear about what it is saying and what it is not saying, and what it does not say is that that individual is the one that was the lead individual in conducting that person's training. It does not say that, and that's what we've been trying to get around.

So unless there's some other body in the regulations that we have not identified that speaks to the contrary, that definition would meet our concerns.

MS. CHIDAKEL: I am not aware of anything in the rule, and correct me -- hang on. There are other people here -- that specifically says that the individual who did the training must be the individual that must be the preceptor. Roger, would you disagree with that statement?

DR. BROSEUS: I'm sorry. I didn't hear

what you said.

MS. CHIDAKEL: My point is I don't think that there's anything in the rule, and I looked to Roger, and I also look to Ron Zelac who is a Working Group member also and certainly has had more experience with the history of this thing, too, than I have; I don't see anything in the rule that specifically says that the preceptor must be the person who did the training of that individual. That's the only statement I'm making and that's my only comment.

Will the Commission buy your interpretation? I can't speak for the Commission, and at this point we don't have anything in the rule one way or the other that defines that the preceptor must be the same person that trained that individual.

CHAIRMAN CERQUEIRA: Well, we agree with counsel on this, and I guess, you know, Charlie and Patricia and Tom, how do we basically codify, solidify, or make certain that our interpretation is what the Commissioners meant when they wrote that?

DR. HOLAHAN: Basically providing comments on the rule.

MS. CHIDAKEL: I agree with that. I

agree with that completely. Like I said, this rule is going to be published in the Federal Register. It's a proposed rule, as has been said before, and you will have the opportunity as the members of the public have the opportunity to comment on the proposed rule before it becomes a regulation, before it becomes finalized.

DR. WILLIAMSON: I would like to, you know, propose we take that one step further, not just wait until comments are being made in the Federal Register, but I think as perhaps another collaborative activity between the appropriate ACMUI members and staff. Evaluate the possibility of being able to, you know, accommodate the current radiation medicine staffing model and credentialing model, you know, basically under the assumption that the current preceptor definition decoupled from board certification recognition is going to remain in place.

I think it would be much better to learn whether they are going to be injurious consequences or legal difficulties in pulling this off sooner rather than later. I guess I mean this as a supported comment to follow our Chairman's suggestion that we need some more assurance.

I think we need to understand whether this can be worked out in guidance base sooner rather than later.

CHAIRMAN CERQUEIRA: Leon.

DR. MALMUD: May I suggest that perhaps that might be achieved in the following fashion with as little conflict and as much agreement as possible? And that is for the ACMUI to quote from 35.2 verbatim the definition of a preceptor and indicate that we are fully supportive of the existing definition of a preceptor and hope that the existing definition of a preceptor as it appears in 35.2 remains acceptable to the Commission.

CHAIRMAN CERQUEIRA: Why don't you make a motion to that regard?

MS. CHIDAKEL: Excuse me a second. Before you make a motion, I just want to emphasize as of right now the definition of preceptor in 35.2 has not been changed.

DR. MALMUD: I know. I know that.

MS. CHIDAKEL: So I don't quite understand what it is that you're proposing.

DR. MALMUD: We are trying to reaffirm by simply quoting the existing 35.2 that we are supportive of it and don't wish it to change, but

we're not putting a negative spin on it. We're putting a positive spin and saying that this committee fully supports the current definition of 35.2 for preceptor and hopes that it will remain as such.

DR. WILLIAMSON: I don't think that's appropriate or necessary. I really think we should address the issue of consistency of the existing definition and what we think is going to be the probable form of the regulation and the current staffing practices.

And then I think a combination of what we learn in that process of working with the staff to determine whether realistic guidance can, in fact, be developed within these legal confines, plus the comments, unfavorable comments, we might get from the public. We would be in a much stronger position if we come back to the Commission and say, "We told you so," and don't go on record contradicting our earlier advise.

So, no, I don't think it's appropriate either for us to launch a frontal attack on 35.2 or a ringing endorsement of it at this point. I think we just need to do some craftsman-like work and figure out whether we can live with this or not.

CHAIRMAN CERQUEIRA: Dick, how do you want to go forward with this now? You're leading the discussion.

(Laughter.)

DR. VETTER: I agree that in my opinion the best way to attack this issue is to comment during the 75-day comment period. You know, we can make motions or whatever here, and that can be supportive as well, but the public comments from us as individuals and even if we wanted to make a public, you know, comment collectively on the proposed regulation is something that the staff will take -- I mean, they have to assimilate that into their deliberations, and I think that's the most meaningful thing that we can do.

MR. LIETO: So maybe we could move forward. We have until December 8th to get comments to Dick who will then --

PARTICIPANT: No, that's on a different issue.

DR. VETTER: That's for the process.

MR. LIETO: The process. Okay. You've got to get somebody from that side of the table if you want other comments collected.

CHAIRMAN CERQUEIRA: Yeah.

DR. MILLER: The 75-day comment period hasn't started yet.

MS. CHIDAKEL: Right.

DR. MILLER: It won't start until the proposed rule is published.

CHAIRMAN CERQUEIRA: Right, right. Ralph and then --

MR. LIETO: Just a quick question on process in terms of the comment period, and I don't know if you're going to be willing to answer this, but would a -- during the comment period, would a statement or suggestions from the Advisory Committee as a whole be weighted more heavily than the individual comments from the individual members?

DR. HOLAHAN: Well, I can't answer if it would be weighted more heavily, but I think if you recall on Part 35 when it went up, we had an ACMUI comment section specifically in the rule, and I think it would be worthwhile to get comments as a committee to put in the final rule as it goes up.

MR. LIETO: All right. That's fair.

DR. MILLER: But by getting a letter from the committee, which Dr. Cerqueira signed with regard to the proposed rule going up, I mean, that was in my view very instrumental in getting the

Commission to at least soften their position to, you know, decouple the preceptor from the board certification. So I thought that progress was made in that regard.

DR. HOLAHAN: And even so, we'd have to analyze each of the comments from the ACMUI in the final rule in addition to a letter.

DR. MILLER: And whether they're your comments or other public comments as part of the final rulemaking, those comments have to be dispositioned and articulated in the final rulemaking package that goes up to show how the comments were dispositioned.

If I could make another comment, and it's just something that popped into my mind, in listening to Dr. Vetter's discussion and his summary of a variety of things related to the information he collected, and I thought there was some good input, one of the things that the staff has done in the past, we were talking about guidance and how to best get the guidance out. One of the things that the staff has done in the past on some rulemakings and what comes particularly to mind to me is when we promulgated a change to Part 20, was we developed a document of Qs and As which was a NUREG, I believe,

and that's what kept triggering in my mind as you went through this, Dick, because there's a lot of questions in there that you could get answers to in a Q&A format that would give guidance to everyone out in the industry and the users as to how to implement certain aspects, and it was a living document whereby as more questions come up and more answers come up, there's an ability to include them in there.

DR. HOLAHAN: And that's already included with Part 35 because there are Qs and As on the Web site. So --

DR. MILLER: Right. We would have to continue to build on that, and we could get them on the Web site, and then there would be information out there with regard to implementation.

And I think it could also include information with regard to how to implement the preceptor statement.

CHAIRMAN CERQUEIRA: That's a very good idea.

DR. MILLER: So I do think that there's a way to do this.

CHAIRMAN CERQUEIRA: Right.

DR. HOLAHAN: And keep in mind that you

can comment on the rule, and I encourage you to comment on the rule as a committee or individually or however you want to, but also keep in mind that you get to see again the final rule when it goes out to the Commission, before it goes to the Commission.

DR. MILLER: We would use you. I mean, when we get the comments back and disposition them, we would use you to help us frame --

DR. HOLAHAN: The answer.

DR. MILLER: -- what should -- we would like to get your input on what the final rule should look like given all of the public input.

CHAIRMAN CERQUEIRA: Right. So I think the action is obviously we as individuals and the societies that, you know, we interact with should certainly send comments in. Now, would the letter from the committee, again, as a comment on the final rule be helpful rather than the individual?

DR. HOLAHAN: Yes.

CHAIRMAN CERQUEIRA: You know, during the comment period.

DR. HOLAHAN: Yeah, yeah, I think so as a comment.

MS. McBURNEY: With our formal comments as the committee as a whole.

DR. HOLAHAN: And we analyze each of the comments that you put in there as a public comment on the rule, and we can put a section in the final rule that goes up to the Commission, the ACMUI comments like was done in 535.

CHAIRMAN CERQUEIRA: Okay, yeah. All right. I think we've hit this now. Jeff had some other -- he had quite a few comments and questions related to this. Maybe we should move on to --

DR. WILLIAMSON: Well, I will yield to Dr. Diamond who I think will introduce the main point that we wanted to make.

CHAIRMAN CERQUEIRA: Okay.

DR. DIAMOND: In summary, I'm optimistic that we have solved one mess today, and I unfortunately have to tell you that Dr. Williamson and I think that we have identified an even bigger mess.

I'm holding SECY 03-145, which is the proposed rule, and within this in Section 35.390, we are concerned that the current language as it has been rewritten may prevent authorized users from the radiation oncology point of view to be able to deliver unsealed byproduct material for which a written directive is required, and it needs a little

bit of background.

Back in the spring of 2002 under Dick's leadership, we went and we wrote a lot of these regulations. I can assure you since I was the one writing these regulations at least at --

DR. NAG: Before you go further, can you tell us what you're referring to so we can all follow?

DR. DIAMOND: Well, this is the second memorandum, 03-0145 that you all got a copy. It's dated August 21st, 2003.

CHAIRMAN CERQUEIRA: I don't think it's in the records here.

DR. NAG: Oh, I'm sorry.

CHAIRMAN CERQUEIRA: It's something that was sent out.

DR. DIAMOND: I brought this with me. This is the proposed rule for training and experience.

But to come back to it, back in the spring of 2002 under Dick's leadership -- page 16 -- under Dick's --

DR. WILLIAMSON: Whether you look at Attachment 1 or 2.

DR. DIAMOND: Yeah, it depends on which

attachment you're looking at.

But under Dick's leadership we went and we wrote these regulations and in 35.390, which is unsealed byproduct material for which a written directive is required, it was our intention, and we made it clear in our version that both nuclear medicine physicians and radiation oncologists would be able to deliver these materials because there's a tremendous crossover in uses and so forth.

Subsequently, at our last meeting, as we all learned, the staff extensively rewrote those regulations, and it was impossible for us sitting here to go and identify the differences between what the working group had developed and those recommendations because it was not a red line copy.

In this SECY statement, there's been a major change that we did not recognize, and that is as part of the training and experience, it includes three years of residency training and 700 hours of training and experience as described in Paragraph B(1).

That itself is fine, and then when you go down and you look at B(1), it's asterisked, and my assumption heretofore was that the asterisked section referred to our original draft document that

was let under Dick's supervision, but in fact, it refers back to that Paragraph B(1) as printed in the Federal Register notice, which is very, very different.

And to cut to the chase, it specifies that the 700 hours are specified to training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for which a written directive is required.

The bottom line is these regs., these proposed regs. were changed. None of us picked up on the change because we had no red line copy. Then when we were reviewing it, we thought that the asterisked area, meaning that the unchanged portion was referring to the working group draft and not to this draft, and as it's written, no radiation oncology resident coming out of training is going to be able to deliver a lot of the isotopes that we currently deliver in practice.

That's the background.

DR. WILLIAMSON: Can I follow with a couple m ore comments?

Okay. You k now, what is the issue? Radiation oncologists have traditionally been recognized by virtue of board certification as being

able to administer radiopharmaceutical therapy to cancer patients, and it is done. It varies from locale to locale as to whether nuclear medicine physician does it or radiation oncologist does it, but radiation oncologists do it a lot.

Now, the way this regulation is written, which is in complete contradiction to the recommendations of our subcommittee and the recommendations made during the July 22nd or July 17th, 2002 meeting, it now says, "Successfully complete a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or program in related specialty that includes 700 hours of training and experience as described in Paragraph B(1) of this section.

And I will read you some of the things that are in here, you know. It has the classroom and laboratory training. I don't think that necessarily is an issue.

A major issue and a central recommendation of our subcommittee was that this should not be, but it says that B(1) includes "administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following four

categories," which you know well.

So this is included as essentially a -- for ABR certification and radiation oncology to be recognized, the ABR must require that the radiation oncology residency include this 700 hours of training and the 12 cases of --

MS. McBURNEY: Radiopharmaceutical.

DR. WILLIAMSON: -- radiopharmaceutical experience.

DR. DIAMOND: But the 700 hours has to be specified to the radionuclide handling of --

MS. McBURNEY: Of unsealed, yeah.

DR. DIAMOND: -- or 700 hours was a more generic 700 hours and covered a whole spectrum of training.

DR. WILLIAMSON: That's correct, yeah. And so what will happen is that automatically now radiation oncology will now be excluded from this as a credential. The ACMUI recommendations once made this more general and put the 12 cases of experience as an additional requirement that bound both the alternative pathway candidates and the board certification candidates.

So that the recommendation of the ACMUI was be board certified by a board that complies with

training and experience distributed this way or alternative pathway requirements and 12 cases of experience distributed according to Paragraph B(1).

So this is a major problem, I think, you know, if this goes through. This is really going to hurt patients, I think, because we certainly don't wish to exclude our nuclear medicine colleagues from this, but radiation oncologists, I think, have a lot to offer patients in this context in terms of being able to provide comprehensive cancer care and integrate these drugs, you know, with other forms of ionizing radiation therapy.

And I think it certainly does the community no good to exclude this sector from the practice of radiopharmaceutical therapy.

CHAIRMAN CERQUEIRA: Dr. Vetter.

DR. VETTER: Well, in fact, today I think you'll find across the country that in some hospitals radiation oncologists administer these radiopharmaceuticals, and in other hospitals nuclear physicians administer them. You know, it depends on how the practice is organized in the hospital.

CHAIRMAN CERQUEIRA: So how could we change this?

MR. LIETO: Well, I think the first

thing we need is -- that's why I think it gets to the request before about having sort of the red lines or strike out what's old and what's new as afar as the proposed rule goes because I think unless we see that, it's really going to be -- because we're working with basically three versions of the rule. Okay? What was published in the Federal Register, what we proposed to the Commission, and then what the final, you know, machination is that's going to go to the Federal Register.

And I really don't know, you know, what's going on.

DR. HOLAHAN: Well, we can certainly get you the red line strikeout version of what you propose versus what's actually in the rule. But to solve the problem, I don't mean to keep falling on it, but comment on the rule because we want to get the rule out, and if we wait, we'll have to go back to the Commission again to ask for it sounds like a significant change, and that will delay the rule.

So comment on the rule.

CHAIRMAN CERQUEIRA: Right, but we can't tell whether this was intentional from the Commissioners in terms of these changes. Was this

just sort of an oversight, is what it sounds like it was in the way it was --

DR. HOLAHAN: Well, we'll develop -- correct me if I'm wrong, Roger, but do you have a red line from what the ACMUI proposed to what the final rule actually is?

DR. BROSEUS: We had a red line strikeout version that was presented to ACMUI in May, but there have been changes to that.

DR. HOLAHAN: Okay. Would it take significant effort to develop that? Could it be done by the end of December?

DR. BROSEUS: Yeah, w can get that eon.

DR. HOLAHAN: Okay. By the end of December then.

DR. WILLIAMSON: My perception is that this is not a change that if were made between -- I think it's hopeless, I'm sure, to make it before this hits the Federal Register -- but this does not sound like it is in direct conflict with anything the Commissioners said in their various SRMs on this matter.

So I think if a strong case is made for it, perhaps when the final rule is sent up to them, it could include this, but I think you really need

to be aware that this is, you know, a major, major problem for the radiation oncology community.

CHAIRMAN CERQUEIRA: Ruth.

MS. McBURNEY: Just a process question. Would this be -- if this comment were to be accepted and the change made in the final rule, would that constitute a substantive change or would it be minor enough that it could be done without re-proposing?

DR. HOLAHAN: Oh, it could be done without re-proposing.

MS. McBURNEY: Right, because I know when we make a substantive change during a comment period on a proposed rule, we have to repropose, but I'm not thinking that this is a substantive enough change that it would have to be reproposed.

CHAIRMAN CERQUEIRA: It doesn't sound like it, although no one is making --

MR. UFFELMAN: Just --

CHAIRMAN CERQUEIRA: Mr. Uffelman?

MR. UFFELMAN: Just to add again to the pot, Bill Uffelman from Society of Nuclear Medicine.

You may recall we had a long discussion this past summer over microspheres which became those sealed sources defined as being less than 100 microns, I believe, and one of the things that we

got hung up on was 390, was unsealed sources and 490 as sealed sources.

And maybe if you were fixing 390 to resolve their difficulty, it ought not to say -- well, it could say unsealed sources and sealed sources less than 100 microns, and that takes care of both problems for people. I think everybody sat at this table and agreed people were adequately trained on both sides of the street to accomplish the administration of those kinds of materials.

And it kind of screws up the NRC's lovely unsealed sources/sealed sources, but these things that fall in the middle fall there anyway, and we either need a new section dealing with sealed sources less than 100 microns or cured all at one time.

CHAIRMAN CERQUEIRA: Well, I think if the SNM would certainly make the appropriate comments to that, it sounds like that would be the most logical place, the most expedient way.

One last comment from Jeff, and then I think we should take the break.

DR. WILLIAMSON: Can I make some comments about deficiencies in the language for radiation safety officer, or my view?

CHAIRMAN CERQUEIRA: Okay. It's important.

DR. WILLIAMSON: Okay. I found it very difficult to read this with the asterisks in place. I do not understand, first of all, why you can't provide us with copies that have a complete text so that at least we only have to hop between two documents instead of three sets of documents.

Anyway, I spent the afternoon on this in the version two or Appendix 2 version of the RSO. My reading of it, because of the way "ands" and "ors" seem to be scrambled is it looks like the sole requirement to be a radiation safety officer is -- the way this is written literally -- is to have a preceptor statement.

So I think there's some issues with grammatical organization. There are some others with the medical one, too, that I hope someone will really take a critical read through this and maybe, you know, consider whether the "ands" and "ors" reflect your intent and hopefully the intent of our recommendations to you.

But, you know, subject to the difficulties of reading this, I think there's some serious problems just in the grammar of the RSO

regulation. Hopefully you will fix that and find that uncontroversial, although I think it might require rearranging paragraphs to get the grammar right so that your intent comes through that the preceptor statement isn't the sole requirement or isn't the requirement for just some forms of RSO, but is a common requirement for all RSOs regardless of their flavor and whether they come through the alternative or board certification pathway. That definitely is not there.

Another --

CHAIRMAN CERQUEIRA: But who would be doing that, Roger? Is that your group or --

DR. BROSEUS: Just let me comment on that since you named me. One of the charges to the working group as we're finishing off the proposed rule is to make sure that the presence of "ands" and "ors," et cetera makes it so that the preceptor statement is required for both pathways, the certification pathway as well as the alternative; that the requirement for a preceptor statement is not a condition of board recognition, et cetera.

One of the dilemmas that we had in the working group, especially when you get into the 390, is if we start rearranging things, the numbering and

so on gets to be a pretty monumental task and so we elected to try to keep the existing structure, feeling that would be more understandable.

So hopefully the issue that Jeff has identified has been cured when we publish the proposed rule.

CHAIRMAN CERQUEIRA: But is there any way that we could assure that, you know, to have maybe, if Jeff spent his time read it, is there some way he could take a look to see if those changes had been made to feed back to you?

DR. WILLIAMSON: If they can show me when I can efficiently read, I will be happy to do it, but not full of --

DR. BROSEUS: We don't have the efficiently one that you were talking about, and we're at the stage now of getting ready to publish, and so we need to have the comments come in during the public comment period.

DR. HOLAHAN: And the reason the asterisks always refer back to the rule that was published, the rule that you provided wasn't actually published as a rule. So the asterisks refer back to that original rule that was published.

DR. WILLIAMSON: I understand that, but

it is very confusing, and I think just sort of if you want people not to make mistakes in interpretation, I'd suggest you get rid of the asterisks and put the complete text in so that someone can sit down and efficiently read this without having to have a stack of documents beside them to cross-reference all the time. It's very difficult

DR. HOLAHAN: -- check with the APA and the Federal Register because the Federal Register wants to limit the pages, and we'd have to check with our office administration.

DR. WILLIAMSON: Well, you might make available then an ancillary document for people to review that's more efficient.

CHAIRMAN CERQUEIRA: Well, on the Web site, is that possible?

MS. CHIDAKEL: Excuse me a second. If I could make a comment on that, I'm very sympathetic to what you're saying, believe me, because we as a working group have struggled with with this, too, trying to make sure, and you say something about checking the grammar. Let me tell you I can speak for myself, and I think Roger will vouch for me. I go over this with a fine toothed comb, and I slap

Roger on the wrist every single time I think that he's made a mistake as far as grammar. I think he knows that I'm tough.

So I give you my word that I, you know -- this is nothing new. This is something that we have all paid a lot of attention to.

I think one of the reasons that this is causing a problem is because as it's set out in the format of when you publish a proposed rule, it says the NRC is proposing to adopt the following amendments to 10 CFR, Part 35.

And therefore, when we then publish the text, what we are putting in print is just what the amended portions of the rule are going to be. So I think that's where the confusion comes in, but that's because of the way that it is being published in the Federal Register, that we are highlighting what it is that we are amending, and everything that you see there is something new, something that we have changed.

The asterisks, as was said, refer back to what was in the rule and will remain in the rule. So I hope that, you know, helps a little bit.

DR. WILLIAMSON: My strong recommendation is that you find a clever way to get

this information across in a less ambitious way because this, you know, isn't helpful. These are very technical issues.

DR. DIAMOND: A clean copy would be very much appreciated. You can spend hours and hours on this with a couple different documents in front of you and still not be able to figure out the way it's done right now, which I've done.

DR. WILLIAMSON: So it wouldn't hurt you to get a secretary and put it all together in one copy so someone could read it in, you know, a normal sort of reading skills.

CHAIRMAN CERQUEIRA: Patricia, is that a possibility for the committee to get a -- Roger, is that?

DR. HOLAHAN: We'll look into it.

DR. BROSEUS: If my boss says do it, we'll do it, yeah.

CHAIRMAN CERQUEIRA: Okay. When will that go out approximately?

DR. BROSEUS: You're asking two different questions. Where does it go?

CHAIRMAN CERQUEIRA: It should go to the committee.

DR. BROSEUS: Right now we were talking

about doing something by the end of December that has a red line strike-out.

DR. HOLAHAN: Right, for the committee.

CHAIRMAN CERQUEIRA: For the committee.

DR. WILLIAMSON: Yeah. I'd like to make one more comment about the radiation safety officer T&E, and this has to do with the provision, you know, that allows, you know, as I understand there are basically three pathways for someone to be an RSO. One is the board certification route, which would be American Board of Health Physics or American Board of Medical Physics in medical radiation protection.

The second is the alternative pathway.

And the third is to be an authorized personage of some other kind.

I am concerned that, you know, if I read this language some very qualified people are left out of the third pathway. You know, for example, someone who is certified by the American Board of Radiology in I think it's called medical nuclear physics, a nuclear medicine physicist or somebody that is certified by ABR in diagnostic X-ray physics may in a small licensee be the most competent and qualified person to serve as an RSO of that

operation and may, indeed, have, you know, the experience, can demonstrate some experience with the specific applications.

But what it says here is that person's board approval counts for nothing because nowhere -- you know, authorized medical physicist basically covers only brachytherapy and 35.600 applications. So there's sort of no place in the regulatory space where these other certifications are mentioned, and I'll read you the language.

"Is an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license, or a medical physicist who has been certified by a specialty board whose certification has been recognized by the Commission or an agreement state under 35-51(a).

Well, there's no law requiring nuclear medicine certification in physics or diagnostic X-ray physics being recognized by anybody. So this isn't going to help, and I think this is not good that this group of individuals has not been, you know, recognized in the rule and that their certification can't count.

CHAIRMAN CERQUEIRA: But shouldn't they be able to meet the criteria by training and

experience?

DR. VETTER: Yeah, they could meet it by training and experience. I assume they would. The point is that they're just making is that the board isn't recognized. However in option one, is that the one for boards?

DR. WILLIAMSON: Yeah.

DR. VETTER: Those boards can apply for recognition.

MS. McBURNEY: They can apply.

MS. McBURNEY: ABS&M I'm sure would apply. They would clearly qualify, and others may apply as well.

CHAIRMAN CERQUEIRA: Yeah, it gives them the option.

I think we should take a break here before we get too far behind on schedule.

I personally would like to thank Jeff and David for all of the work they've done in going over all of the details in this, and again, for the staff, this is not to be critical. This is to try to be helpful because this is very complicated, and we've had so many versions, and when it finally comes out sometimes, you kind of lose track of the "ands" or the "ors" and all the other issues.

And so I think if you can get a copy out to the committee, you can see that people are spending time on this, and will give you the appropriate feedback that will get the rule right this time.

So I'd like to thank again Jeff and David.

We'll meet in ten minutes at 3:20 so that we don't get too far behind.

(Whereupon, the foregoing matter went off the record at 3:10 and went back on the record at 3:24 p.m.)

CHAIRMAN CERQUEIRA: All right. If the committee could take their seats, we're ready to go on to the next agenda item.

And the next item is the Novoste intravascular brachytherapy event analysis, and this was material that was sent out to the committee, and Jeff has done some work in this area before and had actually had a presentation that he put together before. So we thought this would be a good starting point to address the issue.

Jeff.

DR. WILLIAMSON: Okay. Well, I think that as everybody on the committee got the many

pages of material from the FDA event database as well as the nuclear materials event database, and I'm sure that the technical and rather incomplete nature of it was apparent to everybody.

So I thought it would be useful to go over a few of the fundamental features of this Novoste system so that we could put these events in some perspective.

And I think, you know, what I -- although it's longer, I don't think what I have to say in the end is substantively different from what Dr. Diamond and Dr. Nag said in their statements.

Well, in any case, there are actually two Novoste systems that are currently on the market. There's the original beta-cath system, which was introduced, the first system introduced in 1998, and their new beta-rail system introduced in the year 2002.

Maybe what I'll do is jump to a picture of the system and then I'll jump back to that slide and highlight the differences.

Both systems basically amount to a hydraulically propelled system that gets Strontium 90 sources from a protected enclosure through a double or triple lumen catheter into the end of the

catheter which is positioned in the artery of the heart to be treated.

The way this system works is there is a syringe that is filled with water. When one wants to eject the sources, there's a switch here which controls the direction of water flow. Water pushes on the seats, pushes them out through this gate, through the tube, into this location.

When the treatment is over and the operator wants to retract the sources, one moves this lever on the side of the device over here. This reverses the flow of water so that water runs through the other lumen and pushes starting with the distal source, pushes it back into the remote after-loading device.

Some of the terms used in these documents are the gate. The gate is essentially a little sliding door that closes off, prevents pellets from being ejected from this chamber, you know, essentially separates the sources from the catheter part so that the catheter then can be safely disconnected. So that is what that is.

The chamber where the sources are kept is equipped with a viewing window made of thick glass and it's backlit so that actually the operator

can physically see the sources when they are in the chamber.

There is also a little light, indicator light that goes on when the sources are properly retracted.

The water, this is not a closed circuit system. There is not circulating water in the system. Water is supplied by this syringe. It goes back out the other lumen and into a little collection bag, which is attached to the device.

So this shows what the source train is like. The source train in the older beta-cath system consists of discrete seeds that are approximately two millimeters long. These seeds are not radiographically visible on fluoroscopy, but the distal most seed and the proximal most seed are both gold markers, and these are visible. So what one would see when this is in place is just these two gold markers would show up radiographically.

You know, let me jump back to the previous slide.

Okay. So I don't know if there are questions from anybody about that basic description.

There are two versions of the system. The original beta-cath consists of, has 12 or 16

Strontium 90 pellets. It has a five French, or 1.6 millimeter OD triple lumen catheter system. You know, it is still marketed.

The third lumen inside the catheter is actually used for a guide wire.

The beta-rail system, and you know, my experience is only with the early one, was introduced evidently in late 2002. It has a number of engineering improvements that appear to address at least some types of the incidents that were referred to. You know, its major features are that it is a much smaller diameter catheter, 3.5 French or 1.1 millimeter OD, and I'll go through some of the changes a little bit later.

So I think there are some differences between this system and most of the other remote after loader type systems that we are familiar with using in radiation oncology. We're most familiar, I think, with the cable driven source. This would be a type of system in which the source is welded to a physical cable, and basically that cable pushes the source out from the shielded safe into the treatment position.

In this kind of a situation, there actually is automated machine feedback as to where

the source is, for the nucleotron system or the Virion high dose rate remote after-loading systems. For example, they both measure the length of wire that is reeled out of the device. So the machine has independent confirmation where the source is.

Some of those systems have the ability to sense resistance and can tell when the source is at the end of the catheter. This is not so with the Novoste system. So I think this is a major reason why we have so many incidents.

The operator must maintain positive pressure on the syringe at all times from the time the source train leaves the gate in the hand-held device until the sources are safely retracted into the chamber and the gate closed.

If one does not maintain this pressure, the sources will begin to drift and move through the tube under the influence of gravity. For the older five French device, the original beta-cath, the sources and markers can separate. There's nothing holding them together as a source train other than the pressure of water.

One other difference, I think, that is important between a hydraulicly driven system and a wire driven system is that the outer diameter of the

source must be approximately equal to the inner diameter of the catheter. Otherwise there's the possibility of turbulent flow around the edge of the source and the source will, you know, not necessarily follow the flow of the water.

With a wire driven device, one has a little more flexibility, and there can be more tolerance. What this means, I think, is that the mobility in the hydraulically driven system is going to be inherently more sensitive to little kinks and depressions in the catheter. So, you know, a lot of caution has to be taken.

All right. I know there are many technical ways of analyzing events. I, you know, just state -- I shouldn't call this mine, but it is the way I personally think about these events in my own clinical practice. So I thought I would describe these concepts. So there are really three sorts of concepts I want to get across in this little diagram.

One is the dose delivery error. Most of the events, you know, are not necessarily misbehaviors of the system, but there is some event which has health and safety implications for either the patient or the public. So it could be loss of a

source, loss of control of a source, or could be treating the wrong area in the patient or not giving the right dose to the patient.

So this is really, you know, the basis of having to report it as an event. Some kind of an error in dose delivery or accounting of the sources was made. So that's what I call the delivery error just generically.

Then I identify, I guess, what I call a primary cause and a secondary cause. A primary cause is some kind of device failure or initial operator that without detection and intervention would lead to a dose error with high probability. So I call that a primary cause. That could be all of the water leaked out and, therefore, the operator lost control of the source.

A secondary cause is omitting a QA check that had it been properly executed would have detected and reversed the consequences of a primary event. So this is kind of the flow diagram of what can happen.

We have a primary device failure or an initial operator error. If no -- the line is missing here for some reason -- we would go straight to the box, minor or no dose delivery error. Okay.

That would be the sort of normal operation. There is neither a primary causative event nor a secondary causative event.

Okay. The other possibility is that we have some kind of primary event, yes. Okay. The secondary quality assurance or safety check is performed and detects the event. In that event, yes, we go back to the minor or no dose delivery error box. In the case that this check was omitted, we have some serious or significant, reportable, or whatever you want to call it does delivery error or loss of control of the source. So I think that all of these events in my mind can be classified with respect to these three parameters: the nature of the dose delivery error or the incident; the nature of the primary cause; and the nature of the secondary cause.

And the basic theme is that if you have a primary event, but properly follow it with the appropriate QA check, you know, the treatment can more or less be safely given, but if you don't do that, then you're at the mercy f these primary events, which for this system, because of the way it's designed, you know, I think has a higher background incidence of primary events.

So what were the major types of primary causes. Based on reading all of this, I'm sure there are other ways we could classify them, but I classified thusly. So one basic classification is failure of the sources to reach the treatment position.

Well, what could be the two primary causes of this? One is loss of positive pressure. As I mentioned, if you don't continually keep applying some pressure on that syringe, one will lose control of the sources within the closed catheter system. I don't mean lose control in the sense of losing them or dropping them on the floor, but you won't be able to manipulate or control their location in the catheter system

So there are a lot of underlying causes for this. Some of them are user errors. Some of them are failures of the devices, which you know if you read this, a typical user error is fumbling around with a second syringe and not getting it in there in time if you run out of water in the first syringe. Why might you run out of water with the first syringe? Well, there's a history of some of the seals on the device leaking. There's a tendency to push to much positive pressure so that you use

the water more quickly than you need to.

There is a history of seals leaking, as I mentioned, and even parts of the system fragmenting and plugging up the plumbing. So here is an example courtesy of my Dr. Zu Fang Li at Washington University, showing how an O ring got deformed and caused the system to leak excessively, which you know jeopardized the user's control of the sources within the catheter system.

And at least one of the other incidents, some screw evidently came loose inside and plugged up the system and prevented routine operation of the device.

Another major category of events in my mind was the catheter kinking; then if that happens after the source is out, it makes it difficult to retract the sources. If it happens before the sources get in treatment position, you can't get them in treatment position.

So early in the experience with the first generation of the system, tightening the Touhy-Bourst valve too tightly was a common pathway of failure in the, say, period 1998 through 2001. And the Touhy-Bourst valve is an interface. It's a valve on the guiding catheter, the bigger guiding

catheter that's put in through the patient's femoral artery and into the heart before one uses the system.

Then after that guiding catheter is put in, one puts this little valve, the Touhy-Bourst valve, on the end of this to keep the blood from back-flowing out, and what one has to do is unloosen that and put the treatment catheter in and then after it's in place, tighten it enough so that blood doesn't squirt out all over the place, but not so tightly that it crushes the catheter.

And so getting that right and figuring out how to use the protector sheath that was eventually introduced, you know, that's one mechanism.

It appears that the beta-rail 3.5 French catheter -- I don't have direct experience with this -- but it is at least initially, its first generation was quite sensitive to damage during the unpacking or perhaps even in the insertion process. So it would tend to kink, and some of the most serious and potentially harmful medical events that were reported had to do with this being kinked eight or ten centimeters proximal to the target region that one wanted to treat and injecting the sources.

They stop at the kink, and the user didn't recognize this and gave the whole treatment to the incorrect segment of vessel. So underlying causes for this sort of thing might be Touhy-Bourst valve inadequacy either, you know, in terms of its basic design for this purpose or lack of skill on the part of the operator, excessively fragile catheters, or handling that's not gentle enough on the part of the user.

I think these are all underlying causes, you know, might be underlying causes for the various events. It's very hard to tell from the short, one paragraph descriptions that we got.

Okay. So here are some other primary causes. Source retraction failure. Again, I think the two causes of this would be positive pressure loss again after the sources have been delivered to the correct location. Another is kinking, some sort of kinking that occurs after the sources have been delivered, but before they have been retracted.

There were a couple of incidents of incorrect treatment calculation. This seemed to be only two out of the approximately 50 or 60 that were reviewed. One of them, according to the FDA report had to do with a ten percent error in the

calibration on the part of the vendor.

Another had to do with a user error, failing to set the target time properly in the stop watch, I think.

There is a third kind of event that I mentioned, which is the loss of source train integrity. This is where the seeds drift apart, and this, again, can be due to either positive pressure loss or kinking of the tube.

So now what are some of the secondary and primary causes? Okay. So I've gone over the primary causes. So let's consider, you know, some of the events. So one class of dose delivery events was large dose to the wrong site, as I mentioned. So different combinations of primary and secondary events that could give rise to this would be kinking followed by inadequate fluoro localization.

And what do I mean by "fluoro localization"? Well, on the treatment catheter in the first generation of equipment, they were equipped with little gold bands which mark essentially the distal and proximal boundaries of what you want to treat. So when one inserts this treatment catheter into the patient, you know, you don't see this middle stuff at all. All you see are

those two gold bands, and so obviously it is the cardiologist and radiation oncologist's job to make sure that the treatment segment is straddled by these two golds bands.

Then after that is properly positioned and you see that on fluoroscopy, then you connect the treatment catheter and inject the sources. As I mentioned, you cannot see the individual pellets. You can only see the distal and proximal gold seeds. So what you are looking at are these little two gold bands on fluoroscopy, and what you're trying to do is get the little two gold bands to straddle or bracket the distal and proximal gold seeds.

So what you see on the fluoroscopy in addition to the normal anatomy and the contrast material that's periodically injected is you see these four metallic objects. You see the two gold bands which are fixed to the catheter, and you see the two gold seeds which mark the seed train, and you have to keep watching that. And you know, the little gold seeds can move, indicating that the source train has become mispositioned. That's a key, a clue to the operator, you know, to give some more pressure to get them back in place, and so forth.

So radiographic verification would mean clearly being able to observe that these four indicators are properly lined up. Now, if the catheter had kinked and the sources were stuck somewhere proximal to the treatment site, the appropriate secondary QA check would be doing this radiographic visualization, realizing, oh, I only see two gold bands, not the two gold seeds, and then immediately retracting the system. That would give a little bit of dose to some wrong site, but not a lot.

Okay. So the large dose to the wrong site is given by a combination of kinking and failing to execute this fluoro localization test properly or not interpreting it properly and quickly retracting the system when this happens.

So on retraction the same sort of thing can happen. When you're retracting the sources after the treatment, there could be kinking or pressure loss. Either one of those could stop the sources somewhere midway between the treatment site and the hand held device, but there would be no problem as long as you executed a timely emergency response.

So the appropriate QA or safety action

here is quickly detect that either kinking or pressure loss has occurred and the sources aren't coming back like you expect them and yank the system out really fast so that you minimize dose to an unprescribed site.

Another sort of event would be pressure loss or source drift leading to a separation of the pellets. That would be the primary cause, but not doing fluoro localization every 30 seconds as recommended. You might not know that. If you waited until the end of the three minutes, they could have been separated for most of the treatment time and you wouldn't know that.

But if you executed this very appropriate QA test per the scheduled intervals, you would have had an error amounting to only 30 seconds at worst. So that would add minimal consequence to the patient.

I guess the other category of bad things is over or under dose to the treatment site. That could be caused by initial calculation or calibration error. That would be the primary event leading to this under dose.

The secondary -- I'm having trouble with this -- the secondary event leading to this under or

overdosage would be inadequate checks. So obviously the checks would have to be, you know, a careful independent review of the treatment time calculation before you start, and upon receiving the device initially, doing appropriate calibration checks to make sure that the vendor supplied calibration was correct.

Another primary cause could be for an over or under dose untimely traction due to, again, our friends kinking or pressure loss followed by or combined with untimely emergency response, that is, failure of the user to promptly detect and react to the occurrence of these two primary events.

So anyway, this is how I look at it. So I kind of see these things as an interplay between the properties of the device and the vigilance and meticulousness with which the user applies this device to treatment.

Another is obviously loss of source control upon retraction. Okay. Well, what can happen? The FDA reports indicated there were a few reported incidents where the indicator light that indicates green when the sources are properly retracted sometimes didn't always detect that the sources had started drifting back out the tube, and

this is because of the way this little chamber is designed.

The detector is designed to detect the distal seed. Then it goes green, but if from the time you retract the source train, depending on how you orient the device and you don't keep positive pressure on it, it's possible that the source train could drift like this and the detector might detect the proximal seed, meaning that some or all of the seeds are out still in the catheter, and then if you shut the little gate and then disconnect the catheter from the device, well, guess what. You have seeds all over the place.

So here the failure is -- of the device is indicator light says okay, but yet there is source drift. That's the primary event.

The secondary event is failing to keep the positive pressure on and visually look through the little window and make sure that you can see the two gold markers before you close that little gate.

So the proper response would be if you didn't see everything, not to separate the catheter from the device, but put the thing into the bail-out box until it can be examined more carefully.

Similar sort of scenario for sources jamming in the gate. I think obviously various device failures could lead to that event, but either the user should carry out these two secondary checks looking at the indicator light and looking through the little window to see that the sources are there, being aware that this is a possible error pathway.

DR. MILLER: Can I ask a question?

DR. WILLIAMSON: Sure.

DR. MILLER: This is for my own education. Jeff, so your gold seeds give you your indication that you've either delivered the seeds to the right spot or had fully retracked if you can get the indication from both ends.

DR. WILLIAMSON: Yeah.

DR. MILLER: Is there any opportunity, given the design of this device, for an expansion of the catheter in such a way on the diameter such that the gold seed and the source seed would exchange position or is that impractical?

DR. WILLIAMSON: I don't think that could happen.

DR. MILLER: No?

DR. DIAMOND: Yeah, none of the reports

indicated that, and I have not heard that. I did consult several colleagues in the preparation of this.

They actually have in the new system improved the design. They have actually taken and made the source train into an integral hole so that it actually can't drift apart. So they've eliminated several mechanisms of failure in their current generation device.

Can I finish or --

DR. WILLIAMSON: Do you want me to finish or do you want to?

CHAIRMAN CERQUEIRA: Why don't you finish and then we'll come back, yeah?

DR. WILLIAMSON: Yeah, I'll quickly go through this. So what would I think the ideal QA program would be?

Well, it's very similar to what I recommended in, you know, one of the first information notices that, you know, I was unwilling participant in, so to speak, while I was a physicist at Washington University.

We had one of the early Touhy-Bourst valve misadministrations, and as a result we had a major investigation both on our part at Washington

University and the U.S. NRC, and this was the set of recommendations we came up with at the time for how to handle these.

So, you know, some obvious things that we would do with all devices: verify the calibration and labeling of all sources; double check treatment time, et cetera.

More important, we had three types of equipment checks that we recommended. First, before inserting the catheter, treatment catheter, into the patient, do a test run of that very catheter with the remote after loading device that contains the actual radioactive sources. That will test for leaking, a damaged catheter, and malfunctioning of the catheter device interface.

After the catheter insertion, perform a test with dummy remote after loader, with dummy seeds. That will allow you to see without radioactive sources whether you can localize these things properly by fluoro and make sure that the catheter hasn't been damaged during the insertion process.

So those were two tests. Obviously during treatment, initial fluoroscopic localization is essential. It's just essential. It's not just a

passive check. It's essential to the correct operation of the device to make sure the sources are there.

Verify the source positioning every 30 seconds. Insure positive pressure. Have an extra syringe available. Use the Touhy-Bourst protector sleeve if possible. During after-retraction --

DR. NAG: Can you explain what you mean by the protector sleeve?

DR. WILLIAMSON: Which one?

DR. NAG: Touhy-Bourst protector sleeve.

DR. WILLIAMSON: Yeah. After maybe the first couple of years of experience, just after the device got FDA approved, the company introduced a sheath that was made of slightly more rigid material that would actually -- you know, was about, I think, ten centimeters long or so. It would go around the treatment catheter, go inside this valve, and then you would tighten the valve down on that, and this is actually, I think, part of the licensing guidance that you have to use this unless there's some medical contraindication.

It has been somewhat controversial in the community because it is more difficult to keep blood from squirting out.

During an after-retraction, maintain positive pressure until the gate is closed. Visually count the sources before closing gate. Don't disconnect the catheter if you think the sources haven't returned. Survey within window instrument the proper instrument for detecting beta rays, you know, before you release the operating room.

So I think the recent beta-rail has a -- I think this is important to recognize -- the recent system has some improvements. It comes now with a dummy source train that's pre-inserted into the catheter so that, you know, hopefully, you know, when you insert this you can check radiographically. Can you see those spots on the localization dummy?

It may even make the catheter more stiff so that the possibility of kinks might be reduced.

As I mentioned, the Strontium 90 pellets are now encapsulated in some kind of a steel spring so that they can't retract.

My colleagues report that the plumbing is improved. There's less of a propensity for this system to leak, but there are, you know, still some remaining primary causes, the possibility of catheter deformation by the Touhy-Bourst valve.

The dummy source train prevents on-site testing of the catheter or makes it certainly more difficult, and there's kind of a tradeoff there, and you know, I guess it remains to be seen whether the catheter kinking has been reduced.

I guess I'll just jump to my conclusions. So my conclusions are that because of its design, the beta-cath has of the order of a tenfold higher report rate. Well, this is an observation, no "because." Beta-cath has a historically tenfold higher reportable event rate, about ten to the minus three, judging from the number of incidents in my guesstimates of how many treatments have been carried out, and other byproduct modalities.

I believe this reflects a higher rate of primary causes relative to other modalities, such as high dose rate brachytherapy, placing more dependence on meticulous execution of the secondary QA checks by the user than other types of systems.

Most primary failures can be detected by appropriate technique, quality assurance, and training. So I am not saying as an individual, and I don't think anyone else within our group of five would say this system cannot be used safely.

It can, but I think this feature of it has to be recognized, that the sort of background rate of events that you have to respond to is likely to be higher.

Regulators have to realize successful management of primary failures will result in some small, clinically insignificant dose errors. There are going to be, you know, a certain fraction of treatments where these sources are going to be in the wrong place for 30 seconds.

I think in the judgment, again, of the professional community, this is not a serious threat to the patient. Treating the wrong segment to something near the therapeutic dose would be, but this, you know, is going to be kind of a consequence of successful management. So they shouldn't be viewed in the same way as events caused by unsuccessful management.

I think the third bullet point is that there have been some design improvements made to the 3.5 French system. I don't really know how much experience. I take it it has been fairly short, less than a year maybe, and this may reduce the primary failure rate significantly. I think we'll have to wait and see.

So to some extent the backlog of events, you know, really may reflect an earlier, less robust engineering design of the system and may not be reflective of the current one.

So that's it.

CHAIRMAN CERQUEIRA: Thank you very much, Jeff.

You know, as part of this discussion, the American College of Cardiology was also kind of notified, and Dr. Al Raizner, who is an interventional cardiologist is also here, and I think we'd be happy to take questions or make some comments.

And I believe some of the people from the company itself are here as well.

Al, do you have any comments you'd like to --

DR. RAIZNER: Yes. Jeff did a great job. I read through every one of the reported problems, and he did a great job of categorizing them.

I would add a couple of comments that really are not different than what he said, but one is that for the cardiology community, the development of this 3.5 French catheter has been a

great advance from the standpoint of safety to the patient because it's a smaller catheter. It allows getting to the smaller arteries.

It also allows flow around the brachytherapy catheters so that the patients tolerate it, and there's less ischemia, less loss of blood flow during the therapy.

So the big picture has been that it has been an improvement in safety to the patient from the cardiology standpoint.

I particularly liked his thought about trying to do a simulated dummy run. The way this system is designed now, there is a dummy catheter inside that you remove when you position the catheter. So you're not really testing the ability of the source train to get to the site.

And if you look at the numbers of these failures, the overwhelming majority was due to some tortuosity or kinking, where the source train cannot get to the site adequately. So the dummy system that's there now is not a complete dummy run. It partially solves that issue, but it really doesn't solve that problem.

It would be nice, and I don't know. I hope Novoste is here or is aware of some method of

doing an actual dummy run before the real radioactivity is given.

I also want to emphasize that the vasculature in the vascular brachytherapy dose mispositions or dose errors I believe are benign because they will be in arteries that are larger than the artery that you want to get the source to. So the amount of actual radiation that's received by an artery incorrectly or tissues around the artery will be minuscule and I believe probably benign.

The bottom line is that I think it's very important that cardiology continue to have this system available to it. One of the three systems that was approved was already withdrawn by the company because of economic reasons. That leaves two.

This system is very user friendly. We would like to see some improvements in some of the issues that Jeff brought up, but we still think that the large picture is that it has been a very important advance to us and to the patients who present a very bothersome problem of recurrent narrowing within an artery.

Thank the committee for listening

CHAIRMAN CERQUEIRA: Thank you very

much.

Dr. Nag.

DR. NAG: Yeah. Well, one comment and one question. The comment is, you know, Jeff has done a wonderful job. I would like to emphasize one clinical thing, which is that when the catheter is outside the body and it is basically in a straight line, if there is a minuscule increase in friction or resistance, you may be able to get by. Once you are in your situation with what happens inside the body and you have multiple curves, then even the slightest resistance will prevent a source from getting through.

If you have it in the end of a wire, you may be able to push it through, but if you're just having the force of hydraulics, it will not work. So that was my comment.

The question I have is the new catheter design, the 3.5 French, it will be smaller and, therefore, it will have that separation applied to the small artery, but how does that design help to overcome some of these friction problems, kinking problems, increased resistance? In fact, in the smaller catheter, you may have more resistance.

So I'm not following how the new

catheter design will help overcome some of the problems that we've had.

DR. WILLIAMSON: My impression is that in itself it doesn't. It actually makes the problems worse. It seems from the reports it's more inherently fragile and subject to damage and deformation, and plus, it affords the clinician the opportunity, you know, as Dr. Raizner mentioned, to get it into more torturous, smaller arteries. So that in itself increases the likelihood of an event.

Now, you know, as I understand, at least, you know, I talked to three physicists who have had some current experience with the device, and you know, their anecdotal impression is that putting the dummy tape, loading it or inserting it into the patient with the dummy cable in place to some extent protects it from kinking.

DR. NAG: Sure.

DR. WILLIAMSON: Okay. But, you know, that remains to be seen. I guess I think that it's probably on balance something that's good for patients to have this smaller catheter, but I would strongly advise that some sort of realistic dummy run be done to make sure there isn't a kink that prevents the sources or something very close to the

geometry of the sources from going into place.

That would, you know, maybe add a couple of minutes or maybe less to the cardiology, to the procedure time.

As I understand, a dummy hand held device, I think, can be made available by the company if it's requested, but it's not routinely offered with the product when you buy it. It guess it's an option that the user can have.

DR. NAG: And my question is if any of the Novoste representatives are here, they may be able to help answer the design of the catheter. Is anybody here?

DR. SULEIMAN: Could I ask a question? Are there other 3.5 catheters on the market or could that be an underlying -- I mean obviously the smaller, the more difficulty.

And what's the dose? These are used for restenosis purposes? And what are the doses that you normally deliver over what period of time?

DR. WILLIAMSON: Yeah.

MR. REED: I'm Craig Reed. I'm the Director of Radiation Science and the Radiation Safety Officer for Novoste Corporation. We're in Norcross, Georgia, and this is Adam Lowe, who is the

Vice President of Quality Assurance.

And first of all, I'd like to express my gratitude to Dr. Williamson for such a spot on (phonetic) assessment. You know, there are some technical details on the presentation that we can clarify for the old device design and the new device design and some changes, but the general assessment of the user failures and the pathway to failure analysis and the AYX is spot on, and those things are addressed in the user's manual and they're covered in training.

So you know, those things should be pointed out as important to the user, and we're trying to do that.

DR. WILLIAMSON: Not the in vivo dummy run. That is not part of your current procedure. At least I'm told that.

MR. REED: Are you talking about for the 3.5 French system?

DR. WILLIAMSON: Yes.

MR. REED: The user manual does include and mentions the existence of an inactive dummy train and kind of explains the design of that catheter. The newer 3.5 French catheter is a coaxial. There are two lumens; there are two tubes,

and to your question, Dr. Nag, is how do you address the interface issues with the smaller catheter. The source train is smaller.

DR. NAG: Oh.

MR. REED: So in the original system the source train diameter was .64 millimeters. In the new system it's about .47 millimeters, and there's also a coil that holds that train together with respect to source drift, and we can talk about some of those other issues, design changes and improvements in the new system.

But with respect to the dummy run question, the newer catheter has what we call an IST, an indicator of source train. Because that catheter is smaller in diameter and it is, you know, a smaller catheter in order to meet through the needs that Dr. Raizner mentioned, on that wire there are radio peg markers. The furthest distal marker on that wire is actually slightly larger in diameter than the jacketed source train that's used in that catheter.

So upon retraction of that wire from the catheter after it is positioned under fluoroscopy, the user will be able to feel a bump or kink that's created during positioning.

Now, after positioning, the patient moves, the heart moves, the catheters can pop out of arteries. Those things can contribute to the potential for a catheter to kink before a train is delivered or after train is delivered.

So in a situation where it happens before a train is delivered, as Dr. Williamson points out, it's important, very important, that visualization be confirmed under fluoro. It's essential. It's not suggested. It's required.

And in the situations where the catheter kinks after the source train has arrived and the treatment has been delivered and the sources don't return to the device promptly as expected, then the system -- a manual bail-out is initiated to remove the entire system, and that's how that is dealt with.

So were there any specific questions that I didn't touch on just then?

Oh, you asked about dosing, the dosing. The system was used in clinical trials with a prescribed dose or reference dose of 18.4 Gray a half a millimeter into the vessel wall. For the two ranges of vessels that were studied, 2.7 to 3.35 millimeters in diameter and 3.35 to 4 millimeters in

diameter, that translated to reference doses of 18.4 Gray and 23 Gray at two millimeters.

So each certificate that comes with the device provides the dwell times for those two doses and the physician determines which dose is appropriate based on the vessel diameter.

CHAIRMAN CERQUEIRA: If I could just make one comment, too, for those of you that aren't, you know, cardiologists or medically related, I mean, you have to remember that this catheter is inserted into the groin, into the femoral artery, and then it is sort of advanced up into the heart around the arch of the heart, and then you have to position it in such a way that it goes into the coronary arteries, and all of this movement and manipulation is being done at about a foot and a half -- I'm sorry -- maybe two feet from the actual heart.

And so you're twisting this and you're going through these vessels that by definition are diseased and they're twisted. They have calcium in them in some areas, and you finally get out into an area where you've put a stent to open up this vessel, and over time this tissue has grown into it.

So you have to manipulate the catheter a

great distance from the leg. It's a very thin catheter. It has to go through very torturous areas, and by definition you get kinking. There's no way to avoid it.

If you have a proximal vessel, it's a fairly good size and easy to position, but as you go to these vessels that are further in the coronary arteries, they have to go greater distances. There's more tortuosity and the vessels get smaller, and that adds to the complexity from the cardiologist's perspective of getting it to the right position, leaving it there, and then pulling the catheter back.

So you have to understand that context. It's not like, you know, you have complete control over this and you've got these big vessels and you're just putting it there or pulling it out.

DR. SULEIMAN: So what was the typical dwell time?

MR. REED: The typical dwell time might be three to four minutes. The typical dose rate, reference dose rate, is about .1 Gray per second at two millimeters.

DR. WILLIAMSON: I would think though in addition to visualizing what you call the IST and

what I call the dummy source train would be after the retraction of the dummy source train to connect up a hand held, remote after-loading device with dummy seeds in it, do a test run to make sure you can get the seeds in place, see them, get them back, then disconnect the dummy source remote after-loader, and connect the radioactive, the Strontium-90 remote after-loader and do the treatment, would be, you know, a prudent step given the high rate of historically at least of what I call primary causes.

MR. REED: Well, I'll have Adam Lowe talk to the rate so that we can get that in perspective.

What might be prudent for radiation oncology isn't necessarily prudent for individual cardiology. In order to connect the system, to position the catheter, then connect a dummy system, and then disconnect the dummy system is going to introduce a non-sterile fluid into the treatment area. So that adds an additional risk.

DR. DIAMOND: There's also one other concern. You know, some of these patients, Jeff, are unstable, and I'm just concerned that occasionally you'll have a patient who you want to get in and get that catheter out even if it's a 3.5

French system as quickly as you can, and I would assume there are situations that any additional length of time that catheter is in there could have an adverse effect.

Ideally, of course, that extra step only further reduces the likelihood of a serious event from occurring, but I can certainly think of occasions where you want to get out of the patient as quickly as you can with that in the patient's coronary system.

MR. REED: Exactly. It's a balanced risk analysis between an additional dose or an under dose versus a coronary event. Okay? One being a potential harm, one being without question harm.

So there's a balance in that risk analysis which we've done to arrive at this particular device design, and so we understand that there may be situations which such advice would be useful, and we've qualified and designed such a device, but in practice, it's not necessarily feasible or necessarily in the best interest of the patient.

So, you know, we've tried to come up with the IST solution, as well as continued development on the catheter to make it more robust

and resist kinking in areas that might be prone to kinking.

So I'm going to let Adam talk to --

CHAIRMAN CERQUEIRA: I believe Dr. Nag had a question.

DR. NAG: Yeah, one question. The risk would depend on the increased time obviously. How much time are you going to increase by adding a dummy line?

Under half a minute, and I think the increased risk will be minor, whereas if you're going to add two or three minutes, then there's obviously going to be a much bigger risk.

MR. REED: It's a good point. The time you would add would be preparation and qualification of the dummy device because it's still being used on the patient. Okay? So that device has to be bagged, be taken into a sterile field. Syringes have to be prepared. Fluid collection bags have to be prepared. It adds -- it's more than just the time in the patient that contributes to the patient's time on the table.

So it would be more than just the time that the dummy train is in the patient. That's also going to add fluoroscopy time for the patient. So

all of those things add up to additional time and exposure for the patient.

DR. WILLIAMSON: Well, now preparation is going to add to the cost of the health care provider. That can all be done in advance. The patient doesn't have to be lying there while you do that. That can be prepared in advance or collaterally with some of the other procedures, some of the other topics.

MR. REED: Well, to address that question, let me address that. What you're suggesting is that perhaps the medical physicist and oncologist and the cardiologist have all of this time to do the prep when, in fact, our experience is that the medical physicist and oncologist and cardiologist are already pressed for all of the other therapies that they currently deliver, and it's already a challenge on the system to get this therapy to the patients, considering all of the proximity issues and challenges of competing therapies.

So it may seem small and incremental, but what it really adds up to is a patient won't get treated.

DR. NAG: We do a dummy line on a

different system, not the Novoste system, but we do a dummy line on all of our intervascular, and it takes about 20 to 30 seconds extra to do that dummy line, and we have no problem with any increased time because that, you know, -- the whole treatment is still done within about three to four minutes.

MR. REED: And that's, you know, the feature of another system.

CHAIRMAN CERQUEIRA: And you're treating vessels that are much larger in size.

DR. NAG: No, no.

CHAIRMAN CERQUEIRA: Where are you treating, in the renals?

DR. NAG: No, no, no. In the artery vessels with the P-32 guidance system.

MR. REED: Can that system get to all of the same places that this system can get to?

DR. NAG: We do most of the distal arteries, too. So I have never used -- I have never gone to -- I mean, I have seen the Novoste system, but I haven't personally used it, like how much distally you can go further than the other systems.

MR. REED: Other questions that might be asked is was the source on a wire.

DR. NAG: Yes.

MR. REED: What kind of arteries can be navigated? What kind of turns can be navigated?

So there are balances to all of those variables, and I'm not saying one is better than the other. They each have their own particular use for the particular team that's using them.

DR. NAG: Yeah, but what we're saying is that a dummy line can be operated with minimal extension of the time. That's the only thing I'm trying to say. I'm not trying to compare your system with other systems. I'm just talking about the increase in time in getting your dummy line. If it's less than half a minute, it's well worth the time.

MR. REED: Well, that might be offset if you had a different understanding of perhaps the frequency of the rate of events perhaps.

MR. LOWE: You know, one thing that's important to look at --

CHAIRMAN CERQUEIRA: Tom had a question here.

Tom.

MR. ESSIG: It may be for either one of you gentlemen.

I was just curious. Will the three and

a half French system eventually replace the older?

MR. LOWE: The 3.5 French system is obsoleting the five French system.

MR. ESSIG: Okay.

MR. LOWE: But both are currently available at this present time. Maybe one thing to look at is the location of the kinks on the catheter. As we have a complaint handling system and we do record the complaints against the product, two thirds of the complaints register for catheter kinking on the 3.5 French system are proximal, just distal to the proprietary connecter where it connects to the transfer device.

A much smaller number have been reported in the very distal region of the catheter where it's actually at the treatment site.

We've recently gained FDA approval for a modification to the design that adds an additional strain relief and a more robust section back on the proximal end to eliminate any kinking due to handling by the user. The proprietary connector, which is the piece that connects into the transfer device that's attached to the catheter was a very, very short, short member, very difficult to grab onto and to insert into the transfer device.

We have since gone to a much longer honeycomb style strain relief that allows the clinician to firmly grasp the catheter to insure proper insertion, to get a good connection to the transfer device without kinking the area just immediately distal to the small strain relief on the old catheter.

And that was launched in late August, and right now all of the inventory that we're currently shipping out has the new strain relief design. We're currently also working on distal improvements, improvements to the flexibility of the distal point of the catheter, distal end of the catheter that will hopefully minimize kinking.

You can still kink the catheter. You can kink any catheter. You can kink plastic. That's just the nature of the plastic. The only way to keep it from kinking probably is to make it of steel or something.

But one thing that we have seen even with the implementation of a dummy run or the IST, some of the complaint investigations that we've performed where we've gotten the Sun-A (phonetic) images back from the actual procedure shows the catheter being placed, properly positioned.

Everything is looking good. All of a sudden the guide catheter kicks out of the artery. It creates a fulcrum point for the smaller delivery catheter. The guide catheter actually winds up kinking the delivery catheter.

Even if you had a dummy run that you had sent down and then went to switch out the active run, you probably still would have run into that same situation if the guide catheter had kicked out of the artery.

So, you know, even the advent or the implementation of a dummy run over and above the indicator of source train still I don't think would mitigate all of the failures that we've seen on the distal end.

The 3.5 French system is a distal rail design so that it only contacts the guide wire in the last two centimeters of the catheter versus the over-the-wire design of the five French system. So it's a different animal, different technique. Converting the user base from the five French over-the-wire construction to the 3.5 French distal rail construction obviously required some additional training and use in handling because it was a smaller catheter and a different configuration to be

used with the guide wire itself.

Looking at the complaint rates, with the information that was provided to us prior to this meeting, looking at the 2001, 2002, and 2003 complaint rates, breaking the date of event out against our sales, we're running at about four events per 10,000 for 2001, five events per 10,000 for 2002, and about five events per 10,000 for 2003.

So it's really on the order of ten to the minus fourth as opposed to ten to the minus third.

Where we had the largest number or the higher percentage, where it was, in fact, ten to the minus three, was during the clinical trials where we had modified our instructions for use and improved our training program as well as our design to make sure that we mitigated the minor device malfunctions that were reported during the clinical trials back in '97, '98, '99, and into early 2000.

As far as the five French system goes, the issue with the false sensing of the markers on the end of the train, that was eliminated in late 2001. What we did was we replaced the proximal gold marker with a platinum iridium marker that could not be sensed by the sensing system. So even if you had

source drift, if you did not maintain positive pressure and the source train would drift forward out of its home position within the transfer device, the distal goal marker would fall out of the sensing zone. You would get an amber light which would indicate that the source train was out of its home position.

If the plutonium iridian marker, which was on the opposite end of the train which was radiopaque but not able to be seen by the sensing system, if it fell under the sensing system, it wouldn't give you a false green signal saying that the source train was home, indicating that you could properly disconnect the catheter, which then ultimately would lead to separation of the source trains or the loss of seeds outside of the closed system.

So the platinum iridium marker replaced the gold marker on the proximal end of the train in the five French configuration because each of the seeds was its own discrete unit, and since that time we haven't had any false sensing issues.

With the 3.5 French system, it is correct it does have a spring or a coil that contains the entire source train so that you don't

get source train separation. It either gets there in one piece or it stays in its home position in one piece, but it always moves as a single connected train.

MR. LIETO: Why isn't that done with the five French?

MR. LOWE: It was an older design, and as we went through the clinical trials and saw the potential for source drift, the 3.5 French system was the second generation product, and because of the smaller seeds, one, just from a visualization standpoint that we wanted to make sure that we contained all of the seeds.

MR. LIETO: I understand that, but I mean, you're still marking the five French. Why not have that same safety feature on the five French system?

MR. REED: It was a significant development phase investment to develop actually the entire sealed source, the smaller diameter sealed source that goes into that jacketed coil, and to place it in the coil and then to get it welded on each end.

So that source and coil configuration had been approved and available, but it doesn't

obsolete the therapy that's still effective with the unjacketed train.

So the question is really a business question, at which point when do you get rid of the five French train. Well, when you no longer have those sources and you no longer have those devices and when you can make the new devices to replace those.

And, frankly, that's the biggest challenge, is producing the new device design fast enough to replace the old device design.

DR. DIAMOND: Craig, what's your time line for that?

MR. LOWE: Time line?

DR. DIAMOND: Are we talking six months? Are we talking a year? Are we talking --

MR. LOWE: I'm going to say within a couple of months. We've been continuing to convert the existing five French user base over to the 3.5 French system.

MR. LIETO: Well, then how come your new research applications are using the five French system? I mean, you've got these Bravo studies out there, and you're using the five French system. So if you are looking at new research applications with

the larger sources, it would seem to me that it would be good business sense from a safety standpoint to come up with or incorporate these additional safety features that you've designed for the 3.5 French systems to apply to the five French.

MR. REED: that's a two-part answer. The first part is you're right. It would be.

And the second part is those trials were conceived, started, submitted to the FDA back before or in the time period before we had the new system approved. So those systems were designed around initially the catheter designs, the device designs around the devices that we knew we had.

And also, those sources and those devices are going into larger vessels. They're not going into coronary vessels. They were being tried in the legs and in the arms, which have diameters, you know, five, six, seven, eight millimeters.

So we didn't have the technical driver necessarily with respect to access to the lesion to require the jacketed train, but I can tell you that in development we are transitioning to anticipate the use of that jacketed train in that scenario.

So I guess what I'm saying is in the beginning we're starting the research on that

therapy. We started with what we had available. Okay? Which was the large diameter source, and that's a logical evolution, but it just takes a while to implement it.

CHAIRMAN CERQUEIRA: Well, what was the time line then? Are you going to continue the trials with the existing catheters or will you switch over to the 3.5? And what's the time line? You said several months.

MR. REED: Well, I suppose that was really over-speculation on, you know, the progress of the trial, which is a function of patient enrollment and site participation and design.

So if you're asking me when I could tell you that I would have that design ready, I can't because I don't even have that design proven as safe and effective in the patient yet.

So the first step is to find out if that therapy even works in that patient population, and then along a parallel path we had development processes seeking use of the jacketed train in that system.

But you know, you have to balance the investment for the current market we serve in the coronaries versus, you know, the speculative market

in the arms and in the legs. So there's a balance there.

How much do you invest additionally to study these other areas when it may not prove safe and effective? Okay?

So it's a business decision in that regard.

CHAIRMAN CERQUEIRA: David.

DR. DIAMOND: I have a couple of comments. I won't go and read through all of my written comments which you all have copies of, but just to emphasize a couple of things.

Firstly, having done about 1,000 of these procedures with a variety of systems, you know, not every patient is going to be able to be technically successfully treated. We all understand that, regardless of the type of system.

And fortunately, at least in my experience, most of the kinks that I have had, whether it be the Cordis or Guidant system, have been fairly proximal, and you immediately recognize that there is no harm done.

One thing that I don't think Jeff emphasized enough was how many of these incidents were simply not detected -- this is a secondary

point of view -- how many were not detected because you just couldn't tell where these seeds were on fluoro, and I mean poor city (phonetic) or fluoro qualities. The patient moves or for whatever reason it's necessary to get a different projection from when the catheter was originally placed, and sometimes these patients that have a lot of stents or in the context of poor fluoro, in the context of a lot of staples from prior meeting of the sternotomy, it can be a little tricky to see where these are, and simply with a little experience and a little bit of due diligence, that entire class of error should be eliminated.

I personally think that this represents a success story in that as this new technology is introduced, we are recognizing why these errors are occurring, the primary causes, the secondary root causes, and I'm very pleased to say that the most recent generation of the product seems to address a lot of them, maybe not all of them, but certainly a lot of them.

And I think that as long as I'm hearing from the company that all due diligence, all due speed has been addressed to try and shift over from the older system to the newer system, that would

make me happy. If you told me that this transition is going to take a year, I think that would be too long, but if you told me that as these sources or as these devices are due for their standard rotations, the maintenance that you're rotating them through, that would make me quite happy.

As a last point, just because of a difference in design, it is not going to be nearly as easy to do dummy runs in the patient as it is with the Cordis system or the Guidant system, and I think that even with a facile operator to do an in-patient dummy with this Novoste system it's easily going to add another two minutes to the procedure.

And given the type of catheter design that's used, I'm not really sure that it's worth the additional risk to do it that way. Ideally you would, but I'm not sure as a whole --

DR. WILLIAMSON: It's not a centering catheter that they use. There's no centering catheter.

DR. DIAMOND: But it's a de facto centering because of the bulk of it, right? I mean de facto because of the bulk of the --

DR. WILLIAMSON: I guess. Three, point, five French is pretty -- it's not a spiral in this

one. This is actually one that allows the source almost to be up against the artery wall.

DR. DIAMOND: In any event, I'm not sure if you're talking about treating these very small distal vessels or highly diseased small caliber vessels that from large patient populations it would be desirable to keep that catheter in another two or three minutes, but that's just conjecture at this point.

DR. NAG: One technical question. In your 3.5 French system you have a spring, and does that make it more difficult to negotiate a sharp bend?

In other words, if you have individual sources it can bend through a very sharp curve, whereas if you're making it into a straight line it would introduce difficulty when you do a sharp curve.

MR. REED: When we designed the system, we set specifications for use, and the specification for use was a quarter inch turn radius, and that specification hasn't changed and the device still passes.

So I don't think it's more difficult. In fact, to one of the points that Dr. Williamson

made about, you know, fluid use and fluid management, this system because it has smaller diameters, it actually uses less fluid, and it's actually easier to manage fluid.

And really it's the flow rate that's pushing the train, and we've tested and retested to make sure that the jacketed train meets that specification, and it does. So there's no change there.

CHAIRMAN CERQUEIRA: Jeff.

DR. WILLIAMSON: Well, I guess I didn't make particular recommendations. I didn't think it was appropriate. This was meant to be an analysis, and I thought recommendations would follow a discussion within the committee.

I also didn't have a chance to analyze in detail the current guidance, but I think clearly for this system probably the guidance should say, "Thou shalt do radiographic localization," and I think emphasizing that with this particular system in the guidance document is very prudent.

You k now, I think that at least since historically the background error rate and hence the dependence on, you know, user vigilance seems to be higher than other systems, doing what NRC can to

encourage the treatment team to think through and negotiate a comprehensive quality assurance program, you know, is a good idea without, you know, discouraging use of the device.

So I think an information notice where, you know, other sorts of publicity to try to, you know, promote people to work together as a team to do quality assurance, you know, it varies with setting.

Sometimes, you know, it seems to the physicist that our concerns, you know, really -- we're given this argument all the time. Quality assurance isn't helpful. It's dangerous to the patient to add anything more, and really, you know, a good -- it's just desist.

And so I think something to try to, you know, improve a little bit the negotiating position of the physicist so at least those concerns do get really addressed. I think no physicist wants to jeopardize a patient because of quality assurance. We want to add value to the treatment, but I think sometimes it's simply dismissed and not thought through.

So I think there's some intangible sorts of things that could be done to try to raise the

level of consciousness, you know, and make sure that the procedure is thoroughly thought through and decisions, you know, what is tradeoffs between certainty of adequate technical performance versus patient clinical safety, you know, really do get thought through by the treatment team.

CHAIRMAN CERQUEIRA: Tom and Charlie.

What sort of input would you like from the committee on --

DR. MILLER: I think that, you know, what the Commission has tasked us to do is to continue to use the committee to evaluate events when there's a regulatory need, and I think, you know, we've touched on some things, and Dr. Williamson has used terms like changing guidance and information notice, and I guess my first question is, you know, you've pulled together a lot of information in a very short period of time from the time that you were tasked to do this.

Is more time needed to evaluate the information that you've received would be my first question.

And the second question: what will we be looking for, I think, from the committee is any recommendation you would want to take with regard to

any regulatory action we may need to take, including guidance changes or information notice or whatever.

DR. DIAMOND: From my perspective, Charlie, the data I'd be most interested in is to look at the event rate, utilizing the new system. With the current vendor training and the current procedures that are in place, the event rate appreciably drops. Perhaps that would obviate additional recommendations.

If it does not substantially drop, then obviously we will need to go and make some recommendations, some of which I think Jeff has already mentioned.

CHAIRMAN CERQUEIRA: Subir.

DR. NAG: Yeah, one of the main things not in your system, but in any system would be how -- the narrower your catheter becomes, the less opaque it becomes unless you're increasing the density of the material.

Is there any way you can increase the radiopacity of your marker so that they are easier to see even though you may have bone or lips (phonetic) overlying that area?

MR. REED: Well, you know, I would really -- I'm going to resist the urge to speculate

because I think there are a lot of features that play into that, you know, not including the size of the marker, the material of the marker, the system that's being used, not to mention the patient. Okay?

And so I'm not sure how to speculate on that. I mean, I could tell you that as part of our risk analysis that we do evaluate whether or not the system can be imaged and we capture complaints and we would attribute that as root cause, and we would consider that in the full picture of what is the overall risk to the patient versus the benefit.

So we would consider it.

DR. NAG: But the reason I'm asking may not be what -- that's not one of the experimental systems. One of the problems we found was the radiopacity of the marker, and although it was radio opaque in the normal situation, in difficult places it was very hard to see, and the company had applied several different attempts at increasing the radiopacity, up the rate, it might be easier.

CHAIRMAN CERQUEIRA: Leon.

DR. MALMUD: This isn't my area of specialty. So you'll pardon my ignorance. Has the rate of failures varied because of the inability to

image the markers based upon the fluoroscopic system that's being used, by the angiographic radiologic system that's being used?

Do some have better resolution than others, and are you aware of which equipment is used in conjunction with the catheters that you're employing?

MR. REED: Our system is licensed for use at 435 -- more than 400 sites in the U.S., which each probably have different machines and multiple machines. So I think an analysis to figure out, you know, what the exact scenario is for every user would be tremendous.

With respect to these particular events, we do gather the information. We examine the systems; we collect the data. But you know, the nature of the complaint we get or we see is not that the system wasn't visible. It's just that they missed seeing it. Okay?

Either there was conflicting anatomy or conflicting items in the patient's chest, for example, wires and things like that. So you end up with a situation where the source train moves in very quickly and they have to -- and there's usually several people that are watching so that they all

have to see it and agree that they saw it, and then if they agree that they didn't see it or somebody says, "Hey, I didn't see it. I don't think it's there," then they have to add quickly, as Dr. Williamson points out.

DR. DIAMOND: Could I? In my experience what I've seen in that situation, the source is moving quite quickly, and the problems that you've run into, the patient moves as the seeds are going in. There's a temptation to move the table for whatever reason. So the position changes for whatever reason. The cardiologist changes the obliquity of the view.

So one of the most simple things that could be done to prevent that is to simply say once we get ready to go, "Don't move." And it really obviates the problem in most cases.

CHAIRMAN CERQUEIRA: Dick, did you have a comment?

DR. VETTER: Yeah. I would find it interesting to see a comparison of the event rate for this system versus all the other systems that are on the market and a second column that shows the impact on the patient. I mean how significant is this?

One thing that made me think about that is there is an event rate for angioplasty. Not everyone survives angioplasty. Have any of these patients died as a result of these events?

You don't need to answer. That's sort of rhetorical. I'm just interested in how we compare with angioplasty and the other events, other devices on the market.

I'm trying to get an idea in my own mind how significant are these events.

MR. ESSIG: The difficulty we have, Dick, in making such a comparison is we do a fairly good job of collecting data on the numerator, but we have no information on the denominator.

DR. WILLIAMSON: We have that information.

MR. ESSIG: Yes.

MR. SULEIMAN: Well, I want to agree with Dr. Malmud's comment. I think it's extremely important to know the performance characteristics of your fluoroscopy systems. Now, these are in angiography suites. So I assume they're capable of imaging, but there are all sorts of user controls that will vary it by an order of magnitude, and so the low contrast sensitivity of the imaging system

clearly would make the difference between seeing or not seeing something.

It's critical. It's something that people spend an awful lot of time on. So I would strongly urge you to pay a little bit more attention and get the systems maybe evaluated or find out under what conditions that they're being looked at.

Clearly another way you see it is increasing the opacity of the beads, but these are Strontium 90. I mean you don't want to attentuate --

MR. REED: Well, the challenge with that is, of course, you want to get the betas out of the seed. So radiopacity works against you.

But, again, you come back to the overall event rate, three events, four events, five events, you know, per 10,000. You know, it's a challenge to draw a lot of information out of that or indict a lot of X-ray systems.

CHAIRMAN CERQUEIRA: I think some of the factors that David mentioned, that, you know, the patient moves, the catheter moves, the table moves, there are surgical clips from prior surgeries and things, all of those will enter into it, and you know, how much that contributes, it's going to be

difficult to analyze.

Jeff.

DR. WILLIAMSON: Let me ask the staff a question. You know, how many events have been reported per year on average for these systems and how many events have been reported for other intervascular brachytherapy devices?

As I understand, you know, there was quite a large difference in the absolute rate of reporting, and that is why the staff brought this to the attention, I think, of the ACMUI and asked us to get involved. At least I assume that is the case.

So maybe you could comment on what data you have and why you're interested in it.

MR. ESSIG: I don't have the data with me, but it seems like it was at least maybe ten times the rate of others, something on that order. I mean, it clearly was way above.

DR. WILLIAMSON: I think in, you know, other applications, it may have been Patricia who presented this once like five or six years ago.

(Laughter.)

DR. WILLIAMSON: You did an analysis of the misadministration rate before and after the quality management program.

DR. HOLAHAN: Yes.

DR. WILLIAMSON: And it was much smaller than, you know, I think five times ten to the minus fourth. It was really, I think, on the order of ten to the minus fifth for most of the modalities.

DR. HOLAHAN: Ten to the minus five to ten to the minus six, as I recall.

DR. WILLIAMSON: Yeah, it was really low. So this is in order of magnitude higher.

DR. HOLAHAN: The problem was even then we couldn't get a good handle on the denominator.

DR. WILLIAMSON: Yeah.

CHAIRMAN CERQUEIRA: They have 400-plus units out there. Do we know how many units are present from the other systems?

My impression is there are fewer.

DR. DIAMOND: Well, the Cordis system is being discontinued by the manufacturer as a business decision, and even before that decision was made, far fewer centers were using that particular system.

So it's very difficult making these type of comparisons when your denominator is so disparate.

I think a better comparison would be to go and try to get these numbers from the gutted P-32

product because you're talking about a lot of users out there.

CHAIRMAN CERQUEIRA: Ralph.

MR. LIETO: I was just going to, I guess, to get to when I was part of this subcommittee, and when they said "analysis" to me it was to come up with something quantitative, and even just looking at the numerator, you know, there was the NMED data. Then you have the -- is it MAUDE? Is that the FDA reports?

And it wasn't clear to me. I mean, some of the things were in both avenues, and I also get the impression that there's even data that's reported to the vendor that doesn't even have to come to the FDA.

So there seems like there's three database here, and it's not really -- I may be wrong on that point with the FDA and the vendor, but it seems like there's three potential databases here, and nobody is syncing with the other one.

You know, I even wonder if the numerator is even well known. Nobody has come up with a denominator, and I don't know where your denominator came from because I don't think the device records runs. I mean there's not like a chip that records

how many times the sources go out and come back.

MR. LOWE: The first point I'd like to make is that we do report all complaints and we do capture all complaints for the FDA.

MR. LIETO: Well, I'm sure probably databases may be greater than theirs is.

MR. LOWE: But to that point, not every complaint is a medical device report. There's certain criteria to file an NDR, a subset of our complete complaint database are the NDR reports, which is then loaded up into the MOD database. The FDA comes up to our facility, reviews our complaint database, but not every complaint is proactively reported to the FDA.

And that's a little bit different than the misadministrations that are reported because there are slightly different criteria for when to report, when not to report.

But I do agree with you. I think that there are differences in the numbers of events that are reported.

MR. LIETO: Am I right in that the device does not record runs? I mean, there's not like a chip that tells you how many times the source is --

DR. WILLIAMSON: They sell catheters. You can only use the catheters one time in a patient.

MR. LOWE: Right. What I did to get the denominator was to look at the number of net catheters sold, catheters distributed, catheters -- minus the catheters returned to get the total number of catheters, and the catheters are relatively expense. So people typically won't have large inventories of catheters at their hospitals.

CHAIRMAN CERQUEIRA: Yeah, that's good.

Leon, you had one?

DR. MALMUD: In reading the material and having reviewed the material earlier, there are a couple of questions that I had. The first one is this is reported to us, not to the FDA, in contrast to the FDA, because there is a misadministration that's defined by radiation burden; is that not correct?

And yet if I read the notes correctly, the radiation burden is really not a risk to the patient in that if the radiation burden is provided proximal in the vessel because of a kink, it will not be harmful from that which we understand, but it will not have delivered the desired dose.

Am I right so far?

DR. DIAMOND: Yes. The harm is the potential harm in that a patient -- let's say you ended up treating the femoral artery instead of the coronary. The main harm is that the patient who could have benefitted from treatment did not receive it as opposed to the fact that the uninjured femoral artery is going to be harmed to the best of our knowledge at this time.

DR. MALMUD: Well, will the femoral be harmed? You mean the femoral is getting it instead of the coronary? Is that what you mean?

DR. DIAMOND: Let me say that again.

DR. MALMUD: No, I'll restate my statement.

DR. DIAMOND: Given 13 or 15 or 18 Grays to an uninjured femoral artery, we do not think has a significant likelihood of causing detriment.

DR. MALMUD: Correct. Neither do I, and I wanted to make sure that I was correct in my assumption.

Okay. So the radiation burden, which is what we are concerned about as a subcommittee of the NRC or an Advisory Committee of the NRC, is the failure to provide the dose, not the danger from the

dose having gone to the wrong body part because the radiation burden does not seem to cause any harm of which we are aware at this time.

DR. WILLIAMSON: I don't think you can say that.

DR. NAG: That's not correct.

DR. MALMUD: That's my question.

DR. NAG: That's not correct because if it is in the aorta or other really big vessel, then, yes, it is correct, but when you're going into one of the artery vessels, but not the injured coronary vessel --

DR. MALMUD: Right.

DR. NAG: -- in which case that portion of the coronary vessel wouldn't get substantial in a 15, 20 way (phonetic).

DR. MALMUD: It will get the radiation burden that was meant to be provided to the area where the stent is. Again, I'll rephrase my question because I'm not expressing myself well.

Is that radiation burden truly harmful? Is three any evidence that it's harmful to that segment of vessel that should not have received it?

DR. HOLAHAN: Well, I'd like to speak to that because basically we don't look at what the

radiation damage is. We look at the medical event not treating the right treatment -- treating the wrong treatment site, and we get a medical consultant to consult with us on whether there's harm.

DR. MALMUD: I understand that. I fully understand what you just said, and I agree with you.

DR. HOLAHAN: Okay.

DR. MALMUD: But I'm still trying to understand the problem and to clarify it and then bring you to my real question.

DR. HOLAHAN: Okay.

DR. MALMUD: Okay. So it appears that the problem for us is that the radiation was not provided to the correct segment of -- let's talk about the coronaries -- the coronary vessel. Instead it went to a different segment of the coronary vessel. This is a misadministration and which deservedly is reported.

However, no harm is done in terms of there being a patient catastrophe as a result of this, except the patient didn't get the therapy that we expected the patient to get.

DR. HOLAHAN: Yes.

DR. MALMUD: Okay. Now, how many of

these catheters have been sold?

MR. LOWE: Over 70,000.

DR. MALMUD: Okay. Now, there must be some database as to what the clinical negative outcome is to a patient who didn't get the therapy they were supposed to get. This is in the course of being delivered the therapy, yet not receiving it for mechanical problems.

Infarct, or is that proprietary data? In other words, I'm trying to think as a clinician for the moment and not as a nuclear scientist. In the course of trying to provide the therapy, there was a failure for a variety of reasons, all of which may be clinically acceptable, and that the wrong part of the vessel got radiated. Okay. No harm that we're aware of to the wrong part of the vessel.

But in the course of trying to provide this therapy and failing, do any of these patients have an infarct with a kinked vessel -- I mean with a kinked catheter in there?

MR. REED: But the question you're asking is what do we know about that.

DR. MALMUD: Yes.

MR. REED: And these events occurred in the clinical trials, and the sum evaluation for the

patients was the therapy was safe and effective.

DR. MALMUD: So this all occurred during clinical trials when FDA was monitoring it?

MR. REED: Yes. These events did occur, and they're addressed in the user's manual, and it has been resolved.

DR. MALMUD: You've answered my question and concern.

Is that a fair analysis? We've got a representative from the FDA.

DR. SULEIMAN: Generally. I wouldn't agree with all of your absolute conclusions. I think delivering 20 Gray anywhere some would argue is not necessarily safe, but how are you going to determine that when you're having trouble figuring out the efficacy of the procedure?

So, I mean, these are issues. This is research, and so you don't have the answer. So to conjecture without any evidence is of concern, you know.

DR. MALMUD: And right now we have no idea from the data submitted and from the thorough reports which are here as to the incidence of this problem.

DR. WILLIAMSON: The incidence of what?

DR. MALMUD: We know the numerator, but we don't know the denominator.

DR. NAG: Yes, we do.

DR. WILLIAMSON: We know roughly.

DR. MALMUD: We do know the denominator?

DR. NAG: You take the number of --

DR. MALMUD: Seventy thousand, 70,000?

DR. WILLIAMSON: And we have something like 50, 60 events.

DR. MALMUD: In 70,000?

DR. WILLIAMSON: Yeah.

DR. MALMUD: And the alternative therapy, is there another manufacturer that provides a 3.5 French catheter system?

DR. WILLIAMSON: No.

DR. MALMUD: No. So we have to assume that a 3.5 French catheter will go more distally in a coronary artery branch than will a five French. Is that a fair assumption?

I ask the cardiologists that question.

Or will the five French go as far as the 3.5?

CHAIRMAN CERQUEIRA: Dr. Raizner, I think, could be the expert.

DR. RAIZNER: I can answer that very

well. A dramatic improvement in which vessels we could get to in terms of both the distance and in terms of the complexity when the 3.5 French system was introduced.

I also can address the issue of radiating a misadministration in a coronary artery. In every case there's radiation of normal artery. In fact, it's a goal of therapy to radiate the area, but to have a wide margin of radiation proximal and distal to it.

To date there has been no issues related to that wide margin. In fact, there have been issues related to not having enough margin. So I believe that there's data to say that it does no harm to the normal coronary artery in a spot remote from a lesion that you've worked on.

DR. MALMUD: All right. Thank you.

Now, if I may go on with my train of thought, so having answered the earlier questions, which are all clinical questions, and I realize not the purview of the NRC, but nevertheless of concern to me, I may be a patient one day myself.

There is a distinct advantage which is only logical to having a smaller catheter, 3.5 French compared to a five, available. The number of

incidents that has occurred thus far, while it exceeds what we think usually occurs on a statistical basis, is still relatively small. The database is still relatively small, and my own gut reaction is that we would be doing patients a disservice to put restrictions on a mode of therapy which is as promising as this one.

However, I also listened very carefully to what Dr. Williamson said, and it seems that a couple of your subjective recommendations with regard to training or it may be they're objective recommendations, if applied, might continue to reduce the incidence of difficulties which, if I remember correctly, the representatives of the corporation said we're already reduced compared to the earlier incidence, and that we just move ahead and reevaluate the database at a later time.

I have completed my question and my answer.

(Laughter.)

CHAIRMAN CERQUEIRA: Sounds like a very logical approach.

MS. HOBSON: I have just one question. You mentioned that you have improved the latest version, the 3.5 side, but that just happened

recently. Now, will you be retrofitting the other 3.5s that are out there in use or just leave them alone?

MR. LOWE: The old catheter inventory is no longer available. It's not in the field.

MS. HOBSON: Oh, okay.

MR. LOWE: We exhausted existing inventories. We've replaced that with the newer, proximal improvement catheter.

CHAIRMAN CERQUEIRA: Yes. I'm sorry.

MS. HOWE: I just wanted to clarify that one of my co-workers who is now retired was keeping track of the Novoste events relative to the other intervascular brachytherapies, and he was up over probably 85, approaching 100 of different events.

Now, not all of them were misadministrations because some of them were caught before the actual administration, but the other devices that we're looking at and one of the reasons we brought Novoste to you was because the other events were probably you could count on one or possibly two hands.

And one of the things you're also hearing is that because of the event reporting, they're making engineering changes, and that's an

important factor.

And for the record, I'm Donna-Beth Howe.

CHAIRMAN CERQUEIRA: Well, I would bring this back to do you have enough information. I don't know if we can reach any more conclusions at this point.

DR. MILLER: Yeah, I think what I'd like to be able to do with regard to this effort is to bring it to some kind of conclusion, whether it's a temporary conclusion and we wait for more data or what, but I think I'm hearing that we need to give some kind of advice, for lack of a better word, on some things to look out for to improve performance. Is that --

DR. WILLIAMSON: That's what I think. I don't see how that would hurt, to try to make people more aware of error pathways. I don't see how it would restrict the use of the device clinically.

DR. MILLER: Right, but the thing that we have to be careful about is how we give that advice. In other words, we can't impose a requirement other than going through regulatory changes with the regulations. I don't think we're talking about doing that. I think what we're talking about is the kind of thing that we

sometimes put either in an information notice or regulatory information summary that just said, "Hey, be aware about these kinds of things, and here are some things that have been observed."

DR. WILLIAMSON: Well, I think it has to be handled very sympathetically. You know, an information notice could frighten away people from what is otherwise a very good system to use, on balance.

DR. MILLER: And that's not the intent that I'm hearing coming from the committee.

DR. WILLIAMSON: There's a lot of good. It's just, you know, there's some little bit of bad maybe that comes along with a lot of good, and with, you know, appropriate adjustments to the usual radiation oncology mindset, I think it sounds like the system can be used perfectly safely and virtually all but a tiny fraction of patients.

DR. MILLER: Another thing that I've observed over periods of time with various kinds of NRC licensees is that the NRC will look to see is the industry itself taking appropriate action and notification of its end users with regard to things that can be done to improve the performance of the system that they're selling.

And I guess the question I would ask Novoste is: what do you do with regard to getting information out to your user clientele for the products that you market?

That's also something that we can consider. Is the appropriate information getting to the people who need the information, or does the NRC need to take some action to assure that that information gets to them?

MR. REED: Just to address that, we do respond to all complaints. So there's a follow-up to every patient, to every user who files a complaint. We give then analysis of the device and our analysis of the root cause and a recommendation on how to prevent that.

So in every case there is a detailed response given back to the user.

DR. MILLER: Is that just given to the specific user or is that shared globally?

MR. REED: The specific user. It's given to the specific users for that specific situation.

In the broader sense, when we identified the kinking issue at the end of the PC, we issued additional training and required training be

delivered to all uses in that regard and additional documented site training.

MR. LOWE: And also informational bulletins that showed the clinical situation where you could get the kinking, how to prevent the kinking in like a one or two-page flyer so that even people that weren't complaining about it could see what other users were having issue with the catheter, and that they could also consider that as part of their training.

CHAIRMAN CERQUEIRA: I guess the one thing that did come up was this dummy run, where basically that allows you to work out some of the kinking problems, to see if it's going to work appropriately, and we've had some discussion of whether it would be 30 seconds or two minutes added to the procedure.

What's the feeling of the committee to perhaps make a recommendation that that be done and how would we make that suggestion?

Unless we mandate it, I don't --

MR. REED: Could I offer a piece of information before you propose that?

CHAIRMAN CERQUEIRA: Sure.

MR. REED: We are using and distributing

the device with instructions consistent with the clinical trials. If you recommended that, it would be an untried procedure with respect to the clinical trial data. So be careful what you recommend.

DR. WILLIAMSON: This is a different mindset from radiation oncology. You know, it's radiation oncologists and physicists that are responsible for the quality assurance and safety of their patients.

And I think that vendors' views should be listened to, but I think this sort of almost parental attitude, "we know better than you do how to protect the safety of your patients," I find somewhat annoying actually.

MR. REED: Well, let me respond to that. If you look at all of the reports, none of the reports state any harm to the patient. None of the reports state any harm to the user, over exposure of the user. So I guess I'm asking what's the benefit with respect to particular recommendations.

DR. WILLIAMSON: Well, I don't think that is true. In reviewing the analysis of these reports, there certain was a fraction of patients that didn't get the treatment, and it's well documented in the clinical studies, the efficacy of

the treatment, and depriving the patient of the treatment through some sort of an avoidable technical error surely has some medical cost.

CHAIRMAN CERQUEIRA: Dr. Nag.

DR. NAG: Whatever the truth is, I want you to have some notions that I have in my mind within the last one or two hours. One is has the adoption of the new catheter decreased or changed the event rate and how should we provide that data?

You know, with the five French you are having X number or X percentage with the new catheter, you know, what your new rate is; that's one.

The other point is that with the new catheter you can go more distally, but that does not really change the radioactive or you know, our concern about radiation problems in it. That is very good for clinically going into smaller vessels, but that doesn't really change the event rate.

The other thing is that I think the spring source is a considerable improvement because it prevents the detecting of sources and whether that contributes to the adoption in your event rate, you know, is something you need to -- is the data you need to give us.

In terms of the dummy, if it is going to add two minutes like Dr. Diamond says, then I think I would not be in favor of adding a dummy line. If it were 30 seconds, I would be in favor of a dummy line.

Those are some of my comments from the last one hour.

CHAIRMAN CERQUEIRA: Leon.

DR. MALMUD: I'm still concerned about the inherent resolution of some of the cardiac cath. systems and their impact upon the ability to see the catheter, the 3.5 French compared to the five.

I assume that you have in your lab a phantom, chest phantoms with phantom hearts in them in which you can insert a catheter and determine whether or not you can resolve the 3.5 French in a large body the same way that you can a five.

Is that a fair assumption? Has that study been done?

MR. LOWE: We attempted to create a reference system with the smaller 3.5 French system, and I don't know --

DR. MALMUD: Did you do this in phantoms, in body -- a body phantom is like, you know, by chest with a heart in it and so on, and

coronary arteries in the heart?

MR. REED: You know, I have to be careful what I say here because I'm not the expert on that particular part, but I'm sure that there were tests done on, for example, animals to insure the catheter could be navigated, to see that the catheter could be visualized.

With respect to, you know, there is no phantom necessarily specific to IVB that perhaps is the perfect model. So you're right that there's feedback that's necessary, but we get that as part of the complaint process.

DR. MALMUD: Well, it seems to me that we have had and continue to produce body phantoms, the term used for an artificial body which has the same densities as tissue densities of a human, and one can have these of varying dimensions and determine whether part of the problem that you are experiencing -- I'm saying this on your behalf -- is, in fact, not a problem of the product, but a problem of some cardiac cath systems not having the same degree of resolution that others do.

So that when they use the 3.5 French, they are appearing to have problems that they would not have had had they used a new, higher resolution,

if you will, better tuned cardiac cath system. In other words, the problem may not be in the product. It may be in the radiologic equipment that they're using.

And I just put this out as another possibility for why some of the misadministrations might have occurred.

DR. WILLIAMSON: I agree with Dr. Malmud. I mean, I think what came through to me is the importance of fluoro localization, and emphasizing that is like an essential part of the treatment procedure, and I think as a quality assurance procedure, as a physicist, dry runs with anthropomorphic phantoms and optimizing the settings and performance of the systems you're going to use would be an important activity.

I want to say one more thing about, you know, what I've termed the paternalistic attitude of the company towards user initiated QA, is that no other line of radiation medicine products that we use in radiation oncology do we feel ourselves limited or bound by exactly what FDA says are essential quality assurance. In fact, I think it has been more the other way. We have kind of led FDA to in other areas of brachytherapy to a better

perception of what's needed.

So what the companies have to say about their event and risk analysis is clearly very relevant to us as users, and we would never ignore, and what FDA has to say as well.

But I think the corporate culture of radiation oncology with respect to QA systems is totally inconsistent with those statements I've just heard.

CHAIRMAN CERQUEIRA: We'll take a few more comments, but we really have to wrap it up.

DR. NAG: Just one comment on Dr. Malmud's. Having worked with the phantoms, the problem is not so much the visualization within the phantom. Within the phantom I can see them very well.

But the problem is once you add motion, once you add ribs and other bony structures and flips (phonetic), that's when you get the problem. In the phantom, you will probably see the radio picked up in almost all systems. The real problem is when you go into a real live patient with all of the problems in the patient.

CHAIRMAN CERQUEIRA: Ralph, a final comment?

MR. LIETO: I think Sally was first.

MS. SCHWARTZ: I have a question. Is there any recommendations from the company as to the type of fluoroscopy that's best suited to use with your system?

MR. LOWE: I think at this point we haven't studied it quantitatively. I will say to your point that we have evaluated, but more on a qualitative basis with some European clinical trials and clinical use of the product prior to introduction into the United States to get some design validation feedback as to whether or not they could properly visualize the source strain in the proper treatment location.

The feedback that we got from the initial clinical trials in the initial use of the product was that they could adequately visualize it. We didn't quantify that. We did not record the information with respect to the fluoro equipment that was used at those sites. Probably in hindsight that would have been a good thing to do, but it was more of a qualitative analysis.

MS. SCHWARTZ: Do you think that you could look at the problems that have occurred and correlate it with the systems? I mean such that you

could give information out?

MR. LOWE: Yes, we have all of the information on the users and the sites which have the problems, and it's very easy to go back to those sites just to see if there was some additional correlation there of, oh, they've got the same piece of equipment or --

CHAIRMAN CERQUEIRA: That may be worthwhile, but then we've got the patient variables that come into the things that Dr. Nag identified, just as what you can do in a phantom with the particular, you know, fluoroscopy system.

DR. WILLIAMSON: And the operating conditions, too.

CHAIRMAN CERQUEIRA: Yeah. See, those are the problems, but you know, we've identified the fact that if we've had 56 or 86 reported events and maybe 70,000 catheters have been sold. It's still fairly higher than what I guess Bob Ayers had seen in other systems. So I don't want to just dismiss it altogether.

I think the theory is that the potential harm to the patient is relatively low. There are certain ways that may be able to minimize the chances of this happening, and those have been

suggested, and I don't know enough about whether that would really help or not help the situation.

But I'm not sure we're going to be able to reach a conclusion for you to make a decision at this point.

MR. ESSIG: If I could offer just one comment that we have to keep in perspective, and that is the "we" in terms of the regulator here is really the NRC and technically it's the State of Georgia because they did the sealed source and device review for this system. So they ar the regulator, not us.

So, I mean, we're following the events, but at some point if we feel regulatory action is needed, it will be us sitting down with the State of Georgia and just having a dialogue with them.

CHAIRMAN CERQUEIRA: I guess we should poll the committee. Does anybody feel that there should be any kind of restrictions, limitations or --

MR. SULEIMAN: I have, again, one more question, clarification because I thought at one point I heard this was an approved device. Then I heard it was being done under research.

Now, you can't have it both ways. If

it's under an IRB, you have a whole lot more latitude. It is clinical research.

MR. LIETO: There's a clinical trial with the five French catheter or with the new type of catheter.

MR. SULEIMAN: with the three and a half.

MR. LIETO: But it's the FDA approved system. There's not investigational devices being used. It's the catheter that's the research part of it.

I would like to recommend that since we have an idea where the denominator is now and you know the numerator, because we've talked about imaging the sources, but not all of the events are lack of imaging. I mean, there are other mechanical and other issues that come into here that go into the numerator.

And you know, let's maybe trend this, you know, over time, but also look at the other vendor Guidant. I mean, they record their runs of the device into the patient. So they should be able to give you the denominator for their device.

You know, not to pick on one, but let's compare both players out there, which is all of the

players, and let's see if things change, you know, say, from their improvements which were in mid-2003 and see how this before and after is, as well as comparing it, you know, to the other manufacturer.

I am still not convinced that dummy runs in their system would not be valuable. I mean, they were marketing dummy devices to use with this system. So evidently at some point there was value in this.

DR. WILLIAMSON: But they weren't using them in vivo. In their defense, they never recommended or even in early years would allow you even to deviate from their FDA sort of approved protocol. It was always used in sort of an in vitro context on the lab bench test system initially. That's all it was for.

CHAIRMAN CERQUEIRA: So I guess the message is really to continue to monitor it. I don't think anybody feels sufficiently alarmed that, you know, any restrictive actions need to be initiated at this point or any regulatory action.

DR. WILLIAMSON: I would agree.

CHAIRMAN CERQUEIRA: One final comment.

DR. WILLIAMSON: I'm not suggesting any regulatory action per se. I think information

notices and consciousness raising over this all would be what's involved in doing this minimal error would be useful. So you know, I guess some kind of informational vehicle, I think, would be helpful.

Maybe it would be better if it's done in concert with one of the other societies like AAPM. Perhaps it wouldn't be so frightening and intimidating to potential customers of the system.

CHAIRMAN CERQUEIRA: Thank you.

We'll adjourn until tomorrow at eight. Thank you.

(Whereupon, at 5:18 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Thursday, November 13, 2003.)