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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

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Wednesday, June 13, 2007

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The meeting came to order at 8:00 a.m. in room T2B3 of Two White Flint North. Leon S. Malmud, MD, Chair, Presiding.

MEMBERS PRESENT:

Leon S. Malmud, MD Chairman

William Van Decker, MD

Douglas F. Eggli, MD

Ralph P. Lieto

Subir Nag, MD

Sally W. Schwarz

Orhan H. Suleiman, PhD

Jeffrey Williamson, PhD

Bruce Thomadsen, PhD

James Welsh, MD

Darrell Fisher, PhD

Debbie Gilley

NRC STAFF PRESENT:

Sandra Wastler, Designated Federal Officer

Cindy Flannery. Alternate Federal Officer

Angela McIntosh

Ashley Tull

Donna-Beth Howe, PhD

Mohammad Saba

Duane White

Ron Zelac, PhD

ALSO PRESENT:

Gerald White

Dean Broga

Lynne Fairobent

Ann Warbick Cerone

Doug Pfeiffer

Ken Thurston

Armin Ansari

Luba Katz

Mike Peters

Gloria Romanelli

Craig Reed

Bill Metzger

A-G-E-N-D-A

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

8:14 a.m.

CHAIR MALMUD: Good morning, everybody. We'll begin a very lengthy agenda today with the presentation by Donna-Beth Howe on potential changes to 10 CFR Part 35.

Dr. Howe?

DR. HOWE: Thank you, Dr. Malmud.

You'll see the very first thing is the title of this presentation. It is "potential changes." It is not proposed rulemaking. The process at the NRC is that we develop what we call a user need memo that identifies things that we think may need changes in the rule. And this is going to be an attachment to a user need memo that goes over to our rulemaking group.

So you're given a very early opportunity to see if you agree with what the Staff's finding is that we believe we need a change in the rules to fix some of these problems.

You actually have two things in front of you for the ACMUI members and there are extra copies in the back. One is a more detailed verbiage of the potential changes.

To put things on a slide in many cases I had to abbreviate and condense and so you have a

condensed version of the slides. And I've ordered these in order of how they appear in the 10 CFR Part 35.

The very first issue comes from the definitions in 35.2. When we looked at the definition of the RSO, our general counsel has decided that if you meet the definition of an RSO, you are an RSO. And unlike other authorized individuals that can use the notification process, the RSO normally is not recognized on a license until they're reviewed by the NRC.

So in the definition the board certification pathway for the RSO is essentially a definition of a RSO. And that carries onto the fact that if you look in 35.50 and the preceptor statements and the supervised work experience, that's under the direction of an RSO. And OGC has determined that since an RSO is defined in 35.2, that this work can be done under the supervision of someone that is board certified, meets the board certification route but is not actually listed on a license as an RSO. And our question to the ACMUI is is that your intent. We don't believe that was the intent when we wrote the rule, but that is one of the consequences.

I'm looking for comments.

CHAIR MALMUD: Oh. Are there comments?

MEMBER VAN DECKER: Can you rephrase the question?

DR. HOWE: Normally when we have a preceptor or a preceptor attestation, the person that is precepting or providing the supervised work experience is an authorized individual, an authorized user, an authorized medical physicist because they're listed on a license or they meet all the criteria.

For the radiation safety officer we don't identify radiation safety officers except on a license, so you don't have the notification process. So what we have is an interpretation that if you're board certified in health physics or one of the medical physics and you have your attestation that you can function independently as an RSO, you're now eligible to work as a supervising RSO or as a preceptor RSO for someone else.

We think the intent of the rule was to have someone actually functioning in that position versus someone that met the criteria.

MEMBER NAG: The problem is that we are already having something or people who can function as an RSO. If you have dose rate that the person who already has been RSO analyzes many of the smallest --

you'll have problems trying to meet that.

RSO is someone who don't know what it is to be analyzing. They need to know the -- you know, the rules and they need to know what the problems are which would have been met anyway. That's why it's my personal feeling that they don't have to be analyses.

MEMBER SCHWARZ: Ralph, I would think you would have an opinion on this.

MEMBER LIETO: Well, yes. I am probably going to talk about this in my talk a little bit next. But I'm still trying to understand the question that's being asked. I'm --

MS. WASTLER: I think maybe if you look at the description -- this is Sandra Wastler, sorry -- on her handwritten page or the longer definition, I think what the concern is is whether the ACMUI would find it acceptable that someone that is an RSO but is not listed on the license, can they sign attestations as a preceptor even though they're not working as an RSO?

DR. HOWE: And they can provide the supervised work experience to someone that's in training to be an RSO.

MS. WASTLER: But they themselves are not an RSO --

DR. HOWE: Are not.

MS. WASTLER: -- on a license or working in that capacity.

MEMBER LIETO: So what you're saying is someone who meets the criteria of an RSO --

MS. WASTLER: Right.

MEMBER LIETO: -- has never been listed --

MS. WASTLER: Right.

MEMBER LIETO: -- can sign the attestation for an RSO --

MS. WASTLER: Right.

MEMBER LIETO: -- by virtue of the fact that --

DR. HOWE: By the definition of an RSO.

MS. WASTLER: Yes.

DR. HOWE: That's exactly what we're saying.

MS. WASTLER: That's at -- that's the interpretation of that part by OGC. And what we're trying to find out is is that a problem? Is that problematic?

MEMBER LIETO: I would think it would be for your regions because they're going to have to now look at the individual signing the attestation and they're going to say they've never been as an RSO, now you have to submit your credentials to me showing that

you have the training and experience supervised by an RSO. So somewhere down the line someone's going to have to have been listed as an RSO that links all the way back to this individual. And I can just see it being an absolute nightmare.

DR. HOWE: And we understand that. That is one of the effects. Because you aren't able to check and see this person's an RSO.

Dr. Eggli?

MEMBER EGGLI: Could I ask a question about actually 313A form for RSO? The one that I use for authorized users for medical uses asks us in addition to signing off as an authorized user preceptor, it asks us to reference the relevant material's license number. Does not the RSO form do the same thing? Does it not ask you to reference the relevant material's license number, which then gives you a link back to a license where that RSO theoretically is listed?

DR. HOWE: You are asked to provide a license number. And you could still provide a license number, but if you want back to that license number where the person -- if the person is working at a licensee's facility but they're not the RSO, they may be a board certified health physicist, then you will

not see their name as the RSO. As Ralph indicated, the regions would then have to assure that that person met the qualifications to be an RSO, is not listed as an RSO but by definition in 35.2 was one.

MEMBER EGGLI: I think the problem may be solved after -- or at least a recommendation might come forth after Ralph's discussion about the possibility of listing more than one RSO on a license.

DR. HOWE: And this person doesn't have to work at a licensee's facility.

MEMBER EGGLI: Yes. But part of the solution may be in the listing of multiple RSOs on a license. Part of the problem is, again, the inability to list more than one RSO on a license these days.

MS. WASTLER: Well, I don't think this is necessarily tied to that. This is simply by definition of being an RSO it allows somebody to preceptor someone.

DR. HOWE: Yes.

MS. WASTLER: Whether they're listed on a license or not. So it may not even be at that facility.

MEMBER EGGLI: But they have to reference a license number.

MS. WASTLER: They can provide a license

number that they might be at the hospital that they're at. But that doesn't mean that they're on it. They don't have to be on it.

CHAIR MALMUD: Dr. Nag?

DR. HOWE: And they may provide an explanation that they're not at a licensee facility. We would have to go back to the definition and see if that was in accordance with our regulations, and it would be. So they wouldn't necessarily have to be at a licensee's facility.

MEMBER NAG: I see a problem that if that person has to be an RSO on a license, then institutions that have many physicists who serve at assisting RSO or they help the RSO and they provide the training, now this person now, you know, at best they're not on the license. So I don't think you need to be on the license so long you know, you know, what the requirements are to be an RSO.

DR. HOWE: Okay. And I think the thing you have to also is really expand your thinking beyond the person's working at a license facility. The person just has to be board certified, have an attestation and have training in any of the modalities for which they're signing for.

MEMBER NAG: Right.

DR. HOWE: They don't have to be at any licensed facility.

MEMBER NAG: Right.

DR. HOWE: Okay.

MEMBER NAG: I mean, a coach doesn't have to be the best football player.

DR. HOWE: Dr. Malmud?

CHAIR MALMUD: Has there been a problem?

DR. HOWE: I'm not sure how this came up as a question, but it came in from one of our regions and we looked into it. And we went, gee, this really is kind of an issue.

CHAIR MALMUD: It's a theoretical issue?

MS. WASTLER: Yes.

CHAIR MALMUD: So right now it's --

MS. WASTLER: I would suggest, though, that it probably -- the reason the region was asking the question because it had come up in one of their reviews. And because most of these issues that we're talking about here have risen out of questions from the regions, questions from other -- you know the stakeholders. And so where we recognize that there's some nuances here maybe that weren't intended. And I believe this is one of them. So it may not have been a big problem. It may have been on one particular

case. But as a global matter, we would then look at it to see what we needed to do and if it was problematic in a larger scale.

CHAIR MALMUD: So if the individual is board certified and is an authorized user currently, that's sufficient? They need not be working as an RSO in order to precept an RSO?

DR. HOWE: No. The definition of an RSO in 35.2 says that you meet the qualifications in 35.50(a). Let me pull it up to make sure I'm speaking correctly.

This is not 35.50. This is 35.2. To be defined as a radiation safety officer you meet the requirements in 35.50(a) or (c)(1),(a) and (c)(1) are the board certification. (a) and (c)(1) also include that you have an attestation. That you have completed the training that was required for the board to be recognized, and that you have sufficient knowledge to function independently as an RSO.

Then the other requirements in 35.50 are that you're identified as a radiation safety officer on a license.

So it doesn't get to the second part of it: You're identified as a radiation safety officer on a license. That's already recognized. And that is

similar to all of our other cases.

CHAIR MALMUD: Excuse me. It's still not clear to me.

Currently, not in the proposal but currently if the individual is boarded and has an attestation, he or she need not be listed as the RSO on a license in order to sign attestations as a preceptor?

DR. HOWE: That's an OGC interpretation, yes.

CHAIR MALMUD: That's the current?

DR. HOWE: Yes.

CHAIR MALMUD: And the question is should it be changed so that in order to serve as a preceptor, one should be boarded, have an attestation and also work --

DR. HOWE: Function as an RSO.

CHAIR MALMUD: Yes, as an RSO. But each institution only has one RSO. So this really limits the pool significantly. And I don't know what additional level of safety it offers to the public by requiring that. Is there a practical increase in the level of safety for the public and for users by doing this?

DR. HOWE: I think the Commission has had

a concept that it wants people that are actively functioning in the field to be the individual supervising the work experience and providing the preceptor statements. This doesn't necessarily say that they aren't functioning in the field. It just says that they're not -- that they don't have to function in the field.

MS. WASTLER: And I think the question we're asking and based on some discussions I think from yesterday, I think I heard the comment that in radiation safety things haven't changed in many -- significantly in many, many years. So I think the question we're raising is, you know, is this interpretation that exists currently, is this problematic in your mind. You know, does having an RSO working in the field, does the actual being functioning in that capacity during the time when they attest to somebody, does it add significantly to the process and increase health and safety?

CHAIR MALMUD: I understand the question. And I understand what my answer would be. But I think Dr. Williamson is chomping at the bit.

MEMBER WILLIAMSON: Yes. I would say no, that making this more restrictive isn't going to improve safety. And in fact the OGC interpretation

may offer some modest relief to a severe shortage of preceptor-able preceptors who can sign off on radiation safety officers.

So, I would say leave it alone.

CHAIR MALMUD: Dr. Malmud concurs with Dr. Williamson.

DR. HOWE: Yes, Sally?

MEMBER SCHWARZ: I'm just wondering if there's a problem in terms of an RSO trying to sign the attestation, you know that you're not able to document who they are in terms of their ability to sign this form? Maybe they can be submitting their credentials as well.

DR. HOWE: Well, the net effect is if we don't make any changes, then it becomes more of an administrative problem where in the past if you gave a name and you gave a license number, we go look at the license number and we see the name. In this case you give a name, they aren't listed on a license, so then you have to provide that RSO qualifications when you're providing your qualifications. And that could go back several levels. Eventually you would have to end up with, as Ralph indicates, someone listed on a license to confirm.

CHAIR MALMUD: Debbie?

MEMBER GILLEY: I believe it's how quick you want to put this person on a license when it comes to implementation. This is problematic for implementation of getting people as RSOs on the license. If we've got to go back and look at the qualifications of the person who signed a preceptor and they have to go back another level and look at the qualifications who signed their preceptor, we could get in this letters back and forth between the regulatory community and the licensee.

DR. HOWE: And I think this is where the issue of having one RSO on the license, being able to list him on the license, might provide some --

CHAIR MALMUD: Some relief.

DR. HOWE: -- relief.

Jeff?

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I'm always conflicted.

All RSOs are not created equal. So what if you've got an RSO in a very limited facility with very limited responsibilities, board certified, whatever, and attests to some other colleague who is about to take responsibility for a much larger broader program, that would work? I mean it's the quality of -- and this qualification by reference sets up an

administrative -- you know, a real difficult trail. It just creates a lot of extra paperwork.

In the case that precipitated this question, aside from not being able to track it administratively, were the qualifications of the people who were attesting, was that in question?

DR. HOWE: I think this one actually came out of a different question. And in solving that question, we came up with this one. So we were able to solve our original one and then we realized we had another.

There is a caveat here that says at least when you get down to the training part the training can either be provided -- may be satisfactorily provided by being supervised by a radiation safety officer, and then they list other people. And then at the end it says, "Who is authorized for the types of use for which the licensee is seeking approval?" So the person that's not listed on a license wouldn't be authorized for that. So the training part would come in question, but when you get up to the preceptor statement, you don't have that qualification. So you can do the preceptor statement.

Ron? Can I get Ron?

DR. ZELAC: With respect to what you just

said, Donna-Beth, we had a recent interpretation from OGC that the training for the RSO can be given by anybody. It doesn't have to be persons that are restricted to the license. Anybody at all. It may be, and that's why the word "may" is rather than "must."

DR. HOWE: And Ron is right. It is that we did not specify exactly who had to give the training, but if the training was given by a supervising RSO, then that brings it down to here. But you may not consider them a supervising RSO.

CHAIR MALMUD: To the public.

MR. WHITE: Gerald White, American Association of Physicists in Medicine.

We're grateful that the NRC has recognized the potential for increased documentation difficulty in this case. But I should point out, first of all, that this is yet another problem with the preceptor concept for board certified individuals. Again, the simple solution is to do away with the concept.

And secondly, I point out that the documentation problem is not related to the particular issue in question. The preceptor does not need to be on a license at the time the preceptee applies for the status. The preceptor needs to be on a license, have been on the license at the time they signed the

document. And that could as this rolls out in our careers for 20 or 30 years, one would have to document that the preceptor was on a license 10 or 20 or 30 years ago, which can be a very difficult process if the regulatory community decides to require documentation that the preceptor statement was appropriately signed. It's going to require license searches going back decades potentially.

DR. HOWE: Dr. Williamson?

MEMBER WILLIAMSON: Yes, I would say this is not a problem for the regulated community, it's only a problem for you if you insist on verifying the accuracy or veracity of every preceptor's statement. And I think, you know, a more reasonable approach would be to assume, you know, that there is a prima facie legal requirement that the person signed this statement legitimately and honestly. And, you know, if there were a random search of the credibility of these preceptor statements and someone were caught essentially perjuring themselves or fabricating a preceptor statement, there would be a punishment. Because I think that's how most legal documents work. I think it seems irrational to insist on this burden of proof for every transaction. I think you have to believe somebody at some point.

So if you wish to impose upon the public this large cost that seems to add nothing to public safety, well this is your problem, not ours.

DR. HOWE: From the public.

MR. BROGA: Yes. Dean Broga. I had one comment and one question.

The question is I'm assuming you're not eliminating the ability of a previously named licensed RSO who has been named within the last seven years from signing an attestation statement, like Dr. Williamson who has been an RSO someplace --

DR. HOWE: No.

MR. BROGA: -- but isn't presently named, but has been named in the last seven years; they're still allowed to sign the attestation? That's not a big problem for you to check that, right?

DR. HOWE: I don't think we are eliminating anybody that meets the current regulations. We're just saying this is something that looks like it is larger than what we thought it was.

MR. BROGA: Well, but when you introduced that you were saying "presently named." And so if I was -- well, another RSO was named last year at my facility, I wouldn't be presently named although I had been named a year ago. And so I would assume the

seven year time of experience and naming would apply. But I can see where you could have an issue with this if you allow this to go by this way where someone can create an RSO academy outside his institution and bring in people for training and not ever be on a license. But I think a lot of this would be solved if we had either the assistant or the alternate RSO capacity to license so there were more people who could be on a license who would be credible and easily looked up by the NRC.

So, I hope Ralph's going toward something along that line.

CHAIR MALMUD: All right. Ralph.

MEMBER LIETO: Go ahead.

CHAIR MALMUD: I was just going to try and summarize this by saying it seems to me, Donna-Beth, that the feeling of the majority of the members of the Committee is that we should leave it as it is and not recommend the change. There are other elements that will be addressed later, but he probably will bring up, that we may feel need changing. But it seems the majority does not feel this needs changing. Is that the spirit of the Committee?

The answer is apparently unanimously yes.

DR. HOWE: Okay.

MEMBER NAG: Do we want to record it as a vote that we --

CHAIR MALMUD: You wish to make a motion? We will do that.

MEMBER NAG: Yes. I make a motion that the present definition of RSO preceptor not be changed.

CHAIR MALMUD: A second to the motion that it not be changed? Dr. Schwarz.

All in favor? Any opposed. Any abstentions? It's unanimous.

DR. HOWE: Okay. Thank you.

The second issue is 35.12. In 35.12, this is more of an issue on covering all our bases for determining burden for OMB.

Our individuals down in our OMB review group looked at our language in 35.12 and said that because we don't have "or equivalent" in the regulations, that even though our practice is to include any type of amendment or any type of renewal, or any type of new license as a burden attached to the 313 form, and the 313A is a part of the 313 form, that we associate any burden that's associated with information an applicant has to provide on training and experience to the 313 form. And the folks down

that are reviewing our OMB clearance said, "Well, you really need to say that these letters that could also be used," because a new application you do have to do a 313. The 313A has always been voluntary, but you have to provide the information in the regulation, and that's where the burden is coming from. It's not coming from the form, it's coming from the regulation.

That you don't have that these letters have to have equivalent information, and therefore technically the burden for the letters is not included in the 313. And so this is more or less a -- and then you see our rulemaking -- our potential would be to revise 35.12 to add "or equivalent" so it's clear that anytime you supply the information required by the regulation, that burden can be attached to the NRC forms.

CHAIR MALMUD: Does someone wish to make a motion that the letter should be "or equivalent?"

MEMBER LIETO: So moved.

CHAIR MALMUD: Is there a second to the motion?

MEMBER EGGLI: Second.

CHAIR MALMUD: It's been moved and seconded.

Any discussion that the letter should have

"or equivalent" information which is currently in form 313?

All in favor?

(Vote by show of hands).

CHAIR MALMUD: You got it.

Next.

DR. HOWE: Okay. Now we're into 35.50(c)(2), which is an area that is familiar to everyone.

As written the AU, AMP and ANP has to be listed on the licensee's license. While that makes some amount of sense, in other words if the person is listed on the license and they're familiar with your program, and therefore they should be able to step in quickly to be an RSO for similar types of uses, it is to some extent restrictive because you could have an individual that is an AU, AMP or ANP on another license and that individual would be qualified to be -- we believe would be qualified to be an RSO for the similar types of uses. And so the problem is that we think the language listed on the licensee's license may be too restrictive. And so we're looking at making a change that might be similar to this listed on a license or NRC master materials permit that authorizes similar types of use of byproduct material

and the individual has experience in radiation safety. So we're looking to kind of expand that with just the licensee's license to any license having similar uses.

CHAIR MALMUD: Any discussion.

MEMBER NAG: I would support that move.

CHAIR MALMUD: Dr. Nag makes a motion to accept the change. Is there a second to the motion?

MEMBER EGGLI: Second.

CHAIR MALMUD: Any discussion?

All in favor? I need a vote. Did I hear something?

MEMBER LIETO: Well, I have a question. I'm trying to be sure that you're saying that for some reason it sounds like it's going to make it more restrictive.

DR. HOWE: The way the regulation --

MEMBER LIETO: I don't know, from what you just said earlier I don't think that was your intent.

DR. HOWE: No. The way it is written now you have the same verbiage. And when you get to identify, the identified is on the licensee's license. This would expand it to a license or master materials license permit. And the license in this case would be an NRC license or an agreement state license.

I don't have all the words here. And when

we get into rulemaking space, if we get into rulemaking space, then that will be flushed out to say an NRC or an agreement state license for the authorized user, authorized medical physicist, or authorized nuclear pharmacist would also be a permit issued by an NRC or an agreement state broad scope license or a master materials licensee broad scope permittee. So you would have a lot more verbiage in here, but this is just to give the concept.

CHAIR MALMUD: Any other questions?

All in favor?

(Vote by show of hands.)

CHAIR MALMUD: Any opposed? Any abstentions?

DR. HOWE: Ralph is abstaining.

CHAIR MALMUD: One abstention, otherwise all in favor.

DR. HOWE: Okay. Now this is a continuation of the problem in 35.50, and that is that the preceptor RSO is required to provide an attestation, and this is for already identified AUs, AMPs and ANPs that are qualified under 35.50(c)(2) to be RSOs. We find the RSOs are reluctant to sign the attestation.

We also went back and looked at the

original intent of the rulemaking in 2002 and in 2005. And from the statements of consideration it appeared as if the original intent was not to have an additional preceptor attestation. So what we are recommending in this case is to take out the preceptor attestation for the already recognized AUs, AMPs and ANPs. And this is just kind of a potential way of addressing that, and that would say that no attestation is required for those individuals meeting the requirements of (c)(2), the "or" doesn't belong there if they have RSO responsibilities for similar types of use for which the individual is authorized.

CHAIR MALMUD: Is there a motion to approve this?

MEMBER VAN DECKER: May I just ask a question?

CHAIR MALMUD: Okay.

MEMBER VAN DECKER: That one --

CHAIR MALMUD: Beg your pardon?

DR. HOWE: Yes.

CHAIR MALMUD: Go ahead.

MEMBER VAN DECKER: And I'm sorry for interrupting.

So in simple North Jersey language, because I get confused easily in life, this would mean

that essentially we would be back to kind of the old 35 where an authorized user with skills in the modality in which they were trained could serve as an RSO on a small license for that modality; is that where this kind of leads us to?

DR. HOWE: That's exactly right.

MEMBER VAN DECKER: Not bad for North Jersey. Okay. Thank you.

DR. HOWE: Orhan?

CHAIR MALMUD: Any other questions?

MEMBER SULEIMAN: I have a question the way it's worded. In other words, I get the impression that forget the attestation issue which is an issue all by itself, but if in this case they will not attest because they don't consider that person qualified for what they're going to do and may withhold that?

DR. HOWE: The issue is you have to have an RSO. And if the licensee is a small licensee and they lose their RSO, then they don't have a person that knows them, so you have to go outside of that facility to another facility. And what we're hearing at the ACOM meetings is when you go outside of that facility, the RSO on another license doesn't know the individual and is not willing to sign.

MEMBER SULEIMAN: So it's an unnecessary paper exercise? Okay. Okay.

DR. HOWE: And we looked back at the intent of what we have really wanted to do in 2002 and 2005. And because we restructured this 35.50 at the last minute, this type of person --

MS. WASTLER: It was amended.

DR. HOWE: -- came up above the attestation where before they came below the attestation, it was clear that they didn't require it.

MEMBER SULEIMAN: So the failure to attest in this case is strictly that they don't know the individual, rather than they know them and they don't think they're competent?

DR. HOWE: Yes.

Dr. Nag?

MEMBER NAG: The thing is the admission go along with the ACMUI suggestion that the preceptor statement was saying but that we eliminate it, then this is something that doesn't require further confirmation. Because, you know, we are asking the permission that the entire preceptor statement should be adequate for everyone. So then this rule doesn't even need to be there because there will be no need for perceptorship for anybody, including RSO and then

authorized users. So --

CHAIR MALMUD: But currently --

MEMBER NAG: Right.

CHAIR MALMUD: -- it would be a useful addition?

MEMBER NAG: Right.

DR. ZELAC: Point of clarification.

CHAIR MALMUD: Dr. Zelac?

DR. ZELAC: This is Dr. Zelac.

I thought that the approach that the Advisory Committee was taking was to recommend to the Commission that attestations not be required for board certified -- people seeking authorized status via the board certification pathway. What I just heard from Dr. Nag was get rid of all preceptor statements period, which would include the alternate pathway. I didn't think that that was the intent?

MEMBER NAG: Oh, right. The board certification, those who are board certified. I meant for those who are board certified.

DR. ZELAC: Okay. Fine. Thank you.

DR. HOWE: And this is not limited to those that are board certified. This is anybody that's identified as an authorized user, nuclear pharmacist or a medical physicist.

CHAIR MALMUD: Is there a motion to support the change?

MEMBER SULEIMAN: So moved.

CHAIR MALMUD: And seconded.

All in favor.

(Vote by show of hands.)

CHAIR MALMUD: Any abstentions? Any negative?

Unanimous again.

DR. HOWE: Okay. And this is the experienced radiation safety officer. This is 35.57(a). And 35.57(a) deals with experienced radiation safety officers, teletherapy or medical physicists or nuclear pharmacists.

And as written this particular part of the regulation specifically states the individuals need not comply with the training requirements of 35.50, .51, or .55 respectively. The effect of that is that we may have RSOs and AMPs that are either currently at a licensee's facility that gets a new modality, and in this case we're not talking about a new device in an existing authorization for the license, but maybe goes into gamma knife or goes into HDR, or going into tele -- probably not teletherapy. Or they go into manual brachytherapy when they used to be nuclear medicine.

So they're going into some new modality. And the way the experience one reads that person does not need additional training in that new modality to function. So if you're already listed on a license as an AMP or an RSO, you wouldn't need the additional training. And so what we're looking for is a similar statement to what we have for authorized users. And that is that these experienced individuals would be recognized as experienced individuals when using or responsible for the same materials and uses that they were already recognized for. And that would bring in the education requirement if a new modality was added.

CHAIR MALMUD: Dr. Nag?

MEMBER NAG: Yes. Leave it the way it is, but I would suggest why not expand it to experience authorized user as well? Because authorized user, if you have been using that for several years at your institution and you move to another institution, wouldn't they face the same problem?

DR. HOWE: Dr. Nag, this would be making a conforming change to what is already required for the authorized user. The authorized user statement in 35.57(b) states that the authorized user will be recognized as an authorized user for the same materials that he had, was listed for before.

Jeff?

MEMBER WILLIAMSON: Yes. I'm concerned about this change because I think the intent of the grandfathering clause was to in fact exempt a group of previously practicing medical physicists or RSOs and so forth who were basically compliant with the older requirements from having to meet the new requirements so that they would be in a position to sign preceptor statements for physicists and pharmacists and so forth emerging under the new set of rules.

So I would, based on this, oppose the proposal.

DR. HOWE: Ralph?

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. I think this would actually make it more restrictive on previously identified RSOs. And I would move that the Committee not support this change.

MEMBER NAG: Will someone clarify again why would that make it more or less -- let's say you were grandfathered for HDR and so on, and then now you have a new modality like gamma knife that you have no training for, you would not have previously been allowed to have done gamma knife. And now all of a sudden you can use gamma knife? I'm not sure. Maybe

I'm not getting something.

MEMBER WILLIAMSON: I'm not sure you were previously. The only designation that existed was teletherapy physicist. And so that is the only basis at that time for a physicist to have been in the license, so it's necessary for that certification to accommodate HDR --

DR. HOWE: Jeff, that's not right.

MEMBER WILLIAMSON: -- and other modalities.

DR. HOWE: That's not quite true. When the HDRs and the gamma knives came in, NRC started right at the beginning listing those medical physicists and those authorized users for the HDR and the gamma knife use specifically. So we listed more than just teletherapy physicists.

We didn't call them authorized medical physicists, but we did list them for those uses. So in 2002 we had a long history of having many kinds of physicists listed with 600 uses.

The public?

MR. BROGA: Could I just ask for some clarification on this and the last question?

Although you're doing away with attestation, I would assume you're not doing away with

the form that the individual has to submit requesting to be named RSO and to clarify that at least they state that they're aware of the regulations that are in that present form? And the same would be true here if you made this requirement, it would be free of attestation but the individual would have to submit a form requesting it at the time they changed the license?

DR. HOWE: I'd like to go back. When you're talking about the RSO, are you referring back to an earlier discussion?

MR. BROGA: The previous discussion you did away with attestation, but I would assume that the person is still going to have to send a request to be named, and I would assume you would be using a similar form to the 313, it just wouldn't have to be attested to? The individual would have to state they had the things, but there would be no attestation?

DR. HOWE: Our forms today conform to the current regulations. If we change the regulations and that affects the information that is provided, we will make corresponding changes to the forms.

Right here right now I can't tell you if there would be a change and what that change would be. But I will tell you that if we make regulatory

changes, we will bring the forms into conformance with those regulatory changes. So if we no longer require an attestation for something, we'll make it clear on the form there is no longer an attestation for that.

MR. BROGA: But if you made this change right here, unless you took away the attestation, this would require attestation, too; am I not right?

DR. HOWE: If you will wait a minute, you'll see that I have another slide on 35.57(a) that says that if you were to accept this, the Staff's intent is that if the person needs additional training to be an RSO for a new modality or an AMP for a new modality, that we were specifically recommending that the attestation not be required.

MR. BROGA: Thank you.

CHAIR MALMUD: Any other questions for discussion?

Is there a motion on the floor? Will someone make a motion?

MEMBER LIETO: I would move to not support this addition because I think it would make it more restrictive.

MEMBER WILLIAMSON: Second.

DR. HOWE: May I put in? So, Ralph, if I have an RSO that is an RSO in a nuclear medicine

facility, then without additional training that person can be an RSO with a gamma knife and an HDR?

MEMBER LIETO: Well, that's not --

DR. HOWE: That's what the regulation says right now.

MEMBER LIETO: Well, that's not the way I would interpret what you have there. Okay. If somebody says -- say if somebody was an RSO for 100, or say 100 through 300, okay. And somebody goes someplace else and they want 100, 300 and 1,000; they couldn't do it.

DR. HOWE: It would depend on what the 1,000 is. If the 1,000 is similar to 100, 200 and 300, then it's no.

MEMBER LIETO: To me what you're doing, though, is you're making it more restrictive. It creates a paperwork burden for everybody involved. And I don't see what the added health and safety issues are here. Because it states that when you go to apply for an RSO, you still have to demonstrate that you have training and experience in the uses that you're applying for.

If someone says they have training and experience for that purpose --

DR. HOWE: What we're saying is that this

particular regulation as written says you as you're applying for an RSO to a new position with significantly different modalities do not have to provide documentation of your training and experience to handle the radiation safety for those significantly different modalities. Because you are grandfathered here and are exempted from the requirements of meeting anything in 35.50.

MEMBER WILLIAMSON: Well, I believe that's legitimate. That's the definition of grandfathering. I agree with that. That's how it used to be under S Subpart J, and it was not a problem. So the fact that one does not require documentation of this additional training, does not mean that a competent and professional individual would not seek out whatever training they would need. So I believe that other mechanisms within the community to ensure appropriate credentialing would prevail. And given the risk of liability of having a major accident because of an incompetent or poorly trained RSO, I think that hospitals and licensees would be responsible in ensuring that adequately credentialed people were staffing this very important function.

So, again, I would urge the Committee to support Ralph's motion.

DR. HOWE: Dr. Malmud?

CHAIR MALMUD: I have a question. If there is a medical physicist who is the physicist for a nuclear medicine division in a large university hospital and he or she chooses to become the physicist for a teletherapy unit freestanding, not part of a hospital which has a credentialing committee, but a freestanding, currently that physicist can jump from nuclear medicine to radiotherapy in a freestanding therapy unit with no experience in radiotherapy?

MEMBER WILLIAMSON: That's not true.

DR. HOWE: No.

MEMBER WILLIAMSON: No. Because there is never --

CHAIR MALMUD: I'm asking a question. I'm trying to get the answer.

DR. HOWE: In that particular case when they're moving from a medical physicist in one position to be a medical physicist in another position, it's not true. Because we do not recognize and authorize medical physicists in diagnostic nuclear medicine. So that individual would not be an authorized medical physicist and would have to meet the criteria for an authorized medical physicist, which are the uses in 35.600.

If that medical physicist wanted to be the RSO, then they would not have to demonstrate that they had training in radiation safety, regulatory issues or emergency procedures for the new responsibilities of handling the 600 uses.

CHAIR MALMUD: So currently a medical physicist with no experience in teletherapy could go from a radiology department in a university hospital?

MEMBER WILLIAMSON: No.

CHAIR MALMUD: No? That's what I'm trying to understand.

DR. HOWE: Well, if he's a medical physicist -- you have to keep two terms in mind. Is he a medical physicist? Okay. NRC does not regulate or recognize all medical physicists. We only identify those medical physicists that work on teletherapy units, HDRs, gamma knives and eye applicators as authorized medical physicists.

CHAIR MALMUD: Thank you. That clarifies my question.

DR. HOWE: They still --

CHAIR MALMUD: Okay. I understand.

DR. HOWE: Dr. Welsh?

MEMBER WELSH: As I understand it, the problem is that as written right now if an institution

adds a new modality like purchasing a gamma knife, there is no requirement for documentational proof that anybody has experience or preparation that would allow them to use this equipment safely?

DR. HOWE: That is correct.

MEMBER WELSH: And that would appear to be a potential problem? The authorized user, medical physicist and the RSO might appropriately be required to get some vendor training, perhaps, to document that this institution and these individuals can now use this equipment at this institution responsibly and safely. Is that the spirit of what you're proposing here?

DR. HOWE: That is the spirit. The authorized user is already covered because they are only authorized for those uses that they have experience with. And so the authorized user would have to get additional training in the gamma knife. But the medical physicist would not, and the radiation safety officer would not.

MEMBER WELSH: So it would seem that it's logical that we would all favor getting that additional training experience and documentation that is appropriate for illustrating that this equipment can be handled competently and safely at the

institution. But it might be the verbiage that we're not in agreement with here?

MEMBER WILLIAMSON: No, it's not. I'm in disagreement with the concept of trying to restrict the definition of grandfathering. This applies only to a very limited segment of medical physicist, the practitioners; those that meet the recency of training requirement plus were mentioned on a license prior to 2002.

CHAIR MALMUD: Dr. Nag?

MEMBER WILLIAMSON: As an authorized --

MEMBER NAG: Donna-Beth, would you tell us what would be needed for somebody who is a radiation safety officer currently at that institution and now moves to a new institution and is now asked to take charge of any of the modality in addition to what you were trained for? So for example, he never had any training on gamma knife and was an RSO, but then went to a new place that had in addition gamma knife. Would he only require some training for the gamma knife or would it be that well he has to do everything all over again? I think that is the distinction I would like to know.

DR. HOWE: In this particular section on the regulation if he was listed as an RSO on a license

with no gamma knife prior to -- and you can go down to the October 2005, and he goes to this new facility that has the gamma knife, we would not be able to require him to have training in the gamma knife. If we could require him to have training, the training would be the training that's specified in paragraph -- I think it's (e) maybe (d), for the RSO, which is that they would have training in the radiation safety, the regulatory issues and the emergency procedures for the gamma knife. We would not require him to start all over again as a radiation safety officer. We would just require those modality-specific training elements.

Dr. Eggli?

MEMBER EGGLI: Is there any in this retraining or additional training? Who sets the threshold for what represents sufficient training? Is that a case-by-case basis? There is some potential for inconsistency in determination of what's adequate training. Does the individual site determine what's adequate training? Does NRC Regions individually interpret what's adequate training?

DR. HOWE: We don't prescriptively say what the training, how you have to get the training. We do indicate that we would assume that it is

acceptable if the training was provided by: In the case of the RSO, it could be an RSO with experience in that modality, an authorized user with experience in that modality, an authorized nuclear pharmacist with experience in that modality, or an authorized medical physicist with experience in that modality.

MEMBER EGGLI: The problem is it may be --

DR. HOWE: So it would be somebody authorized with the modality.

MEMBER EGGLI: Okay. It may be hard to come across that kind of training. Most of the training delivered for new modalities in reality is delivered by the vendors. And that's how most of this sort of new modality training gets delivered in finding someone that actually -- where you can go away to a site that has a volume adequate to be trained by an authorized individual of some class, is potentially problematic.

DR. HOWE: Well, Dr. Eggli, I want to clarify that we don't specify where you get the training. We say you may get it. That does not preclude you from getting it from a vendor. And we like it when you get vendor training because we feel you're getting it from the horse's mouth.

So we are not excluding vendor training at

all.

I think the way it was written was the idea that we're not talking just about new modalities where the vendor training is probably the best. We may be talking about an RSO going into a facility that already has experienced people there, and then he needs additional training on what he sees there.

MEMBER EGGLI: Thank you.

CHAIR MALMUD: We have a member of the public.

MR. WHITE: Yes. Gerald White, AAPM.

I'm trying to understand this discussion with the one that's to follow, because I think they're inextricably linked.

But it seems to me that we have already eliminated everyone board -- with the exception of the 50 or health physicists people, we've eliminated everyone board certified prior to now from using the board certification pathway for this. And now we're eliminating any experienced RSO who didn't have experience with the particular modality in the new institution prior to October of '02.

For example if one did not have a gamma knife in 2002 but had one in 2005 and wanted to go to an institution that had a gamma knife, would they be

excluded then from using the experienced pathway to --

DR. HOWE: No. No. The intent, and let me go to the next slide, would be if we make this the revision ahead. Our intent is not to require attestation, but just to require the completion of the training that would be required in 35.50(e), that would be say for the RSO. And if it was the authorized medical physicist, it would be the training that's in 35.51. And it's always specific to whatever this new use is.

It's the radiation safety, it's the regulatory issues, it's the emergency procedures for that new use that that person didn't have responsibility for earlier. So we would be saying we would expect an experienced authorized user or medical physicist -- because the nuclear pharmacist really doesn't have any other area than nuclear pharmacy. And so when they go from place-to-place-to-place they're doing their same thing. So it's the medical physicist and the RSO.

If you do not have responsibility for those things, we're saying you need the additional training. And we're saying because you're an experienced individual, we would not require you to have an attestation, but that you would have completed

this additional training. So that you know the radiation safety, the regulatory issues and the emergency procedures associated with this modality that you didn't have experience with before. That's all we're saying.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Dr. Malmud, two points. One we've made a motion and I think maybe we need to vote on that motion.

But in terms of background, we didn't see this until we walked in. And it seems like we're getting into a debate on revising the rules on information none of us had seen before we walked in here. And I think, you know, it's one thing if some things are like really, you know, black and white changes like the equivalency request and so forth. But, obviously, we're not convinced by this change. There's not any support on the Committee on this. And we're getting into debates on trying to convince being convinced that we want to make this change.

I think if there's some health and safety issue that's really urgent that needs resolution at this meeting, I think Staff needs to come back to us to prove what health and safety issue is being resolved or being solved by this issue, by changing

this rule.

And also I think it would -- I think with all these proposed rule changes, or I should say not proposed rule changes, but suggested rule changes, I think it would have been nice to have this at least maybe a day beforehand to digest to see if there are some other issues. What we're basically doing is flying on the cuff.

And so back to my original point. If we need to make a motion on this before we can move forward --

CHAIR MALMUD: You did make a motion.

MEMBER WILLIAMSON: You made a motion and it was seconded.

MEMBER LIETO: And I would like to move forward.

CHAIR MALMUD: You made a motion, it was seconded and we're discussing the issue. And I don't believe that we have heard as yet the feelings of the whole Committee. But we certainly know your position and Dr. Williamson's position.

If you would prefer rather than moving on your motion, to have this issue tabled for a later date, this one specific issue, we can do that.

MEMBER LIETO: That would be fine.

MS. WASTLER: I would propose --

MEMBER LIETO: Well, no. I was --

MS. WASTLER: First of all, I'd like to apologize. You know, sometimes we do our best to try to get this information out to everyone ahead of time. But as you are all aware that, you know, that sometimes isn't possible. And in this case was one of them. You didn't get it until this morning.

So unless there is something burning done about that I'm not aware of, I have no objection if the Committee would like to table the rest of the discussion so that they could look at the information and we can bring it up in another venue at another time.

You know, I understand that it's difficult. Part 35 is difficult. And basically you need the time to review it, and I understand that.

So I would like to put that on the table as well.

CHAIR MALMUD: Getting back to your motion, would you rather have your motion on this item tabled? In other words, table this item?

MEMBER LIETO: On this specific --

CHAIR MALMUD: This specific item?

MEMBER LIETO: I'll leave this one on the

table since I'm not going to change my mind later on. So I'm changing the grandfathering. So I'd like to keep this issue on the table with the motion seconded by Dr. Williamson.

CHAIR MALMUD: All right. So we have the motion moved and seconded. We've had some discussion. Is there any further discussion of this particular item? Any -- yes, Dr. Welsh?

MEMBER WELSH: From my interpretation of what I've read and what I've heard during the discussion, I'm strongly in favor of it. Because it's coming to us at such short notice and there's obviously dissension, I would favor tabling this and allowing us to digest it, to think about it more carefully, read exactly what it says and resume discussion at a later time.

CHAIR MALMUD: Thank you.

Dr. Schwarz?

MEMBER SCHWARZ: I agree with that. I think it would be helpful for those of us who --

MEMBER NAG: And I think a vote on this issue is limited here. We need more discussion. And I'm in favor of tabling it.

CHAIR MALMUD: The motion to table supersedes the original.

Is there a motion to table?

MEMBER NAG: Second.

CHAIR MALMUD: Dr. Welsh, Dr. Nag seconds the motion to table.

Any discussion of the motion to table, if not all in favor of the motion to table this issue, this one item?

(Vote by a show of hands.)

CHAIR MALMUD: Opposed to tabling the item? Three opposed.

PARTICIPANT: Four opposed.

CHAIR MALMUD: How many? Four? Five? Who's for tabling it? One, two, three, four, five. And opposed? One, two, three, four.

So the motion is tabled.

MEMBER NAG: The closest vote we've ever had.

CHAIR MALMUD: Yes, it is. It is. However, it does fulfill the spirit of your concern, which is that we should not move on it today. So I hope that you recognize it. It is a partial victory.

MEMBER LIETO: You recognize I won't change my mind.

CHAIR MALMUD: All right. Dr. Howe, can we move on to the next item?

DR. HOWE: The next one is 35.75, and you may also want to table this one because it may involve quite a bit of discussion.

As written 35.75 says that patients can be released if they're not likely to exceed five millisieverts or .5 rem. There is no addition in here as to the time frame that this can be given in. If we go back to our statements of consideration and review of when this rule was put into effect, it is clear that the Commission did not want to require people to keep records, but it is not clear that the Commission didn't believe that the radioactive material given or the radiation treatment given was for any more than one year. And so the Staff in going back now sees that our rulemaking language was not in keeping with the intent and is recommending changing it to 5 millisieverts per year.

CHAIR MALMUD: Dr. Eggli?

DR. HOWE: Dr. Eggli?

MEMBER EGGLI: Probably this affects me more than anybody else because you're probably dealing with nuclear medicine type therapeutic procedures.

If I'm going to approach a five millisievert per year exposure to a family member, which is really what we're probably talking to because

the general public is very unlikely. So anybody who lives in close proximity. I'm going to be at the higher end of the dose range.

The calculations come out around 180 to 185 millicuries is what it takes to produce that 5 millisievert dose. The likelihood that I would repeat that in one year because of questions of bone marrow suppression is very unlikely.

So I actually don't have a problem with this.

DR. HOWE: Okay.

MEMBER EGGLI: Because I don't think it's going to impact my practice.

CHAIR MALMUD: Could you clarify it for us, Dr. Eggli, when you say you don't have a problem with it, you don't have a problem with changing it or with leaving it the way it is?

MEMBER EGGLI: I do not have a problem adding the per year stipulation.

CHAIR MALMUD: Thank you.

MEMBER EGGLI: That will not change my clinical practice.

MEMBER NAG: From a radiation oncologist perspective, it's not going to change. And in fact, having it per year may be helpful, because otherwise

someone may say that 5 millisieverts refers to the entire life span, which means that you can't repeat. So I would be in favor of per year.

CHAIR MALMUD: You're in favor of per year?

MEMBER WILLIAMSON: Yes, I like it.

CHAIR MALMUD: Any other --

DR. HOWE: Wait a minute. We have a public --

CHAIR MALMUD: Dr. Williamson, I think you're next.

MEMBER WILLIAMSON: Yes. Donna-Beth, has there been a particular case or incident that motivated consideration of this change?

DR. HOWE: Yes, there has. There was a case in which three different administrations were intended to be given that in the end would take the family member over this limit.

CHAIR MALMUD: I think Dr. Suleiman, then a member of the public.

MEMBER SULEIMAN: Is the five millisieverts, that's a general public? Did we ever come up with a caregiver limit? I know we debated this quite a bit about a year or so ago. I mean, I'm all for considering family members or caregivers in a

slightly different category. But I would be concerned that this say any individual. I think if the family could keep track of their individuals, this could easily be managed around. But I think there's a real concern with multi-modality imaging and other technologies and people being given care in different facilities that we're seeing people getting multiple examinations and sometimes they're therapeutic at different places. So that potential exists. I don't know if it's completely relevant here, but --

DR. HOWE: This particular regulation is not restricted to family members. It is written in very broad terms. It is any individual that is likely to exceed level. And then there's --

MEMBER EGGLI: The one year wouldn't hurt. It would just require a little bit more attention to managing the patient and whom those people are going to be exposed to, which I think should be good practice in the first place.

CHAIR MALMUD: Members of the public?

PARTICIPANT: I concur with Dr. Howe.

CHAIR MALMUD:

Please introduce yourself?

MR. BROGA: Dr. Broga, DCU.

I concur. This does happen, and it also

if it's going to stand like this, I don't know what we're defining as a year, a calendar year before the date of the therapy or 12 months of the date of therapy. Because we do have individuals who are getting multiple therapy in a 12 month period of time. And it would employ those applying the therapy to ensure that it has not occurred in the previous 12 months. So there would be a necessity for people to ask patients have you received the treatment in the previous 12 months before we released under these criteria.

CHAIR MALMUD: Thank you.

DR. HOWE: Dr. Eggli?

MEMBER EGGLI: I would have to know that anyway before I treated a patient again. Again, because of the cumulative effect of bone marrow exposure over a short period of time. I'd have to know even if I didn't treat them, I would have to know if they were treated in another facility. And I would have to factor the effect of that treatment on the patient's bone marrow into my calculation of a future treatment.

So, again, I think that all rolls through that it's not going to effect my practice to change the regulation to reflect per year.

DR. HOWE: Dr. Nag?

MEMBER NAG: I'm thinking of a new angle, What if someone was taking care of a particular individual and now has to take care of a different individual, maybe the brother or maybe someone else in the family, then you are likely to exceed and you wouldn't know it because you did not treat the other family member. How do we -- I mean what limit do we give for those. I haven't thought about that until -- again, I think I haven't time to think about many of these things.

CHAIR MALMUD: How this addresses.

DR. HOWE: I believe in this case the dose to the other individual has to be from this patient. Because it says, "the total effective dose equivalent to any other individual from exposure to the released individual."

CHAIR MALMUD: Yes.

DR. HOWE: So it doesn't take in a dose received from another released individual, this particular part of the regulation. Because it's trying to determine why I can release this particular patient.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Well, I don't think the

question got answered about are you talking calendar year or 12 month period. Because it makes a difference because keeping records and checking and everything, it's just like occupational records, okay. You don't do it from a May 1st to a May 1st; you do it from a January 1st to December 31st. And so it does make an issue if you've got individuals that are going to get multiple therapies in a calendar year or in a 12 month period.

The second thing is hasn't NRC already published something in their newsletter that went out to licensees about this issue already stating that this was the fact? There was something that's already gone out. There was something along this line within the last year where NRC has already stated that this -- so I'm kind of wondering if you've already gone out and told all the licensees this is the way it is, why are you coming back to us?

DR. ZELAC: Can I speak to that? This is Dr. Zelac.

CHAIR MALMUD: Dr. Zelac?

DR. ZELAC: I was the author of the newsletter article to which you refer. And we received an interpretation from our Office of General Counsel that although the intent, as Donna-Beth had

said, of the Commissioners is clear, the rule language does not support that intent. So what we said is in fact incorrect. The rule as written is not, and cannot be interpreted on an annual basis.

There will be another newsletter article coming out, hopefully, in the near future which will make it clear that this issue continues to be under discussion, but at the moment the regulation as written cannot be supported on a per year basis. That's the reason for this proposed change or suggested change to the rule.

CHAIR MALMUD: I have a question for you, Dr. Howe. Does this relate to outpatient therapy of I-131? Is that where it came from?

MS. FLANNERY: Can I respond to this one?

DR. HOWE: Yes.

MS. FLANNERY: As far as this particular case, this was a series of six administrations of iodine-131 given over a period of a couple of weeks time frame. And what was calculated is that each release would result in a 250 millirem dose to a member of the public for a total of 1.5 rem.

CHAIR MALMUD: Six I-131 therapies in --

DR. ZELAC: Not oral. Not oral iodine. This was a labeled antibody, if I recall.

CHAIR MALMUD: I see.

MEMBER VAN DECKER: That must have been an investigational therapy.

MS. FLANNERY: That I don't know. This is a question that came in from an agreement state, so I don't know anymore detail than that.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Well, I think this kind of gets back to Dr. Suleiman's point about caregivers. And I thought we had sort of a upper guideline of around 2 rem in the information notice or regulatory issue summary, whatever format it was in, that went out on this.

So I would like to make a motion. I think some of these have a lot more currents underneath them than we're seeing right here. And I'd like to kind of maybe take a look and get some more information on these things before we make a judgment. Could I make a motion that we maybe table all these until we get some more background information on these proposed changes? Because I think the more we talk about this and go back and forth we see that there's more issues than maybe we're seeing at first blush in discussing these. And I'd like to move that we just --

CHAIR MALMUD: Mr. Lieto has made a motion

to table this item. Is there a second?

MEMBER WILLIAMSON: He wants to table all the items.

DR. HOWE: He wants table all the items.

MEMBER LIETO: I would table all these.

MEMBER WILLIAMSON: I would table this one for sure, since we can't seem to get to the bottom of it.

DR. HOWE: I would like to bring up one of the items just so that you have it in mind for a later discussion by Mr. Nag.

CHAIR MALMUD: What?

MEMBER NAG: One thing we can do instead of tabling everything, we can go more at an information item. Next, I would suggest let Donna go through it as an information item without voting on the issues. We can vote on the issues later.

MS. WASTLER: That's also a viable option so that you could ask what questions you have, and then any motion could come at a later time after you've thought about the responses or --

MEMBER NAG: Because otherwise, you know, if we don't go through it, later on we have to start all over again. Here at least we can have an introduction to the problem and that will allow us

time to think about it at a later time. And if needed, we can even do the motion on a telephone conference call.

MEMBER SULEIMAN: I agree with what he's saying.

MEMBER LIETO: I agree.

CHAIR MALMUD: Dr. Nag, thank you.

DR. HOWE: Sally?

CHAIR MALMUD: Yours is a motion that we accept these as informational items. Is there a second?

MEMBER SCHWARZ: Can I ask one more question. Dr. Schwarz?

MEMBER SCHWARZ: I mean in terms of what is being discussed, I mean it seems like there is significant background for each of these issues that's really -- you know, it's coming out from Ron and Cynthia. And it would be helpful if rather than -- that it actually is presented, all the information that's known about the case that brought it here to begin with, rather than having to kind of piecemeal add it in, it would be helpful for us.

CHAIR MALMUD: So are you seconding?

MEMBER SCHWARZ: Yes.

CHAIR MALMUD: All right. So Dr. Nag's

motion to listen to all these as informational items has been seconded by Sally. And any further discussion of that motion? If not, all in favor of the motion.

(Vote by show of hands.)

CHAIR MALMUD: Motion carries.

So, Donna-Beth, could you go on to the next item?

MEMBER EGGLI: Well, actually, could I pursue this current item just a little further, sir?

CHAIR MALMUD: Okay. Sure.

MEMBER EGGLI: What it sounds to me, Cindy, is that this is really a caregiver exemption, which is really different than this issue. That, first of all, again it takes over 180 millicuries with standard precautions to create a dose of more than 5 millirems. So we're talking about some kind of a high dose therapy. And it sounds like the exemption being asked for was the caregiver issue that we've discussed in the past and not this same issue of the exposure to the general public. And if you're going to put together the information for this, I think it would be very desirable to separate whether we're looking at a caregiver exemption versus a concept of the exposure to the general public in looking at this. Because I'm

still having trouble imagining any standard radioiodine therapy where you would give so much over a short period of time that someone other than a caregiver of a very ill person would get that kind of exposure.

DR. HOWE: And you may also be looking at you cannot have the normal assumptions that you have when you release patients. There may be additional care -- there may be additional close contact that you're not anticipating.

MEMBER EGGLI: Right. But that would probably fall under the caregiver exemption rather than the general release role.

DR. HOWE: Right now the caregiver exemption I believe is only in Part 20 for patients that are hospitalized.

MS. WASTLER: No, Donna-Beth. They're talking about the care --

MEMBER EGGLI: Yes. And I understand what you're saying --

DR. HOWE: But I think the simulation is what --

MS. WASTLER: Yes. Okay. You're right.

MEMBER EGGLI: I understand what you're saying.

MS. WASTLER: It is in relation to hospitals. But, yes. But the concept may transfer?

DR. HOWE: Yes.

MEMBER EGGLI: Yes.

DR. HOWE: Okay.

MS. WASTLER: So we need to look at the two together. Okay. I agree.

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Well NCRP if my memory is right, commentary 11 addresses caregivers. And I think some new ICRP guidance also distinguishes caregivers from the general public. So I think this issue has traction. And I think the NRC, it would be good to sort of address caregivers and family members and so on in a separate category. And I think it would make life a whole lot easier for both the patients and the users. Because the way that reads, that's any individual. So that would preempt any caregiver. That basically says anybody other than the patient.

Some of this have always felt this was a simple solution, but I think this is something that should be addressed in a very clear manner, and I think it would be good to find out what other guidances or other agencies are doing.

DR. HOWE: All right.

CHAIR MALMUD: Dr. Fisher?

MEMBER FISHER: There's a medical rationale for protracting a high dose radio-immunotherapy infusion. And what I think is interesting here is that the regulations could prevent a protraction of a high dose therapy where an infusion is given, say, in six multiple infusions. Normally a high dose radio-immunotherapy procedure such as 600/700 millicuries is given in a single dose. The patient can be held in the hospital for a number of days, seven or eight days, and then released.

It sounds like an investigator is trying to give a high dose infusion over six different infusions, which would cause, according to this rule, that the patient could not be released over a long, long period from a hospital. So I think we need further background on this issue.

DR. HOWE: But you would also think that one way to bring the dose down would be if he's giving it over six different parts, he may hospitalize him for a small period of time on each one, because that brings the total dose down. But that's just another way of looking at it. It's not saying you have to be hospitalized for the entire time, but you might have

-- if I could move on to my next one?

CHAIR MALMUD: Please do.

DR. HOWE: This is 35.491. And this training and experience requirements for ophthalmic, eye applicator devices. And this one I really want to bring up now because Dr. Nag is going to be talking about the new technology. And we looked at the -- it's a new technology. Our current experience when the rule was written in 2002 and 2005 was the eye applicator that was placed on the exterior part of the eye. And the new use is where you actually go into the eye with strontium device and treat inside the eye.

We took a look at it and we thought that there may be significant training issues that are associated with it. And that it might be over in 35.1000 or we might want to revise the training requirements in 35.491 to include this new device.

And so if in fact we decide -- Dr. Nag's going to present a more in depth discussion of the device itself and how it's used and what it does. And our thinking was that if we were to go into 35.491, we would want to distinguish between what is currently done, and that's a superficial ophthalmic radiotherapy procedure and a training and supervised work

experience in this new intra-ocular ophthalmic radiotherapy device. And we would consider the basic radiation safety that is required in 35.491 to be the same but that the supervised work experience would be more particular to --

MEMBER NAG: My suggestion is that we table the discussion of this after my presentation when the ACMUI had their understanding of what this new technology is. And you can bring up under the discussion after my presentation. You know, I haven't described --

DR. HOWE: And that's exactly what I intended to do. Is just bring it up as we know it's coming, we know Dr. Nag is going to talk in a lot more detail about the device and you'll have a much better idea of what you want to think about then. But just to bring up that these were kind of our preliminary thoughts, too.

MEMBER WILLIAMSON: Is this an interstitial brachytherapy device?

MEMBER NAG: Well, we'll talk about it.

DR. HOWE: Yes.

MEMBER NAG: It penetrates inside the eye. It's not superficial. It's not surface.

DR. HOWE: They pen the eye and insert the

probe.

MEMBER WILLIAMSON: So maybe it would be best to leave this in the hands of a radiation oncologist.

DR. HOWE: So this is just to kind of introduce you to the concept. Okay.

MEMBER WILLIAMSON: The 35.491 is for the ophthalmologist, correct?

DR. HOWE: Yes.

MEMBER WILLIAMSON: To be able to perform strontium 90 eye plaque therapy independently of --

DR. HOWE: Yes. And because 35.491 is written in very general terms, it just talks about ophthalmic radiotherapy treatment, but the terms themselves are general enough to include this new device. And the question is should this new device really be included in 491. And that's going to be the issue for you. And Dr. Nag will give you a better perspective on what the device is.

So if I can move on --

CHAIR MALMUD: Thank you.

DR. HOWE: -- in 35.400, .500 and .600, which are sealed source and devices we require licensees to only use the sealed sources and devices in these sections as approved in the sealed source and

device registry. This creates some issues for us.

The manufacturers will indicate uses for their devices and sources. Those uses may not be all encompassing, they may be presented much earlier in the sealed source and device registry history. They may be out of date. And the individuals that are doing the sealed source and device registry are not really looking at the medical use. They're looking at it as examples of ways the source and the device can be used. And so we think it is inappropriate to tie medical users to only -- to only use the sealed sources and devices as approved in the sealed source and device registry. And it came up recently with the gamma knife Perfexion. Because the gamma knife Perfexion is slightly different. It can encompass a larger area for treatment, and yet the manufacturer wrote in a very narrow limit. And our regions said well that means any use outside of that because it's not in accordance with the sealed source and device registry is research. And we're trying to say no, that's practice of medicine and we'd like to try to address the problems with this particular requirement in such a way that we can use the sealed source and device registry for the reason it was intended, which was the radiation safety aspects of the device or

source and not get into the practice of medicine issues.

And so I don't have any specific wording for this. I just have a concept that somehow we revise these particular sections to exclude the specific medical indications provided by the manufacturer while retaining the type of medical use, manual brachytherapy, gamma 9, HDR, something like that, the large grouping.

MEMBER NAG: I think this is something that I would be -- you know, I would be attracted very much about, and therefore I would like some time to think about it.

I do not want to be restricted, that just because they showed it would double up for treatment of prostate cancer, you know, I can't modify and pre-rectal cancer, too. I want to digest this a little bit.

DR. HOWE: We don't want him to be restricted. When they wrote the rule in 2002 they thought this was a basket that would answer everything. And we tried to point out that there would be -- people might interpret this as restrictive medical use, and we did not want that.

CHAIR MALMUD: Thank you. That completes

your information items?

DR. HOWE: Yes.

CHAIR MALMUD: Thank you.

Sandi?

MS. WASTLER: Oh, I was just going to point out that we are behind schedule. And we were scheduled for a break at 9:30, so I would offer that maybe it might be a good time to go ahead and take a break.

CHAIR MALMUD: Yes. Thank you.

MEMBER NAG: Yes.

CHAIR MALMUD: Dr. Williamson would like to offer a brief parting comment.

MEMBER WILLIAMSON: Yes. I think these particular issues to give opinions on for proposed rulemaking or concepts of rulemakings are especially complicated. We do have to render some sort of a decision or opinion. So unlike maybe some informational items where we really don't have to react so specifically, it might really be a good idea to try to get these out more in advance.

MS. WASTLER: Oh, well I already have that done as an action item that in the future anything along these lines, and we do have these. I mean, granted, we had a long discussion yesterday about

implementation issues. But as we work through things, we get, you know, here's a tweak, here's a problem. And so we have to come to the Committee to vet those to make sure that we're moving in the right direction and that in the future we'll make sure that you get those ahead of time and provide any background information that might benefit you in making your determination or benefit the discussion.

CHAIR MALMUD: Thank you. Can we resume at 10:00? Fifteen minutes. Thank you.

(Whereupon at 9:43 a.m. a recess until 10:05 a.m.)

CHAIRMAN MALMUD: Can we get started, please? We have a very extended agenda for the day.

MS. WASTLER: Dr. Malmud, if I could, I would like to just take this opportunity to welcome Dr. Bruce Thomadsen, who has joined us today. He wasn't available yesterday. He is going to be the ACMUI medical physicist in the next year. And basically his full membership is still pending his security clearance, but I just thought we would take this opportunity to welcome him.

MEMBER THOMADSEN: Thank you.

CHAIRMAN MALMUD: Thank you. Welcome, Dr. Thomadsen.

MEMBER THOMADSEN: Thank you.

CHAIRMAN MALMUD: And your home base is?

MEMBER THOMADSEN: University of Wisconsin.

CHAIRMAN MALMUD: There's another Wisconsinite here.

(Laughter.)

MEMBER WELSH: I know him.

MEMBER NAG: By the way, could you --

MEMBER NAG: Would you clarify what Bruce's status will be at this meeting? Is he an observer?

MS. WASTLER: He is.

MEMBER NAG: Can he vote? What will it be?

MS. WASTLER: I believe that he is a nonvoting member --

MEMBER NAG: Okay.

MS. WASTLER: -- because his full ACMUI membership won't be established until he completes the security clearance. But right now, yes, he will be Jeffrey Williamson's replacement in the therapy medical physicist position.

MEMBER NAG: Yes. I just wanted to clarify.

MS. WASTLER: No problem. Thank you.

CHAIRMAN MALMUD: If we may, we will move on to the next item on the agenda, which I believe is Mr. Lieto.

MEMBER LIETO: Thank you, Mr. Chairman.

10. ONE RSO ON LICENSE

MEMBER LIETO: One thing I just kind of wanted in terms of, I guess I should say, some background information, I regret that Dr. Vetter is not here since he is the RSO member, but I would like to point out that he has seen my slides and had the opportunity to comment and improve on them, hopefully. And so he is fully aware of the content of this presentation.

So, with that, I want to address the issue of why only one RSO on a license, not so much maybe the history of this but sort of what my impressions are on it, but also the current situation and maybe provide some discussion that we might be able to come to some resolution on, maybe not at this meeting but at least establish as a future agenda item with some action that the Committee can take on this issue.

In researching this, some of the things that have come to my attention are that there is only one RSO that is issued on a license. And I believe

that's true also in agreement states, but I may be wrong. But I will speak definitely as a non-agreement state, an NRC state medical physicist, and an RSO that there is only one listed on the license, but it's not required by regulation. There's no regulation that says you have to have only one RSO on the license.

In trying to find some background information as to why is there only one RSO on a license, neither NRC staff at headquarters or in the region that I inquired was able to provide any information as to a policy statement that exists why there is only one RSO on a license. There is not any Office of General Counsel statement or policy or NRC document to this.

So I've kind of made some suppositions on this and that looking back at licenses that I've been involved with that go back a few decades, that the officer concept probably suggests an old AEC or military-origin concept of a singular person with duties for radiation safety for a facility or area. And I think that is just carried over.

There may have been a written policy to this extent directing this, but, again, there does not appear to be anything in writing that exists regarding such a policy.

The other thing that I wanted to point out from a background standpoint is that the existence of a singular RSO predates the NRC establishment of management being responsible for radiation safety programs.

That largely came about, I believe, in the late '80s or early '90s. And I'm sure if I am wrong, NRC staff will correct me. But that was about the time frame where management really became the focus for the responsibility for radiation safety programs.

Current regulations that address Part 35 are found in section 12. You have to submit the training and experience and qualifications for a radiation safety officer when you apply for a license or renew a license or make an amendment that specifically addresses the radiation safety officer.

The amendment changes are addressed in section C of section 13, which states that you are to make that amendment change for an RSO before changing RSOs except as provided in section 24(c), which I will get to in a second.

Section 24 addresses the responsibilities and authority of the radiation safety officer under the program. It states that the RSO is appointed by management, the RSO has to agree in writing with

management that they will be responsible for the program on a routine basis and that basically the RSO is the licensee management's proxy for the performance of the radiation safety program to comply with regulations and license conditions.

Now, one point I wanted to make and bring to the Committee's attention is that in section 35.24(c), which addresses the authority and responsibilities under the program, it allows under regulation for a temporary RSO for up to 60 days.

And it states that the licensee can authorize or permit an AU or an individual who meets the RSO qualifications to be the RSO for up to 60 days in a calendar year. And this is what they categorize as a temporary RSO and some other things that the licensee has to meet which are already in place. And they have to notify the NRC within 30 days that they have made this temporary appointment.

Now, nothing changers on the license. Okay? There's no record of this that goes anywhere other than simply a notification to the NRC office or I'm assuming the agreement state radiation control office.

It also permits up to 60 days the simultaneous appointment of more than one temporary

RSO in accordance with the 24(c) that you see in the top paragraph there. And it says that the management can do this, if needed, to ensure that the licensee has radiation safety officer coverage in the appropriate area.

So obviously if you have a multi-modality with maybe HDR and radiopharmaceutical therapy and diagnostic applications, you might have multiple individuals with temporary RSO responsibilities but, again, remembering that the RSOs that are temporarily appointed are notified to the NRC or the agreement state office and that they're allowed to do this for a two-month stint.

Now, looking at the guidance under the NUREGs that address the radiation safety officer, this is the guidance that is given to licensees as they submit license applications or renewals or so forth in complying with the sections that I just addressed.

It states that the RSO is responsible for the day-to-day oversight of the program. It permits consultants to perform these responsibilities. It also indicates that it does not need to be a full-time employee, even for a broad-scope license.

Now, I think some of us may have a little bit of heartburn with that, but under the guidance

document, that would be permitted. And there might be certain circumstances maybe with limited broad scopes that that might be appropriate or so forth. But, nonetheless, it is permitted and then that it meets the qualifications and "is available for advance and assistance on radiological safety matters." So obviously this guidance is used in the case of consultants where they're not needing to be on site for the day-to-day oversight activities.

Now, who is allowed to be or who currently can have multiple listings on licenses? Well, obviously your authorized users' positions have their multiple authorized users. You could have multiple AMPs on a license. You can have multiple authorized nuclear pharmacists on the license.

At one time I know for a fact that NRC regions were designating multiple RSOs on licenses, but that has since been discontinued. So obviously there may have been a policy or some type of statement or guidance from headquarters that allowed this as a possibility to be done.

Now, who isn't specified on the license? Well, management isn't. They have the ultimate responsibility for the radiation safety program and are not named. They're not named by office. They're

not named by individuals' names. They're not named by title. Okay? So the people that have the real ultimate responsibility for the program are not listed anywhere.

Also not listed are health or medical physicists, technologists, technicians, who may have the actual daily program duties and responsibilities for compliance. This obviously could range from a very small imaging facility that would have maybe a single authorized user and a single technologist or the authorized user may or may not be there on a daily basis.

Yet, the day-to-day management and responsibilities fall to a technologist or technician up to maybe very large programs under multi-modality broad-scope medical licensees, where you may have a staff of health physicists, who again cover all the areas, have day-to-day responsibilities, but, again, are not listed because of the RSO is the manager of that program.

So what are some of the issues and concerns that have been raised regarding the issues revolving around having just a singular RSO named on a license.

Well, obviously if you had multiple RSOs

designated by area of expertise, there could result in areas where there is commonality of responsibility and you end up sort of getting this finger-pointing, "Well, it's the other guy who is supposed to be taking care of that."

And NRC at the regional level has indicated that this was a problem in some licensees, resulting in citations and I think maybe was some of the impetus in going away for maybe the previous situations, where multiple RSOs by area were listed.

I also know that in certain types of broad-scope licenses, where you had large research programs and medical programs, there may have been a research RSO and a hospital/medical center RSO. And, again, areas of commonality under the program, there may have been some deficiencies that occurred and concerns by NRC licensing staff with this type of a problem.

Licensees also have expressed concerns and issues on the singular side because they have staff who perform these duties, meet the qualifications. Yet, these qualified individuals are not named on the program.

And also with the current T&E interpretations of boards and the recentness of

training, you could have individuals that have been with a program for many years not listed, done the duties, leave the program to be an RSO. Yet, they have never had the RSO designation and have to go through this whole documentation route, yet have actually been performing the duties.

Other problems also that arise that, you can't automatically replace an RSO if they leave, either due to illness, extended leave for personal reasons, that you don't have this very, shall we say, quick, automatic change of who is listed on thee license.

Some other concerns with having a singular that increasingly with small medical licensees, 100-200-type licensees, the situation is occurring where you are having a single RSO listed on multiple licensees.

So obviously this was -- I think this was brought up yesterday by I think a member of the audience and commented by Dr. Fisher that basically what happens is you are diluting this individual and performing the "day-to-day oversight" activities that need to occur and that basically they're available to provide assistance on more emergent radiological matters, rather than day-to-day situations.

And also by the fact that you're allowing one individual to be on more and more licenses, you're, shall we say, not bringing in new RSOs to fill the pool that might be needed.

I think this problem is going to become exacerbated by the fact that authorized users are reluctant to be named on the license as an RSO for the reasons that practices are now covering more areas. They're rotating to more sites, having more clinical responsibilities, and don't want to have the responsibility of the RSO.

And also with the fact that doing more and more duties, be it teleradiology, PAX-types operations in this digital age, your fine physicians are at one site and can cover from the standpoint of clinical interpretation many more sites than were possible just a few years ago.

So what are some suggestions? One suggestion we thought that the NRC should consider and ACMUI is the listing of the temporary RSO on the license. And that should be under some other designation to resolve the hierarchy concerns that previously existed by NRC or were indicated by NRC staff before.

In other words, you would have an RSO.

And you would have this other individual with some other designation. I like the term "radiation safety specialist," but some other terms that have been suggested are "associate RSO," sort of using the academic type of hierarchy of full professor, associate professor.

You would have the RSO and associate RSO type individuals such that if the RSO left the institution or was going to be gone for weeks at a time, that it was obviously by management designation because of this situation that the associate RSO could fill in and there would not need to be any concerns about coverage and monitoring on a day-to-day basis.

Another point that should be made is that if you have an individual that meets the RSO qualifications as a temporary RSO and has qualified to do it for two months, why not just recognize them altogether and put them on a license?

The fact that someone can cover a licensee for two months at a time while meeting the RSO qualifications, yet the only thing that occurs is a notification to the regulatory office really I think is not productive and would address those issues where you might have multiple individuals that meet RSO qualifications and it doesn't require a regulatory

change.

Also maybe go back to permit listing of these other RSOs, again maybe radiation safety -- the term used here is "radiation safety specialist" -- and designating the area of where they would have radiation safety responsibilities, especially your high-risk areas. That's what you want really covered.

I think 100 and 200 -- hopefully the Committee would agree with me -- really are not areas of high risk. Basically it's your radiopharmaceutical therapy, your brachytherapy, and 600 applications.

There's obviously the need for a documented policy. Now, I don't know if this needs to come from the Office of General Counsel regarding some written interpretation, but obviously there needs to be a documented policy from headquarters level down to the regions and hopefully with input of the agreement states -- and I think ACMUI needs to be involved in this -- that would authorize that the multiple RSOs be listed on licenses and that there be some hierarchy designation to indicate that there's sort of a top-down responsibility for the management of this program.

The last item I have here, replacing "officer," is just sort of a pet peeve of mine that it

sort of has this policeman-type attitude or designation, which I don't think anybody that has ever been listed as an RSO likes.

Some people maybe like to carry a big black baton and wear dark boots. I don't know.

(Laughter.)

MEMBER LIETO: But I have never liked to. I never liked the term, and I don't know if it could be changed because it is so firmly ingrained into the history of regulatory space, but those are my suggestions on maybe addressing the multiple RSO situation without requiring regulatory change.

CHAIRMAN MALMUD: Thank you.

Sandi, you wanted to say something?

MS. WASTLER: I just wanted a clarification. So my understanding of what you are saying is that on any one license, there would be one RSO, who, as you I think stated, would be management's proxy that's responsible for all the radiation safety.

And underneath him would be in a hierarchical manner maybe temporary RSO, whatever the term, assistant RSO. And those assistants could be broken down by specialty, HDR, whatever, based on their background or could actually be someone that could cover multiple.

MEMBER LIETO: I mean --

MS. WASTLER: I mean, is that the thought pattern?

MEMBER LIETO: Yes, that's the thought. I think if someone is authorized for the high-risk areas, say like radiopharmaceutical therapy, you know, the 100s and 200s would fall under that automatically, the same thing for brachytherapy.

I think that if you have the qualifications for radiation safety with brachytherapy, I think that you have the training and experience for being capable assuming they know the regulations and so forth, being the RSO to manage the radiation safety program for nuclear medicine imaging.

CHAIRMAN MALMUD: Jeff?

MEMBER WILLIAMSON: The listing of these associate RSOs in the license, would they just be like listed as associate RSO, period, or would it specify? Would it be hardwired into the license document itself what their scope of --

MEMBER LIETO: Yes.

MEMBER WILLIAMSON: Is that desirable or necessary?

MEMBER LIETO: Well, I guess I would leave that open for discussion, but the person and the

designation would be hardwired, would be listed physically on the license.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: This is just semantics, but my suggestion would be that anyone who qualified to be an RSO by whatever, 35-50, whatever, would be called an RSO. There can be multiples of them. And then the one who links with the management or the one who will oversee all the operation in a big institution that will have many RSOs would be called the chief RSO.

(Laughter.)

MEMBER NAG: No. But the thing is that anyone who is an RSO could qualify to be the certified person, you know, could be doing anything that the other RSO is doing. So that would possibly solve the shortage of RSOs.

So you still call them RSO. They are not assistant to anything. They are RSO. But the one who is overseeing the whole operation would be named the chief RSO and linked to the administration.

CHAIRMAN MALMUD: Doug?

MEMBER EGGLI: I like the concept of associate RSO. And anyone who meets the qualifications to be an RSO could be potentially then listed on a license as an RSO.

As far as the "O" part, the officer part, it is ingrained in not only NRC but in corporate governance. There is a chief executive officer, a chief operating officer, a chief financial officer, a chief information officer.

The term "officer" in this case implies someone who has a responsibility for a sphere of activity and governance. So I don't have a problem with the RSO term, but allowing the designation of associate RSOs then solves the preceptor problem.

I would hardwire the names of those individuals onto the license applications, but I would be very reluctant to see a sphere of responsibility for that associate RSO hardwired into the license application and allow them, the institution, by internal policy to either have an associate RSO who covers everything that the RSO does or to assign spheres of responsibility within an institution. But I think it's a good idea to hardwire those spheres of responsibility over the license applications.

MEMBER LIETO: You don't?

MEMBER EGGLI: I would not hardwire the description of the responsibility. I would hardwire the associate concept and the name of the person but not the sphere of responsibility.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yes. I like Dr. Nag's suggestion of calling all of the RSOs RSOs because that is transparent. It doesn't require changing the rule language anywhere else in the regulation. We only have to be changed in one place that does have some sort of a designated or executive RSO that would actually have overall responsibility for the license.

And I also agree with Dr. Eggli's suggestion that the function not be hardwired and the like.

CHAIRMAN MALMUD: We have Dr. Suleiman?

MEMBER SULEIMAN: I also think the concept is good. I would prefer senior RSO.

(Laughter.)

MEMBER SULEIMAN: I would let the associate thing drop, either way. But, rather than try to categorize it by class of product because you may have departments that may have multiple modalities and so on, I would try not to bind that into some sort of a regulatory hierarchy so that it would be clarifying and useful to the facilities, to the licensee to show that this RSO or associate RSO is responsible for radiology or nuclear medicine or oncology or endocrinology, I mean, whenever they may

be using radioactive materials.

And that may very well vary from site to site. But at least it would probably be much more clarifying for the licensee.

MEMBER LIETO: A further thought. It's probably a good point because if you did hardwire it by sphere, if you wanted to change it, you would have to go back and amend the license.

MEMBER SULEIMAN: Oh, absolutely. I can see where we're --

MEMBER LIETO: And I don't think you would want to. I think you want to try to avoid that as much as possible.

MEMBER SULEIMAN: I always ask people what department. And I get a different answer almost every time. So most institutions are structured very differently.

MEMBER LIETO: Good point.

CHAIRMAN MALMUD: Member of the public?

DR. BROGA: Dr. Broga. Up until the late '90s, at least in Region 2, the NRC named all RSOs on licenses, dozens of licenses, listed them, and required the same submission documentation from the management as was for the RSO.

Somewhere in the late '90s, a decision was

made from the NRC to stop allowing alternate RSOs to be listed on licenses. I don't know the reason for it, but there was at least a decade of history of alternate RSOs being named on licenses.

CHAIRMAN MALMUD: Does anyone know why that practice stopped?

MS. WASTLER: I think, unfortunately, as Mr. Lieto said, that many of us weren't here. And we have not been able to locate any document that specifically says.

But that's a good point. You said Region 2?

DR. BROGA: Yes.

MS. WASTLER: Did you talk to Region I?

MEMBER LIETO: I talked to Region 3 and they --

MS. WASTLER: Three? We might be able to get some more information, maybe going to Region 2. I think we need to obviously look into this a little more, but I am not aware. And I checked with my touchstones, Donna-Beth and Ron, who have been with the program for a lot longer.

And I'm not sure that any of us are aware of any policy statement. So, you know, why the decision was made at this point I can't tell you. It

may be buried in some of the enforcement cases, you know, that it came out of and where there was no -- as you said, there is nothing in the regulations that says you can't do it. The reverse is it does not say that you cannot.

So, you know, someone had made a decision for some reason. And more than likely, my inclination would be it's related to some kind of enforcement problem that the decision was made.

And because there wasn't any requirement for any change from a regulatory standpoint, it was kind of part of the process just got incorporated in the way we do business. And, unfortunately, it wasn't documented.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: I would have to check to make sure, but I believe that we had our associate RSO listed on our license. I remember we sent in an amendment for that.

MEMBER GILLEY: Is this to Wisconsin?

MEMBER THOMADSEN: Yes, right. So at least I think one agreement state does do that.

MEMBER GILLEY: I think we had one in Florida, but I couldn't speak for all of the agreement states because they are all different. But we do

corporate RSO. And then we let you include site-specific RSOs in the application you submit to us.

So in some of the broad-scope licenses, they have an assistant RSO at each facility. We have 14 or 15 facilities in the State of Florida. So they would as part of their application or renewal process submit that in, which is, of course, included in the catch-all or the last statement of the license. So there already is some flexibility.

But they're not specifically listed on the license. The information submitted becomes legally binding.

CHAIRMAN MALMUD: Member of the public, I believe, is waiting.

MEMBER SCHWARZ: Maybe Linda is --

MS. FAIROBENT: Lynne Fairobent, AAPM. Unfortunately, I am going to truly date myself now.

(Laughter.)

MS. WASTLER: I would have to admit that only Lynne and I go back too many years. So you are dating both of us.

MS. FAIROBENT: In 1977 and '78, when I was in the Region 3 office, we did back then have more than one RSO on a license. In 1979, when I came to

headquarters to licensed materials programs, again it was allowed.

I think part of the change came about -- and I probably do have documents, unfortunately, in my garage or basement because I'm a pack rat. But after TMI, there were a lot of discussions in the nuclear power industry about strengthening the role of the radiation safety officer in commercial nuclear power plants.

And there was an awful lot of discussion and flow-down from that in the 1980s and late '80s. And when I was with the Nuclear Energy Institute in the middle '80s, a lot of these changes came about in the power industry and agreeing to give and acknowledge the authority and responsibility to the radiation safety officer to shut down a nuclear power plant.

I think around that same time, which would have been late '80s, early 1990s that Dean is referencing, some of this just trickled down across the agency for consistency.

I don't know that there was any real policy statement that did this, but there certainly was general discussions amongst the community for consistency of what was being done across all licensee

categories.

We can talk afterwards, Sandi, but I may be able to help point in some directions. But, like I said, I do know originally back in the late '70s, we did have multiple RSOs, at least in Region 3 and then from headquarters, when we at that time were doing all of the licensing except for the pilot program in 3 back in '78-'79.

So I think it's just been historical changes but no real regulatory hard hammer or meat behind the justification to do that.

MS. WASTLER: No real policy paper but just, you know, the concept floating down.

MS. FAIROBENT: Right. And I think if you go back and look at some of the old statements and considerations for some of the amendments that predated the wholesale revision to Part 35, you may actually find some bits and pieces, but those records are --

MS. WASTLER: It might be buried, really buried.

MS. FAIROBENT: -- probably buried and hard to extract that data.

MS. WASTLER: Yes.

MS. FAIROBENT: But that is where I

suspect that it may be hidden.

MS. WASTLER: Okay. Thank you.

CHAIRMAN MALMUD: If I may? Excuse me. Dr. Fisher?

MEMBER FISHER: Just a quick question. What is the current practice of the NRC if it receives a license application listing two names as RSO?

MEMBER GILLEY: I can speak for the State of Florida. We would send it back and say you needed to identify the RSO.

MS. WASTLER: The RSO. I think that it would be the same thing for us. You would have to name an RSO. And that RSO would be the only one that would be put on the license.

You might have to list it. But as soon as you said Joe X is the RSO, that's the person that would be put on --

MEMBER FISHER: So if two names were listed on the application, it would be sent back?

MS. WASTLER: No. Well, I can't necessarily speak. Donna-Beth, are you aware of whether they send the application back or -- licensing is done in the region.

DR. HOWE: I don't think they necessarily send the application back, but there is a request for

additional information. The request for additional information is, who is your RSO?

MS. WASTLER: Right.

DR. HOWE: You have given us two people. Which one is it?

MS. WASTLER: Right. And basically, I mean, your application might have five RSOs listed, but only the senior, top, executive RSO would be the one that would be on the license.

CHAIRMAN MALMUD: Ralph, in summary, then, would it be acceptable to you for someone to make a motion that there be more than one RSO permitted per organization, that there be -- obviously for management, there has to be one person in charge. So that the others might be called associate RSOs, leaving the term "RSO" intact. Too many changes at one time might bring rejection.

So that there would still be a designated RSO. And others would be listed on the license as associate RSOs with recognition that their roles as associate RSOs qualify them for application to other institutions having had RSO experience.

Would that cover the spirit of what you wanted to get across?

MEMBER LIETO: Yes. And a documented

policy by NRC of guidance to its regions for that. I think there needs to be some written --

CHAIRMAN MALMUD: The request of documentation of policy. All right. So if the recommendation is that there be more than one RSO per institution, there would still be an RSO who is the senior RSO designated as the RSO. The others would be associates with a request from the NRC for a policy. That's a motion, your motion?

MEMBER LIETO: It can be.

CHAIRMAN MALMUD: Seconded by Dr. Schwarz. Is there any discussion of the motion? Dr. Williamson?

MEMBER WILLIAMSON: Yes. I would be careful about locking the motion into specific terminology, such as, as you have phrased it, RSO versus associate RSO. It might be better and more straightforward to amend the regulations if it's chief RSO versus RSO. So I think you should leave it open.

CHAIRMAN MALMUD: Okay. That sounds reasonable as long as --

MEMBER WILLIAMSON: The concept is one has to be designated as --

CHAIRMAN MALMUD: Somebody has to be in charge, right.

MEMBER WILLIAMSON: -- the RSO of record.

CHAIRMAN MALMUD: Right.

MS. WASTLER: As Mr. Vetter noted, this policy is implementation of existing regulations. There is no change that will be taken. It's simply a reinterpretation of the existing policy. And the policy statement would define the terms per se.

MEMBER WILLIAMSON: Well, this is the concern why I suggest the term "RSO" be left intact. Otherwise I'm afraid it might be subsequently interpreted that associate RSOs cannot be preceptors for RSOs.

MEMBER NAG: I would like to amend the motion.

CHAIRMAN MALMUD: Please do.

MEMBER NAG: The amended motion would be that multiple RSOs be allowed on the license and that one of those RSOs be identified to be the RSO in charge. So don't use associate or anything like that.

And, you know, you can call them whatever you like, chief RSO, RSO in charge, senior RSO. You can name whatever you want, but all of them are RSOs. One of them is the one who is put down.

You know, just like a department has many radiation oncologist, but one is a chief radiation

oncologist.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I second the motion.

CHAIRMAN MALMUD: The motion will state that there will be more than one RSO at an institution with a designation of one of the RSOs as the person in charge.

MS. WASTLER: The first motion is off the table now? Oh, it was amended. Okay.

CHAIRMAN MALMUD: It will be amended with the approval of the --

MS. WASTLER: It was a friendly amendment?

CHAIRMAN MALMUD: Was that with your approval?

MEMBER LIETO: I have no -- yes, I would agree.

CHAIRMAN MALMUD: Dr. Suleiman, it's with your approval? All right. It's been amended. Do you wish to amend the amendment?

MEMBER SULEIMAN: No.

(Laughter.)

MEMBER SULEIMAN: Are we discussing it?

CHAIRMAN MALMUD: Sure. I mean, you've got it. You got what you just asked for.

MEMBER SULEIMAN: I think it's a perfect

solution. I'm just curious. Does anybody see something wrong with it?

MS. WASTLER: As we say, the devil is in the details, but --

MEMBER SULEIMAN: But if something is obvious, let them speak now.

(Laughter.)

CHAIRMAN MALMUD: I mean, we could table it and give them time to think about it. That was meant to be in humor.

(Laughter.)

CHAIRMAN MALMUD: All right. Sally?

MEMBER SCHWARZ: I just have a question. Since it will be a matter of our minutes of this meeting, I mean, will it be written anywhere that it would become like guidance document, I mean, such that, you know, it actually will happen?

CHAIRMAN MALMUD: Yes because I understood that this really is not a change in policy. This is just the ability to designate more than one RSO at an institution for purposes of labeling them as RSOs, still identifying one of those RSOs as the person in charge.

MS. WASTLER: We would have to obviously put together some document, choose the appropriate

vehicle, but because it isn't a change in the regulation, it is an interpretation, it would probably be some kind of generic communication that would have to obviously go through OGC.

MEMBER GILLEY: Could you do this as an information notice?

MS. WASTLER: It's a RIS. I have to look at my experts. I always get them mixed up. Basically a RIS is just a general clarification document.

CHAIRMAN MALMUD: Was there another comment?

MS. WASTLER: One thing I was going to raise was, did the Committee want to put together a subcommittee and participate in the development of this document?

MEMBER NAG: Which? RSO or which document are you talking about?

MS. WASTLER: The one we were talking about just now, for the RSO, the policy statement or document. I'm simply raising it --

CHAIRMAN MALMUD: With all due respect, I think that we have made a recommendation.

MS. WASTLER: Okay.

CHAIRMAN MALMUD: It is going to be the OGC who eventually blesses this or not.

MS. WASTLER: Yes.

CHAIRMAN MALMUD: And then it will be a memo coming out of NRC staff. I don't know that we need a subcommittee to do that.

MS. WASTLER: Okay.

CHAIRMAN MALMUD: But we still haven't voted on this. So may I call for the vote?

MEMBER NAG: I think there are still some questions or comments.

CHAIRMAN MALMUD: There are two more comments, yes. One from the public?

DR. BROGA: I would like to recommend that we go back to using the term that the NRC had used before. And that was "alternate RSO." And the implication at the time was that that person would be credentialed the same as an RSO, would have the same level of authority from the management to serve in the RSO's absence and would be a fully qualified RSO if there were a transfer. And it seems less than an associate and a chief and all of those things. And it had been in play for years.

"Alternate" implies that they are equally qualified as the RSO in my opinion. And I would be happy to write that down if anybody would like that in policy.

CHAIRMAN MALMUD: There was another comment. Dr. Zelac?

DR. ZELAC: No. I have covered it.

CHAIRMAN MALMUD: All right. So the suggestion --

MEMBER GILLEY: I am muddying the waters again, but I would like to encourage agreement state participation in this thing so that we have consistency from agreement states and NRC states.

MEMBER VAN DECKER: Would you like compatibility B?

(Laughter.)

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: I would propose that Ralph be appointed as the representative of ACMUI to this working group on the RIS.

(Laughter.)

MS. WASTLER: First of all, it wouldn't be a working group, but --

MEMBER WILLIAMSON: Whatever it is.

MS. WASTLER: -- we can definitely -- I mean, part of the process would be to bring that, we could very easily bring that, and provide it to the Committee as well as the agreement states to review and comment on.

MEMBER WILLIAMSON: I think I would also suggest to hold off on micromanaging the name of this individual and give the people who put the proposal together opportunity to come back with a more detailed proposal. I think the intent of the motion is clear.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: I changed my mind. I actually do have something to say on this. I think that while the intent is laudable, the practicability is that we will not have this occur without a rule change.

The rule as it states now says "a radiation safety officer," one person, period. Now, if there are going to be multiple people, the rule is going to have to be changed in some way.

MEMBER LIETO: I think the adjective is also the same in front of an AU, an authorized nuclear pharmacist, and an AMP. So I think if you -- well, again, I would go back to --

MS. WASTLER: We'll have to go to OGC.

MEMBER LIETO: -- OGC, but I think if you are going to take the adjective and use that to direct a policy, we are going to be micromanaging until the cows come home. And I don't think that's the intent. And reading that rule fully, I did not get that interpretation myself.

MS. WASTLER: We can't speak for OGC here, but I think, suffice it to say, we need to look at it and prepare something and then put it to OGC to see if we could achieve the result that we want given the regulations and the statement of consideration and all the documents supporting that regulation, whether we can manage that that you desire given that, the information as it is written in those documents.

So we can go forward. Can we guarantee that OGC once we put this together is going to buy off as we planned? Maybe not. We can't guarantee that. But we will definitely be in contact with the Committee on how this proceeds. And when and if there are stumbling blocks, you will be made aware of them.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I just want to say this so that it goes down on the record. I agree with what Ralph said. I think "a RSO" could clearly be delineated in policy as the RSO who is in charge. And all the other secondary or adjunct or alternate or associate or whatever category you want to call those other additional RSOs would clearly not be the RSO. So I think there's room here to interpret.

MS. WASTLER: That's what I tried to portray in terms of what the statement of

consideration and some of the supporting documents to the regs might say. And that may give us the room or the ability to do something along these lines without a rule change because if the intent was to simply make it clear that there is one individual who has the ultimate authority, then maybe that is sufficient for OGC. And what we're doing is not violating that.

Basically the bottom line is we have to take it back through our office of legal counsel and see where we end up.

MEMBER NAG: We still have a motion on the table that has not yet been voted on.

CHAIRMAN MALMUD: All in favor of the motion.

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: Any opposition?

(No response.)

CHAIRMAN MALMUD: It's unanimous. Thank you.

MEMBER LIETO: Just one final comment. I am going to be working on this with staff, with agreement states. I think also Dr. Vetter should be involved as the RSO.

CHAIRMAN MALMUD: By all means.

MS. WASTLER: We'll make sure that that goes through.

CHAIRMAN MALMUD: Thank you.

We now move on to the next item on the agenda, which is discussion of the microspheres.

11. Y-90 MICROSPHERES GUIDANCE

MS. TULL: Cindy is giving handouts right now. It is my presentation and also -- the presentation is in the back for anyone who didn't get it. And the revised guidance is also in the back.

I am Ashley Tull, as Dr. Malmud said. I am going to talk about the changes to the microspheres guidance. I am going to outline the changes in my slides. We can discuss the issues. And then we are asking for ACMUI input on several of the issues.

At the conclusion of the meeting, the NRC staff path forward will be to take this to the Office of General Counsel to get a no legal objection.

And then we will publish the guidance to the Web. And then we're also open to pursue additional discussions, either teleconference or maybe at the next meeting if we still have things that we need to talk about.

I would like to note that this is

guidance. These aren't regulations. So even though this doesn't get published in the Federal Register and doesn't go out for official public comment, it is open for comments basically all of the time.

So the first change is based on the ACMUI recommendation at the April 2006 meeting. And they recommended that nuclear medicine physicians be included. So we have revised the guidance to say "Authorized users must meet the training and experience requirements of the specific vendor training in the use of microspheres and the microsphere delivery system as either 10 CFR 35.390 or 10 CFR 35.490."

So I think we have captured that. Are there any comments or any discussion on this?

(No response.)

MS. TULL: Everyone is happy. Second change, case work. This was also discussed at the April 2006 meeting. And it reads now "Individuals must have work experience, including at least three cases for each type of Yttrium-90 microspheres for which the individual is seeking authorized user status."

The second part is "This work experience must be obtained under the supervision of an AU who is

authorized for this type of microsphere."

Any comments or questions on that?

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: Again, for first-time training at an institution who has not previously done the microspheres, the typical approach is for the vendor to come in and train, rather than an individual to go away and work under the supervision of an AU elsewhere.

So how would you deal with the issue of sort of the first person who is getting qualified at an institution, again because that training typically comes from the vendor, rather than from another authorized user?

MS. TULL: I'll refer to Ron or Donna-Beth. I believe our approach was there are enough people out there currently using these now that it shouldn't be an issue. Am I correct, Ron or Donna-Beth?

MEMBER EGGLI: That's an issue.

DR. ZELAC: It is an issue, but it depends on where the microspheres are coming from. My understanding is that at least one of the vendors has set up to have the training provided to new users at the facility of an existing licensed user.

And on that basis, there will be an authorized individual at that facility who could assume and document responsibility for the training being provided under the supervision of an authorized user, even though the principal portion of it would be coming from the manufacturer.

It may not apply to all microsphere providers but at least the one that I'm aware of.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: We have used both of them. And in both cases, the manufacturer has sent an authorized user to our facility for training was the three required cases.

CHAIRMAN MALMUD: Do I understand you to mean that the manufacturer contracted with an already approved --

MEMBER THOMADSEN: That's correct.

CHAIRMAN MALMUD: -- authorized user to come visit and show?

MEMBER THOMADSEN: That is correct.

MS. TULL: So, then, this wouldn't be an issue in that case.

MEMBER THOMADSEN: That is correct.

MEMBER NAG: Now, on this thing, do we need to have the word "authorized user"? "Under the

supervision of someone who is authorized" would mean that person could be the vendor, that person could be an authorized user at another institution.

MS. TULL: I think we intended to say AU.

MEMBER NAG: Okay. And the second question there is, you know, for example, high-dose rate. There are at least two, but there are more manufacturers having high-dose rate. We don't get a separate license from one or the other.

I mean, we are trained in them. And if we go to anything using that has a different machine, we get some training from the vendor, but we don't necessarily put that in the license.

So I'm wondering if someone has used the Sirtex, he goes to another institution and goes for the TheraSphere, most of the trainings are similar. Do you need again to do any of the certifications or just have the vendor show you what the differences are?

MS. TULL: I'm going to go to Ron and Donna-Beth again. There are differences from last time.

MEMBER LIETO: Yes to Dr. Nag. Yes, because they are classified as brachytherapy devices under 1,000. So they're both considered different

brachytherapy devices. So you would need to get the cases for each one.

MEMBER NAG: What I'm suggesting is that they are similar. You have experience in one. Otherwise you can have for high-dose rate the high-dose rate machine made by Varian has some differences from the high-dose rate machine made by Gamma-Med and Nucleton.

Well, if you have done high-dose rate, you are now licensed for high-dose rate. But now you did that with Varian. So now you have to get a separate license because you are now going with Nucleton.

So I would suggest that -- this is my suggestion -- we say if you have three cases of yttrium-90 microsphere and not relate that to which manufacturer.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: Perhaps Dr. Welsh would expand on this more, but medically the two devices are not similar. And mechanically they are not similar. And the training on one modality is not directly applicable to the other.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I would agree with what Dr. Thomadsen just said, but I also agree with Dr. Nag's

point in general terms. Three cases for Sirtex, for example, is necessary, sufficient.

But then if somebody who has had dozens of cases of using SIR-Spheres wants to learn TheraSpheres, do we need three cases of that? Perhaps just one or two examples with the vendor training and certification would suffice in that context.

MEMBER NAG: Yes. I mean --

MEMBER WELSH: As written now, it says at least three cases for each type.

MEMBER NAG: Right. I mean, you know, it's a similar example I'm giving to the high-dose rate machine. Each high-dose rate machine is entirely different. They have many different nuances. And when you change from one to the other, you do get some vendor training, but that is not written into the license.

My objection is writing it into the license. I'm not objecting to having vendor training when you shift from one manufacturer to the other.

CHAIRMAN MALMUD: I think the next person was a member of the public.

MS. WARBICK: Hello. I'm Ann Warbick from MDS Nordion. I would like to explain to you from a very practical perspective what actually is working

today.

MDS Nordion has established centers of excellence in the various jurisdictions throughout the world. In the United States, we have a center of excellence which I guess we would have what's called a preceptor at that center of excellence who provides training to all new users. And I mean all new users.

So all new users will go to that site. And at that site, they will receive didactic and very practical training where patients are actually being set up on the day of their visit to be treated. There will probably be two to three patients treated on that particular day.

And then following that, the physician who is going to become an authorized user of TheraSphere goes back to this site. And he is then proctored for the first three administrations. And he works very closely with the preceptor on these administrations.

Though the preceptor may not necessarily be present at the time when the administrations are taking place, there is a proctor present at the site at the time of the first three administrations. If the site needs more than three, they can have more than three preceptored administrations.

One of the issues that I would like to

bring up is we have discussed this guidance with our preceptor. And he has some concerns about the use of the word "competency." And the use of the word "competency" is discussed in paragraph number 4. And that's a term that was brought up yesterday as well.

MS. TULL: I will be covering that in my presentation if you want to wait. It will be the next slide.

MS. WARBICK: Okay. Thank you.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Well, I think the vendors can recommend or require what they want, but, you know, in the end, I really wonder if Dr. Nag doesn't have a very good point here.

When 390 authorization is given to a physician, they are not expected to do three cases for all of the dozens of radiopharmaceutical products that are available. They are expected to show 12 cases distributed among 4 different modalities as a kind of a baseline minimum to document their competence.

And I'm wondering if this class of devices shouldn't be treated the same way, at least. From a regulatory point of view in the community, one, of course, can have more rigorous training standards.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I have a question. How accurate is the activity that's administered? And could any of the manufacturers maybe address that? Because I think dosimetry is one of the fundamental issues in using this technology.

MS. TULL: Dr. Malmud, that is an issue in my presentation as well. If you guys want to wait to get to that, there's a slide on it.

CHAIRMAN MALMUD: Go ahead. Mr. Lieto?

MEMBER LIETO: It seems like the presentation just given by MDS Nordion, there are actually six cases, three of which meet this requirement. I guess you have work experience versus proctoring. I don't know if we want to make any distinction between that, but it would seem like what they're doing now more than meets what we're asking for anyhow.

I would hate to reduce the number of cases. And my reasoning is such that currently there have been several medical events over the past few years involving this modality. And I don't think it would be prudent to reduce the number of cases below I think these three if it's especially something that's being done already by the vendors.

MS. TULL: This is something that I took

directly from the transcript at the last ACMUI, not the last one but the April 2006 ACMUI meeting. This was discussed in detail, 60-something pages of this. And so this is coming directly from your discussions, just for new members and --

MEMBER LIETO: We're not allowed to change our minds?

(Laughter.)

MS. TULL: You are allowed to do anything you want to do. I mean, I literally went through the transcript and pulled out action item, action item, and my slides are based on basically your recommendations from that meeting.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Again, I am not trying to cut down the number of things that you need to do. What I am trying to say is that if you have experience in one modality, if you have done 1,000 cases of manufacturer A's, you know that there are some differences between the two spheres. So you multiply your insertion in that way.

You do not need any identification because then if you have this, you are going to translate that to other modalities. And the example I gave you was 690, where there's a difference between a Gamma-Med

high-dose rate and a difference between Varian high-dose rate.

And, again, you know, if you have done 1,000 cases there, you do need some vendor and stocks who knows the differences but not the licensing requirement. And what I'm against is the licensing requirement when you already have experience in one and you are licensed in one to go through any of the -- it's not a different modality. It's the same modality.

So I'm trying to make that distinction between someone who has no experience in the modality but with someone who is well-experienced in the modality using one manufacturer's microsphere versus the other manufacturer's microsphere.

CHAIRMAN MALMUD: Okay. Dr Nag, how does that resolve with Dr. Thomadsen's point that sometimes the two different modalities are quite different?

MEMBER NAG: They are different. The microspheres are different. I led the consensus panel that gave the guidelines for using microspheres. And in that document, we made very clear the differences between the two.

Similarly, I mean, when I have a license for iodine-125 used for manual brachytherapy under

490, they are entirely different. I don't need a separate license now to go in and do iridium. And if I had to do that for 490, I would require three cases of iridium, three cases of iodine, three cases of whatever new isotope is coming in. They are entirely different isotopes, here the same isotope.

Here they are all encapsulated. One is heavier than the other. One has a larger size than the other. There are minute differences. But the entire concept is still the same.

PARTICIPANT: I don't think we are requiring an additional license, are we?

CHAIRMAN MALMUD: Dr. Welsh, yes?

MEMBER WELSH: I agree with what Dr. Nag is saying again in general, but the way it is worded now is such that it's automatically taken care of with the vendor training. The vendor training is going to provide at least three, typically six from both of the FDA-approved devices. And from a practical perspective, it's already met.

MEMBER NAG: Well, 490 if you're not approved, you do iodine-125 implants. When you go to iridium, it's an entirely different isotope, entirely different technique. You are going to have another reapplication for a license because that is exactly

the same similarity. In fact, there is more similarity in between TheraSphere and Sirtex Yttrium-90 than between iridium-192 and permanent 125 implant.

I am just trying to make the rationale. If you are trying to make the rationale there is some minute differences between TheraSpheres and Sirtex, my contention is that might make a difference between each of these up to 490.

CHAIRMAN MALMUD: Thank you.

Dr. Zelac?

DR. ZELAC: I should note, Dr. Nag, that for 490, there is no specific training requirement. It's only for 690.

MEMBER NAG: Well, even for 690, the differences between Gamma-Med, between Varian, and between Nucleton, under the sources cited, there are lots of differences. The training, the way you do the treatment planning exam was different, too.

DR. ZELAC: If I can add one more word, this question of whether the type of use was device-specific or not was brought to NRC counsel for an interpretation. My recollection is that it was not to be specific to the particular device but just to the type of device; HDR, for example. But I'm not

sure, and we'll have to check.

CHAIRMAN MALMUD: Thank you.

DR. ZELAC: I am not sure what the interpretation was from OGC. I was of a differing opinion.

CHAIRMAN MALMUD: Did you mean the Office of General Counsel?

DR. ZELAC: Yes.

CHAIRMAN MALMUD: Comments from the public?

MR. PFEIFFER: Doug Pfeiffer. You made a comment about citing the fact that the manufacturers are currently providing training that meets these requirements.

I think it's dangerous to form a regulation around what a manufacturer is currently providing, that if the manufacturer would decide to change what they're doing and may become a burden to try to meet what that requirement is, that they should be fashioned around what is truly required.

And if the manufacturer can help do that, that's great. But don't make it dependent upon what the manufacturer is doing in case they would change it in the future.

MS. TULL: I would like to note this is

guidance. So it's not going to be the same as regulation. It's a 1,000-use. So if we found out, if we were notified that the manufacturers changed their procedures and that, all of a sudden, users couldn't get approved because they couldn't get these three cases, again, we would come back and revise the guidance. It's much more easily done than rulemaking. This isn't in a regulation yet.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. I just want to go back to Dr. Nag's point about doing it by isotope. As Dr. Thomadsen pointed out, looking at the radiation safety considerations, not the isotope, these are two distinct performing types of devices and radiopharmaceuticals. And they have distinct differences that affect the radiation safety characteristics.

And so I think as long as they are going to be under 1000, they don't want to put them under 390 as a non-sealed radiopharmaceutical and they are going to be considered a device with these distinctions, then I think that the number of cases.

And, as it says, for each type of -- to address Dr. Zelac's point, it says for each type of microsphere. So it would apply to both different

vendors as currently written.

And, to support Ashley's point, that's what we did agree upon at the last meeting, when we discussed this.

CHAIRMAN MALMUD: Thank you.

Let's see. Dr. Thomadsen?

MEMBER THOMADSEN: Well, I'll reflect back to Dr. Eggli that I may be allowed to change my mind and that I think good points have been made that if you do have experiences with one, even though there are differences, maybe you don't need the three proctored examples with the other.

I'm not sure of what the number would be. And the difference between three and one is not that great. And it may be more complicated to try to craft this to allow previous experience with one to reflect the other or any others that come into the field, but I wouldn't be dogmatic, as it sounded at first.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Well, I think that the way this is written, it really kind of micromanages by saying who has to supply the training. It requires an authorized user to be flown in. This is going to add to the expense of the ultimate procedure.

And I think, you know, if you're making

the case that this is important, Ralph, you need to justify it on grounds of health and safety. So I would say make it more generic, that there should be a minimum case experience of three cases with products of this type and for additional models or forms, similar forms, of the same product.

Users should be expected to follow vendors' recommended training and leave it at that so that there is some flexibility to tailor this to the differing levels of expertise so that cost of health care might be appropriately minimized.

CHAIRMAN MALMUD: May I ask a question of NRC staff? Has there been any reported event thus far of a case in which there was a new technology being employed and in which there was an error occurring because the individual was new to the procedure?

DR. HOWE: Yes. And for the microspheres, when they were first introduced, the first three cases were medical events. And in the last three or four months, we have had four medical events with the microspheres. And that's based on the delivery.

MEMBER NAG: I think your question was slightly different. Your question, I believe, was that someone who has already been experienced in one kind of microsphere went into a different kind of

microsphere. And then did it result in a medical event? Am I right?

I mean, there are problems. There are misadministrations with microspheres in general. We know about that. But that is not because of one strange individual going from one system to the other.

CHAIRMAN MALMUD: That wasn't my question. My question was, in the application of new techniques, have there been reported events?

MEMBER NAG: Of course.

CHAIRMAN MALMUD: Because I am thinking now from the standpoint of a patient. If I were a patient in an institution of great reputation and I was told that I was going to be the first patient to have this new technique applied, I would want to have confidence that the people who were doing this had been trained in doing it, even though they had vast experience in other areas.

And my question is, has there been an incident or have there been incidents in which this new technology is being applied by people who are not trained in that specific new technology and, as a result, errors occurred?

I think, Dr. Zelac, you had your hand up?

DR. HOWE: And the answer is definitely

yes. The answer is definitely yes. And the answer is definitely yes for this particular type of --

CHAIRMAN MALMUD: So if the answer is definitely yes and definitely yes, then it's definitely of concern for the public's interest that there be supervision, meaning experience on the part of the individual who is introducing this new technique at his or her own institution.

Did that cover your point, Dr. Zelac, or are you going to make another one?

DR. ZELAC: Just to make it even clearer, anecdotally there was a case recently where a medical event did occur because the stop-cock was turned the wrong way. The material, instead of flowing into the patient, flowed into a waste reservoir.

MEMBER NAG: Yes, but --

CHAIRMAN MALMUD: Was this a new application?

DR. HOWE: I believe that was an experienced site, but I'm not sure.

MEMBER NAG: I think --

DR. HOWE: We have had them for the new applications because it --

MEMBER NAG: No. There's a difference in new applications and someone already experienced in

one microsphere shifting to the other microsphere. You are probably talking about someone who is doing the

If someone doesn't know anything

DR. HOWE: I believe we have had medical events in both cases. I would have to go back and check.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think that, again, I would like to come back to the under the supervision of an authorized user. These events if they are going to occur, the question is, are they any less likely to occur because an authorized user is standing there, as opposed to an expert provided by the vendor who knows their system inside out and the training and is providing the training for the use of the device?

My concern is under the supervision of an authorized user. I will agree that vendors are currently providing an authorized user, but, again, that may not permanently be the case. I seriously doubt that the presence of an authorized user provides any level of safety above and beyond the other expertise that the vendor can provide during training and that public safety is not enhanced by having an AU stand there, as opposed to the representatives of the

vendor. And it certainly adds cost to the process and may limit entry of practitioners.

DR. HOWE: Dr. Malmud, can I make a point?

CHAIRMAN MALMUD: Yes, please.

DR. HOWE: The ACMUI seems to be focusing on when the device comes into a facility for the first time. This guidance is also used to train additional users at an established location. So this would be --

MEMBER EGGLI: But that doesn't change the rule for the new user. I mean, your impact --

DR. HOWE: This is for any user.

MEMBER EGGLI: I understand the training of subsequence. But if you're going to train, when the device comes in for the first time, this is an impact as the devices come in the first time and I think an unnecessary impact.

CHAIRMAN MALMUD: Let me, if I may, just explain why I asked the question. I asked the question because it is of concern to me that a technique being used by someone who has not had experience before puts the patient at risk.

So that in looking at the statement currently on the slide, it seems to me that that risk to the patient could be covered by changing the second quotation, which begins "The work experience must be

obtained under the supervision of an experienced user."

And that experienced user could be a physician. It could be someone from the manufacturer but someone with experience. Otherwise it's the unknown. It's the inexperienced supervising the inexperienced. Even though the person may be an authorized user, that person may not be an experienced authorized user in the technique being employed. What we are seeking is someone who has done this before.

I don't know that the authorized user satisfies that, and I certainly would not put into regulation something that depends upon the vendor but simply identifying under the supervision of an experienced user.

Does that seem reasonable? Dr. Zelac?

DR. ZELAC: If you continue on to the remainder of the quotation, it does limit that authorized user to be one who has experience in the use of those particular products.

CHAIRMAN MALMUD: Yes. Well, of the particular technique for which the individual was seeking approval.

DR. ZELAC: Right. So it removes, I think, the concern that you had about somebody being

an AU and not really knowing what they're doing but, yet, supervising the training of someone else.

DR. ZELAC: Oh, I wasn't suggesting that the AU didn't know what the AU was doing. I was suggesting that the AU might not have had experience in that particular microsphere if there is this generic argument about the microspheres.

I just think if I were a patient, I would want to know that if I am going to be the first patient to have this technique applied to me at this outstanding institution, that someone is there who has done this before. That's the assurance that I want as a patient.

Now, it may be that person may make an error, but that person is less likely to make an error that someone who has never done it before. And that's what concerns me from our role in protecting the public.

I'm sorry. Dr. Williamson?

MEMBER WILLIAMSON: I think we could argue and argue what should be the minimum level of training. I think in other cases, like gamma knife and high-dose rate brachytherapy, rather than try to solve the dilemma of what the minimum content of device-specific training is, we basically say it's

what the vendor recommends.

So user should undergo the minimum training, as recommended by the vendor for a new user, period. And if the vendor's protocol allows for the internal transmission of knowledge from an in-house experienced authorized user to another, so be it.

If the vendor requires a trained technical representative from their company to come whenever a new authorized user is added to the license, so be it. But that way we don't have to micromanage it. And we could handle it the same way high-dose rate and gamma knife training is handled.

MS. TULL: Dr. Malmud?

CHAIRMAN MALMUD: I'm sorry. So are you supportive of the statement as it appears in --

MEMBER WILLIAMSON: No, I am not.

CHAIRMAN MALMUD: You're not. Okay.

Dr. Nag?

MEMBER NAG: I think, again, you make the right point that as a patient, you don't want to be the first one, and you want to have someone who has been supervised.

My objection is if you have been experienced in one kind of microsphere, most of the things are similar. There are certain individual

differences. You know, the procedure is being done by someone who is experienced in microsphere, but the manufacturer of the microsphere is different.

So I don't think you need to be reproctored by -- well, another certification just because you are changing the microsphere because if you are going to do that, you have to do that for every other thing.

Any time you change from Strontium to some other thing or from -- they are entirely different things. I mean, the decay for iodine is different from the decay point for iridium. So if you know iodine and you have done 1,000 iodine implants, you're going to iridium, you need to have another license all over again.

CHAIRMAN MALMUD: Thank you.

DR. HOWE: If I could just make an interjection? I don't really want to expand this, but Dr. Nag's point is, say, for manual brachytherapy or for HDR.

And in those, the training and experience that is required is three years of clinical experience. And in that three years of clinical experience, there is an assumption that you will see a variety of things in your training and experience.

And so you will have already been subjected to a variety of things, a variety of isotopes, a variety of procedures. This is an emerging technology, a new technology.

People have not been exposed to a variety of these. We're in the beginning stages. There are significant differences in the delivery of the TheraSpheres versus the SIR-Spheres. And you just cannot go from one to the other without really truly comprehending those differences and the mechanics of those differences. And that's why we put in that it would be the microsphere-specific training and the experience to try to eliminate the problems of going from one to the other and having problems. One floats. One doesn't.

CHAIRMAN MALMUD: We have a comment from the public.

MR. THURSTON: Good morning. My name is Ken Thurston. I represent Sirtex Medical, but I have also had extensive experience with TheraSphere. In fact, I was responsible for starting the clinical development of this device in 2000.

And to your point about inexperienced users, when we went to treat the first patient because the technology had been somewhat dormant for about ten

years, we had a medical event. And there was contamination of the laboratory as a result of a technical issue.

And, as a result, MDS already went through some extensive revisions to the product. And this is the nature of new product development and new technology development.

I think that both manufacturers in the last -- and then, of course, SIR-Spheres were introduced in 2002. In the last six or seven years, both manufacturers have gained considerable experience and have done a much, much better job of training and specifying site qualification and checklists and procedures. And both manufacturers do a very, very diligent job of that endeavor.

Having said that, as people have pointed out, medical events will occur with any new technology, with any new user. And I think that all of that needs to be taken into context here in terms of this regulation because the other thing that is happening is that there are other Y-90 brachytherapy devices that will be coming into the fore as patents run out and as the technology expands.

So I think that there needs to be a balance between ensuring safety in terms of radiation

safety procedure, safety to the patient, and coming up with regulations that everybody can live with.

And I think Dr. Williamson's suggestion about generic training, from a medical and safety perspective, and then provisions as additional devices come on board or additional manufacturers come on board is probably a good one.

Thank you.

CHAIRMAN MALMUD: Thank you.

Another member of the public?

MS. FAIROBENT: Yes. Lynne Fairobent. I have a slightly different twist on this. And part of it goes back to Ashley's comment of this being guidance.

Yes, while it's true this on the face of it is guidance because this is a Part 1000 regulation, we are actually regulating by guidance. And, in fact, if you look at your draft regulation, this requires a license amendment by existing individuals to adopt a new guidance before they can continue. So we are regulating by guidance.

When Part 1000 was originally conceived, it was with the intent that it would not stay in Part 1000 forever. We now have between five and seven years.

My question comes down to, when are we going to develop and put this into one of the existing parts of the regulation, take it out of Part 1000, and truly put this out for public review and comment?

I applaud NRC for working with the vendors to help develop this guidance, but to my knowledge, this has not been distributed or asked for any public input. Perhaps that's coming down the pike, but in the past, the guidance has simply appeared on the Web site without formal notice for public comment.

I just raise the question because this is another example of seven years down the road under Part 1000 implementation. And it was never intended for emerging modalities to live in Part 1000 forever. We have never defined what the appropriate length of time is for moving something out of Part 1000, but we continue to regulate by license amendment.

MS. TULL: To address part of your question, guidance, you're correct, does not go out for public comment. That is not the current NRC practice. That's not how guidance is done.

For rulemaking, I will have to ask Ron or Donna. Do we have anyone from DLR here for rulemaking?

MS. WASTLER: With regards to?

MS. TULL: How long it takes to go from guidance to --

MS. WASTLER: Well, part of the problem I think is, one, being new modality. When you move something into regulatory space, you want to make sure that what you have set forth is appropriate.

In other words, you know, it is a new modality. Things change. Problems occur. What you start out with -- I think this is the thought process behind the 1000, is that as you move through these, you know, initial stages, what you conceptually thought might work as you move through it, you know, after the first case versus the third versus the fifth, that things change.

And so putting something in 1000 allows us -- because it's technically draft guidance, it's out there. And anyone can comment on it. Anyone can point out the changes. And we can go in and say, "Okay." Based on, say, comments from ACMUI, we can go back and say, "This isn't working." And then we can put another version on it.

I agree with Lynne. Some of these have been on for a long time, which in some cases is a result of budget. You know, I mean, it's not a necessarily satisfactory answer, but it is the reality

of the situation that when you go to rulemaking, it is an extensive process. It is a costly process.

Being the fact that we do accept any comments at any time on it, you know, from anyone, you know, I think we're trying to meet our obligation of being responsive to any problems that come out of it.

MS. TULL: Which is why my name is on the Web site now.

(Laughter.)

MS. WASTLER: Now I can point to her.

CHAIRMAN MALMUD: Dr. Welsh and Dr. Suleiman. Dr. Welsh?

MEMBER WELSH: Going back to what is written there, it says, "at least three cases." Question mark. But should it really be there in the license requirements?

Right now the vendors provide at least three, six cases in most situations. So I feel that that is being met. And I am comfortable with it saying "at least three cases" because I know that we are always getting at least three, typically much more.

As was pointed out by a member of the public, what if the vendors decided one case is all we are going to pay for? Well, this takes care of that.

That way it answers Dr. Malmud's point about whether an authorized user has experience with this apparatus if that patient is one of the early individuals coming to this institution to get this.

As I look at paragraph number 2, it seems that the authorized user is experienced by paragraph number 1. And, therefore, paragraph number 2 is okay since an authorized user based on paragraph number 2 is somebody who has experience from paragraph 1. And, therefore, I think it's fine the way it's written.

MEMBER EGGLI: Except that authorized user is a special category recognized on an NRC license.

CHAIRMAN MALMUD: That was Dr. Eggli saying that "Except that authorized user is a special category recognized on a license."

MEMBER WELSH: And somebody with specialized training and at least three cases of documented experience.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: All right. I am not sure when I wanted to interject this, but I think it would help a little bit. I think there are radiation safety issues here clearly, which I think is the role of the Advisory Committee.

I would like to clarify the specific

indications for which these two products were approved by FDA just to remind people that we are dealing with a very specific application.

The TheraSpheres were approved with a humanitarian device requirement saying -- I'm just reading from the label -- "Authorized by federal law for use in the radiation treatment or as a neoadjuvant to surgery or transplantation with patients with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters. The effectiveness of this device for this has not been demonstrated."

The indication for TheraSpheres -- excuse me. That was the warning. The indication for TheraSpheres is "TheraSphere is indicated for radiation treatment or as a neoadjuvant to surgery or transportation in patients with unresectable hepatocellular carcinoma who can have placement of appropriately positioned hepatic arterial catheters."

The indication for the SIR-Spheres is "SIR-Spheres is indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy."

So we're dealing with very, very specific

approvals. And also obviously these can be used under the practice of medicine based on the experience of the physician.

So we're dealing with clearly a new, very, very new, modality with some real risks. But are the issues radiation safety? Are the issues practice of medicine?

I mean, there are some gray areas here. We are dealing with a very vulnerable population, you know, very, very unique patient population here.

CHAIRMAN MALMUD: The issue for us is the radiation safety.

MEMBER SULEIMAN: Right.

MS. TULL: Dr. Malmud, on that same note, we actually had a teleconference with one of the manufacturers. And when they talked about this, I mean, they stated what it is being used for in the U.S. is not really what the clinical trials were at all. There were 74 cases. And it was used as a first-line treatment.

And in the U.S., it is not used that way. It's usually a last resort. So the way it is being implemented in the U.S. is not -- I mean, what they submitted to FDA and how it got approved, under the practice of medicine, it's being used very

differently.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yes. Again, I wish to clarify or state I am very much, we are very much aware of what the FDA approval was, but that was, what, several years ago. However, the current indications and the current way it's used, it's basically a higher percentage of off-label use, not the way -- because almost everyone is going to be off label because this was with Sirtex. It was with the use of chemotherapy. Now that chemotherapy is no longer used.

So I am aware of all of these differences. And what I am trying to say to the rest of the ACMUI and the NRC, we literally spent hours and hours on discussion when we made our recommendation from the panel.

And the indication, we get that there was a difference between these two microspheres, but in terms of the medical use, they have been used almost identically.

And if you have the training, you know where it is to be used, what the signs are. You know, that is an important part of the training. And that training is the same for both.

So the differences between the two microspheres are something that can be taken care of by vendor training without needing licensing requirements.

My objection is putting it into the license, not in the training. I am all for the training.

CHAIRMAN MALMUD: Therefore, Dr. Nag, how would you alter this proposal that's on the slide?

MEMBER NAG: And I would like to make it in the form of a motion.

CHAIRMAN MALMUD: What is your motion?

MEMBER NAG: My motion is that the individual must have work experience, including at least three cases of Y-90 microsphere. Take out that word "for each type of." So that's one.

Under the second paragraph, the word "experience" might be obtained under the provision of AU. You know, you have to substitute with someone with experience with the microspheres. So then --

CHAIRMAN MALMUD: That is your motion?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Is there a second to Dr. Nag's motion?

MEMBER WILLIAMSON: I would offer a

friendly amendment --

MEMBER NAG: Yes. That's fine.

MEMBER WILLIAMSON: -- to Dr. Nag's motion. I would in the second paragraph put "under the supervision of a representative that complies with the vendor's training protocol."

MEMBER EGGLI: I would second the amendment.

MEMBER NAG: I would agree with that.

CHAIRMAN MALMUD: There is now a motion which has been amended. Is there any discussion of this motion? Mr. Lieto?

MEMBER LIETO: I am very much opposed to those changes. I think this is a minimum requirement based on current vendor practice. We discussed this at 60 pages at length. And, actually, you're probably going to get another 60 pages on it now.

(Laughter.)

MEMBER LIETO: I think if it were my family member or whoever that was going in this, I would want somebody with not 3 cases but probably 300. But it probably is not going to be the case.

You're looking at a use that has medical events. It's a new modality. And I think we're ratcheting it down to basically saying you only need

three cases of any sort without even having an AU present during the training and experience.

I think that AU brings not just the radiation safety aspects but also the clinical aspects of training and expertise in these work experience sessions.

And most of these people that are starting up in this have never done anything of this nature with unsealed radiopharmaceuticals. And so I think to minimize it below what the vendor is already doing, I would not support.

CHAIRMAN MALMUD: Excuse me. So your objection is one which would be overcome by accepting the statement as it is presented?

MEMBER LIETO: I would like to keep it just as it was --

CHAIRMAN MALMUD: So you are in favor of it as it was presented --

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: -- versus that which Dr. Nag has proposed?

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I have to disagree with Ralph on the issue that having an AU standing there

brings much to the table over the vendors' training program. I just have to really strongly disagree with that.

I think those of us who are practicing this understand the radiation safety issues. And it's just learning to use the device. And having an AU from another institution stand there doesn't bring anything to the table that the vendor training doesn't bring.

I understand your concern about number of cases, but I really object to the AU part of that training requirement.

MEMBER LIETO: But no. What you're changing to is that you never even have to have an AU.

MEMBER EGGLI: No, that's not. They're saying for the training. This only says work experience must be obtained. That's for the purpose of getting onto the license. You have to be an AU to get onto the license.

The second paragraph deals with who provides the training necessary to achieve AU status.

MEMBER LIETO: Right.

MEMBER EGGLI: I don't think that training needs to be provided by someone who carries an AU. In the other modalities, in higher risk modalities,

high-dose therapies, you don't have to be trained by another AU.

You have to be trained by the manufacturer's representative or you have to be trained to the level required by that manufacturer, whatever that manufacturer recommends for the use of equipment at far more risky therapies than this one.

The standard is that the vendor determines what the threshold is. Why should the standard for microspheres, which is, in fact, lower risk than high-dose rate therapies, be any different?

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: Perhaps that second paragraph, that first sentence can be modified to say "under the supervision of an experienced AU who is authorized for this type of microsphere for which the individual is seeking approval."

At an institution where an authorized user has done a few hundred cases and then another individual comes to that department seeking AU status for this particular microsphere application, why does the vendor have to come and provide 3 cases when the authorized user at that institution might have done 300 and be the one that goes to other institutions to --

CHAIRMAN MALMUD: I think you're looking at start-up.

MEMBER EGGLI: I was looking at start-up.

MEMBER WELSH: But I think this is a general plight here and not exclusively for start-up.

CHAIRMAN MALMUD: Dr. Zelac I think was next.

DR. ZELAC: I think it might be useful to take a look at the training requirement that exists under 690 and the wording that is included there. Again, this is for the various therapeutic devices, "Has received training in device operation, safety procedures, and clinical use for the types of use for which the authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist as appropriate who is authorized for the types of use for which the individual is seeking authorization."

PARTICIPANT: I like that.

PARTICIPANT: I like that, too.

MEMBER NAG: I have no problem.

MEMBER EGGLI: And that's for higher-risk

therapy. Why should that same training -- you know, if that were applied to microspheres, I would be perfectly satisfied.

PARTICIPANT: I agree.

MEMBER FISHER: I would agree to that also.

CHAIRMAN MALMUD: Dr. Nag, would you agree?

MEMBER NAG: Yes, I would agree to that second paragraph. My objection was on that first paragraph, where having experience in one kind of microsphere and now you go and do it again just because you're changing the manufacturer. My objection was not with supervising. I absolutely agree there.

I think, again, maybe I can ask my colleague, Mr. Lieto, if you had a relative who was going to undergo this therapy, would you rather do it by someone who has done 1,000 cases of --

MEMBER LIETO: Yes.

MEMBER NAG: Okay. You said "Yes" already before I finished my sentence. All right.

-- 1,000 cases of Sirtex and is now going to do TheraSphere versus someone who has never done any case of any kind and has just finished 3 cases of

TheraSphere and is now going to do the fourth case on your relative?

MEMBER LIETO: Yes.

MEMBER NAG: Which would you rather prefer?

MEMBER LIETO: Yes because he's experienced for the type of use he's going to be doing, not the one he's not trained for.

MEMBER WILLIAMSON: Ralph, you're consistent.

(Laughter.)

MEMBER NAG: And that's all that I'm saying, that if you have done microspheres, that is all that you need, not which kind of microsphere.

MEMBER WILLIAMSON: Yes.

MEMBER NAG: That was my point. You would rather like someone who was experienced in microsphere and is just changing the type of microsphere. I'm taking your own question.

CHAIRMAN MALMUD: Thank you.

We have a comment from Debbie.

MEMBER GILLEY: I am enjoying this.

(Laughter.)

MEMBER GILLEY: First, I have two questions. First is I believe this was a

brachytherapy sealed source device registry part. When did it move over to radiopharmaceutical therapy?

MEMBER LIETO: It's not.

MEMBER GILLEY: Okay. But you're now looking at allowing nuclear medicine therapy physicians to administer it because it's a Part 1000?

MEMBER NAG: In addition.

MEMBER GILLEY: In addition to the brachytherapy. Okay.

The second thing is, could you please define for me, what is supervision? Because I have four different definitions of supervision in my regulations. I have direct supervision. I have remote supervision. I have supervision. And I have general supervision. So which one of the supervision is this? Because they all have very specific meanings to them.

CHAIRMAN MALMUD: Does anyone wish to address the answer to that question?

DR. HOWE: I will try, but I probably will not be too successful.

(Laughter.)

DR. HOWE: In this particular case, we're not talking about the supervision that you see in 35.27 because the supervision in 35.27, your

authorized user doesn't have to be anywhere near the department. We are talking about supervised work experience.

And I think there is an understanding in supervised work experience that the supervising person is at least there to help supervise the work experience. So the person getting the supervised work experience has hands on. And there is someone there guiding them.

MEMBER EGGLI: The answer to your question is direct supervision.

MEMBER GILLEY: Well, if that is the intent, then that needs to be specifically stated. If not, the way it is written out, the supervision could be removed. It doesn't have to physically be --

CHAIRMAN MALMUD: We have a member of the public.

MR. WHITE: You raised an issue that transcends this particular issue. And that is the issue of supervision. I would just like to suggest that as you consider this, you think about the CMS definitions for supervision, widely accepted throughout the federal government and also adopted recently by ASTRO and the American College of Radiology in these contexts.

And that is a general supervision. The supervisor is generally responsible for what is going on, has taken the responsibility for training of the individuals and delegating them tasks but need not be physically present; direct supervision, in which the individual exercises general supervision and is physically present within the facility available for consultation during the procedure, if necessary.

And the third is personal supervision. And that is where the practitioner, the supervisor, is physically present at the site of the procedure; that is, in the room essentially at the bedside.

And, rather than reinvent categories of supervision, you might consider those three levels, which are, again, widely accepted in use in other contexts and I think define the possible universe of supervisory activities.

CHAIRMAN MALMUD: Thank you. Gerald White.

Dr. Williamson?

MEMBER WILLIAMSON: Well, I think the word "supervision," then, has a problem in this context because the vendor's representative or the remote authorized user from some other license has no standing or authority in the institution to make

medical decisions for that patient.

I mean, this is a patient of the physician being trained. And that physician must be responsible for the decision-making. So it is impossible to use the word "supervision" in this context.

MEMBER WELSH: Can I make a comment there?

CHAIRMAN MALMUD: Yes, please, Dr. Welsh?

MEMBER WELSH: In most, in at least some, of the supervision provided by vendors, the one who is seeking authorized user status goes to an institution where they might do three or four cases a day and so will be getting direct supervision from an authorized user at an institution where that person who is the authorized user does have privileges at the hospital answering that point.

MEMBER NAG: No. I am telling you he will be an observer. He is not performing the procedure. So he has not been supervised. You know, he is an observer there. If you go to another institution, that is the basin in that institution. So you are an observer at that institution. That is not supervised. You are not being supervised there. You are an observer. You are learning.

Then when you do it in your institution and you have someone else coming in, authorized user

or vendor, then you are being supervised.

MEMBER WILLIAMSON: In some sense.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: What the supervising external person is mostly doing is monitoring in this case, rather than supervising, to throw an additional possible word into the mix.

CHAIRMAN MALMUD: We do have a motion on the table. And that is the motion which Dr. Nag had made and was amended. Do you recall the motion?

MEMBER NAG: Yes.

(Laughter.)

CHAIRMAN MALMUD: Would you like to call for a vote for the motion?

MEMBER NAG: Go ahead.

CHAIRMAN MALMUD: All right. Now, all of those in favor of Dr. Nag's motion? Do you want to repeat your motion briefly?

MEMBER NAG: The motion is that the individual must have work experience, including at least three cases of Yttrium-90 microspheres.

CHAIRMAN MALMUD: Deleting the words "for each type of."

MEMBER NAG: Right.

CHAIRMAN MALMUD: And otherwise the

statement is fine?

MEMBER NAG: Yes. And the second one I am not even worried too much. "An authorized user is someone who is experienced." I mean, the idea is it has to be done in the presence of someone who is experienced and knowledgeable.

MEMBER WILLIAMSON: I think that my amendment was that for each type of medical device, that the physician to become an authorized user undergo the training program recommended by the specific vendor.

MEMBER NAG: Right.

MEMBER EGGLI: Jeff, would you consider amending that further to incorporate the language in 690?

MEMBER WILLIAMSON: Yes. So I would recommend, yes, replacing this whole thing by the 690.

MEMBER NAG: The second paragraph with language similar to 690.

MEMBER WILLIAMSON: Yes.

MEMBER NAG: Agree.

CHAIRMAN MALMUD: So the motion, then, is to accept the first clip of the paragraph, omitting the words "for each type" and then in the second paragraph it being substituted with the existing

language from 690?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Opposed?

(Whereupon, there was a show of a hand.)

CHAIRMAN MALMUD: One opposed. Abstention?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Two abstentions, three abstentions. How many? Four. Five. Five. Five are for, three abstentions, and one opposition. Close one.

CHAIRMAN MALMUD: Thank you for having brought such a noncontroversial item before us.

MS. TULL: You haven't seen the next slide yet.

(Laughter.)

MS. TULL: I'm not even going to put it up there.

MS. WASTLER: Don't even put it up there yet.

MS. TULL: Yes. Maybe we should go to lunch.

MS. WASTLER: The question is, do we want

to continue? It's noon. I know everyone is sitting here probably getting hungry. Do we want to take this opportunity for a breaks?

CHAIRMAN MALMUD: The Chair defers to the wishes of the majority of the Committee. All of those in favor of lunch immediately raise your hand.

(Whereupon, there was a show of hands.)

MEMBER NAG: Before that, the question is, how are we going to make up the rest of the time?

MS. WASTLER: That's an issue we'll have to discuss over lunch.

CHAIRMAN MALMUD: That is the second question.

MEMBER LIETO: As soon as we finish this issue. I would like to finish what Ashley has first.

CHAIRMAN MALMUD: No one was in favor of lunch immediately.

MS. WASTLER: Okay. Go ahead, Ashley.

MS. TULL: All right. I will preface this by saying --

MS. WASTLER: First take a deep breath.

MS. TULL: Yes. Everyone breathe.

MS. WASTLER: Take a deep breath. Okay.

MS. TULL: This presentation --

MS. WASTLER: This was prepared before

yesterday's discussion.

MS. TULL: Yes. And --

MS. WASTLER: Okay.

MS. TULL: Be nice.

MS. WASTLER: Go for it.

MS. TULL: Attestation. This is paralleling the current NRC regulations. That's why we proposed this change. It was not recommended by ACMUI at the April 2006 meeting. This is an NRC staff change.

MS. WASTLER: Based on yesterday's discussion, we understand exactly what the latest position is.

MS. TULL: Yes. Is there a specific recommendation to reword this based on yesterday's discussion?

CHAIRMAN MALMUD: Who among the members of the Committee would like the opportunity to reword this?

MS. WASTLER: Again, this is draft guidance. So while we might not be able to --

MEMBER EGGLI: I will take a shot at one word.

MS. WASTLER: -- do much with regard to how it has been written in 35, as it currently exists,

this is guidance.

CHAIRMAN MALMUD: Dr. Eggli?

MS. WASTLER: So we have the opportunity of possibly putting forth some of what you have recommended yesterday, shall we say, as a trial balloon? Because it does have to go through OGC.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I would change one word. In the third line up from the bottom, "competency," I would change that word to experience and then say "An individual must obtain written attestation signed by a preceptor stating that the individual has satisfactorily completed training and experience requirements and has achieved a level of experience sufficient to function independently as an authorized user for the medical use of Y-90 microspheres." I would change one word.

MEMBER WILLIAMSON: I would offer a further amendment. Starting with the three dots, dot, dot, dot, I would delete the remainder of the paragraph.

MEMBER NAG: I was going to suggest the same thing, "stating that the individual has satisfactorily completed training and experience requirements."

MEMBER WILLIAMSON: Period, period, period.

MEMBER EGGLI: I could go there.

MEMBER WILLIAMSON: Yes, period.

MEMBER NAG: "As an authorized user."

MEMBER WILLIAMSON: Period, yes.

MS. TULL: Ron?

CHAIRMAN MALMUD: Are you suggesting that the sentence end at the word "requirements" or that you leave out the "and has achieved a level of competency"?

MEMBER EGGLI: Just the whole thing ends at "requirements."

MEMBER NAG: Just say "completed the training and experience requirements through function as a authorized user."

MEMBER WILLIAMSON: I don't think that is necessary. I think you can just end at the word "requirements."

MEMBER NAG: Right. That's fine.

MEMBER WILLIAMSON: Okay. So the three of us agree.

CHAIRMAN MALMUD: So the three of you are making a motion that that be accepted with the word "requirements" being the last word, followed by a

period?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: That is your motion?

MEMBER WILLIAMSON: Yes.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Okay. Any further discussion of that motion? Behind me, member of the public?

MS. FAIROBENT: Lynne Fairobent, AAPM. I think that before you delete what comes after the ellipsis, you need to look at the written text to get the full statement that precedes the ellipsis, which is "training and experience described above." Without the "described above" after "requirements," it could be training and experience for anything.

MEMBER NAG: Right.

MS. TULL: I see what you're saying.

MS. FAIROBENT: Yes.

MS. WASTLER: So we would have to --

MS. TULL: It might have --

MS. WASTLER: So you would have to refer to the training and experience as described.

MS. FAIROBENT: But as this motion, it would not include "as above."

MS. WASTLER: Okay.

CHAIRMAN MALMUD: You are correct.

MS. FAIROBENT: And then I have a question. Is the "signed by a preceptor" given yesterday's discussion going to be tabled depending on what happens with that discussion?

CHAIRMAN MALMUD: We were going to go to lunch, Lynne.

(Laughter.)

CHAIRMAN MALMUD: May we take this as a two-step process? The first step -- oh, excuse me. Dr. Schwarz?

MEMBER SCHWARZ: I have a question. In terms of 690 uses, what exactly is required that the authorized user obtain currently?

CHAIRMAN MALMUD: In terms of the 690 uses, what is required with the authorized user obtained currently? And I will defer to Dr. Howe for an answer to that question.

DR. HOWE: Okay. If you are already a 690 user, then you have to receive training in device operation safety procedures, clinical use of the types for which your authorization is sought. And it can be obtained from any one of a number of ways.

But you also have to have obtained a written attestation that the individual has

satisfactorily completed the requirements in paragraphs -- and that was paragraph C, so there is a requirement for paragraph C of this section -- and has achieved a level of competency sufficient to function independently as an authorized user for each type of therapeutic medical use for which the individual is requesting authorized use or status.

And the written attestation must be signed by a preceptor authorized user who meets the requirements in 690 or equivalent agreement state and is authorized for the type of use that you're applying for. That's the current requirement.

CHAIRMAN MALMUD: Thank you for clarifying that.

Dr. Williamson?

MEMBER WILLIAMSON: Well, I think then we could amend the motion to basically delete the entire paragraph since the individuals who have come forth as authorized user candidates already have signed attestations for either 35.300 uses or 35.400 uses, which should suffice.

And if we're taking more the analogy that we are treating this like adding another modality to one of these broader armamentariums covered by 34.400, then there shouldn't have to be a preceptor statement.

There only needs to be on record, you know, if called to defend it documentation that they have completed the vendor-recommended training program.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: If I could make a quick comment? If you want to use the model in 390, then the model is that you have clinical experience and the preceptor authorized user has to have clinical experience in what you are applying for also.

So the modality would be this would be an additional modality that you would need new authorization for. And in 690, it would be the same concept. This would be an additional modality that you would need an additional preceptor attestation for. So that is the current regulatory model that is in existence.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I am going to make a suggestion, which goes along, that would support the travesty of the previous slide that replacing the word "preceptor" with the supervising manufacturer's representative. So basically the person that supervises the training and experience attests that they have satisfactorily completed.

It's not the preceptor. So it's not an

authorized user but simply change the word "preceptor" to something like the "training manufacturer's training supervisor" or whatever term you want to use, the person that's there supervising the training --

MEMBER WILLIAMSON: An individual supervising the training in paragraph whatever. I think that would solve it. Yes. So "Individuals must also obtain written attestation signed by the individual supervising the training in paragraph" X, "stating that the individual has satisfactorily completed the training and experience requirements," period. How is that?

CHAIRMAN MALMUD: You are using the word "individual" twice and referring to two different individuals. So you might want to use a synonym for individual.

MEMBER WILLIAMSON: Okay.

CHAIRMAN MALMUD: Something to clarify. Is that a motion, Dr. Williamson?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: Is there a second to Dr. Williamson's motion? There's no second.

PARTICIPANT: There is a second.

MEMBER SCHWARZ: Dr. Malmud, Debbie just made a comment.

MEMBER GILLEY: Why don't you just put that they have to complete a manufacturer-specific training and provide documentation when completing the manufacturer-specific training program? That says the same thing, I think, with a lot fewer words and very clearly.

MEMBER WILLIAMSON: We were trying to comply with their regulatory model. That was why. But if your OGC will let it by without having to have reference to that model, hey, I would agree completely with Ms. Gilley's proposal.

MS. TULL: The current guidance does read "Authorized users must meet the training and experience requirements of the specific vendor training."

PARTICIPANT: Yes.

MS. TULL: If that is what you are asking for, that is in there. In the second paragraph of the guidance, it's the first sentence. That would be covered.

MEMBER GILLEY: Then why would you need this at all?

MEMBER WILLIAMSON: Yes. Then I would say delete this paragraph if possible.

CHAIRMAN MALMUD: It is suggested that

this is an unnecessary addition?

MS. WASTLER: What it doesn't convey I think that Debbie Gilley was providing is written documentation that the authorized user has completed the training. That's the piece that is missing.

MS. TULL: We could make it say they must meet and document --

MEMBER NAG: Then add that in that previous paragraph, then, when you're talking about manufacturer's training.

MR. THURSTON: Yes. Both manufacturers currently provide such documentation that the new user has indeed completed the training. However, we cannot sign off on the competency of the individual, but we do provide the other --

MS. WASTLER: I'm sorry. I didn't --

MR. THURSTON: The manufacturer can't attest to the competency of the individual in this therapy. We can provide documentation that they have been through our training, our radiation safety procedures, and have been duly monitored and supervised by the appropriate representative. And we do currently provide that for every site, both manufacturers.

MS. WASTLER: Understood. Thank you.

CHAIRMAN MALMUD: Therefore, what is the motion currently on the table?

MEMBER WILLIAMSON: The motion is to delete this paragraph and incorporate in the paragraph described by Ashley "requiring completion of the vendor training, that written documentation of same be retained."

CHAIRMAN MALMUD: That is the motion?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER NAG: Second.

CHAIRMAN MALMUD: Dr. Nag seconded it. Any further discussion of that motion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: Unanimous.

MS. TULL: I am impressed.

(Laughter.)

MEMBER NAG: I have a motion that we break

for lunch.

CHAIRMAN MALMUD: Dr. Nag has a motion that we adjourn for lunch.

MS. TULL: We're getting to the end. That was the worst part. That was the worst part.

MS. WASTLER: There are only three more.

CHAIRMAN MALMUD: Ashley's suggestion is that we try and plow ahead.

MEMBER NAG: Okay.

CHAIRMAN MALMUD: Go ahead, Ashley.

MS. TULL: Okay. Team approach, again taken from the April 2006 meeting, -- this came directly from the transcript -- now reads "Microsphere brachytherapy treatment is usually conducted using a multidisciplinary team approach. The AU should consult, as necessary, with individuals with experience in oncology, catheter placement, radiation dosimetry, and safe handling of unsealed byproduct material." And we also added that one individual may satisfy more than one of the listed areas of expertise.

Any problems with that?

MEMBER NAG: No problem. That was the same thing we had in our --

PARTICIPANT: We agree. We agree. Go.

CHAIRMAN MALMUD: Comment?

PARTICIPANT: Call for the question.

MR. WHITE: Gerald White, AAPM. I'll just call to your attention that the American College of Radiology and ASTRO have described the process of care for these procedures. It's very detailed, and it's described most recently in the ACRS drug coding guide.

I would urge both the Committee and the NRC to review the process of care for this procedure because it's much more specific than what is described in this slide.

I think it would be preferable if the NRC did not reinvent the process of care that the medical community has already agreed on. In particular, there is no mention of medical physics in this list, but I will refer you to the general descriptions in the ASTRO process.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yes. I mean, we went over this with the Committee. And the reason why it was worded this way is that in some centers the oncology class may be provided by a medical oncologist, by a radiation oncologist.

Catheter placement would be provided by interventional radiologists or by other radiologists.

The radiation dosimetry would be by a dosimetrist or an AMP. And safe handling in many places is done by a physicist or an RSO. That's why we have put it that way.

CHAIRMAN MALMUD: Yes, Dr. Eggli?

MEMBER EGGLI: I think this description covers the categories of expertise required without specifically naming individual roles that are required to satisfy. I prefer the more generic description.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: My concern is with the term "oncology." In this country, the reality is that oncology is synonymous with medical oncology to 99 percent of medical practitioners. As written, it could be misinterpreted to mean medical oncology when I think we mean an individual with expertise in oncologic management of cancer patients.

MEMBER NAG: No problem there, I mean, excepting oncology you can take cancer treatment.

MEMBER WELSH: As written now, it would be interpreted as medical oncology by 99 percent of medical people.

MEMBER EGGLI: Could you put in parentheses "medical and/or radiation" behind it?

MS. TULL: To answer your question, we did

have that in there at one point. I did have parentheses because that came out in the transcript. And then through many, many, many revisions, we took it off and just said "oncology" to keep it as broad as possible.

If you guys want to bring it back to more specifics, I don't think NRC staff is opposed to that.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER EGGLI: It's not broad as written.

MEMBER THOMADSEN: Well, sort of to that point, I would have assumed that the oncology here being basically a radiation oncology, is more to the point, somebody who is well-versed in the biological and medical effects of high doses of radiation in body organs and systems, which a medical oncologist would not -- leaving that open for a medical oncologist would be a mistake in that case.

CHAIRMAN MALMUD: The motion was to approve it as is. Is there an amendment to the motion or should we --

MEMBER NAG: I would amend the word "oncology" be replaced by "with expertise in" --

CHAIRMAN MALMUD: "Cancer treatment"?

MEMBER NAG: -- "cancer treatment."

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: That doesn't really come to the issue because medical oncologists are quite expert in cancer treatment. The point here is high doses of radiation involved in --

MEMBER WILLIAMSON: We've got already an AU who is either a 35.300 or a 35.400. That means the person either has the broadest category of radiopharmaceutical treatment, which generally is radiation, often high doses, for oncologic management or it's a radiation oncologist. So isn't it kind of redundant to have the word "oncology" there? Why not just strike it out?

MEMBER NAG: No because you need someone who knows about cancer treatment for the overall medical management of where the cancer is and so on. I mean, if you want to put "cancer treatment" anyone with experience in, well, radiation dosimetry there, radiation dosimetry and radiation effects, you could do that.

MEMBER WILLIAMSON: So you are not satisfied that the AUs cover what is intended by oncology? What is the problem?

MEMBER NAG: Oh, yes. Okay.

MEMBER WILLIAMSON: AUs are either 35.300 or 400 practitioners. So I am arguing that the

reference to oncology, special reference to oncology is unnecessary. So I think that if you just deleted the word "oncology," it would be fine.

MEMBER NAG: No, no, it wouldn't. Delete "oncology" but replace with "by someone with expertise in cancer treatment." The reason for that is that AU may not be a radiation oncologist. The AU may be a nuclear medicine physician. So that would certify the AU requirement.

MEMBER WILLIAMSON: I see.

MEMBER NAG: It can certify someone who knows about radiation. But that person may not know how to treat cancer. We want an expertise in cancer in that.

So I think I agree with Jim Welsh that oncology may be misinterpreted as medical oncology. And, therefore, I would say "individual with expertise in cancer treatment," "cancer management."

MEMBER WILLIAMSON: All right.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I would like to propose we table this, have a chance to review the standards of care that Gerry White was just talking about. I get a sense that this may not finish in the next minute or two. And I think it would be nice to find

out what else exists. And we have tabled some other things.

CHAIRMAN MALMUD: There is a motion to table the discussion for the moment.

MS. TULL: This does conclude the major changes.

MEMBER NAG: In that case, I mean --

MS. TULL: There are other changes, but this is basically it.

MEMBER EGGLI: A motion from Mr. Lieto?

MEMBER NAG: I would like to make a motion that we accept it as.

PARTICIPANT: A motion to table trumps all other motions.

CHAIRMAN MALMUD: Mr. Lieto, are you seconding the motion to table?

MEMBER LIETO: No, I'm not going to. No.

CHAIRMAN MALMUD: Okay.

MEMBER LIETO: Thank you.

CHAIRMAN MALMUD: There is a motion to table. All in favor of the motion to table?

MEMBER EGGLI: It wasn't seconded.

CHAIRMAN MALMUD: Is there a second to the motion to table?

(No response.)

CHAIRMAN MALMUD: All right. There is no second to it. Okay. We move ahead with the motion on the table.

MEMBER NAG: I would like to make the motion that we accept it as is, replacing the word "oncology" with "expertise in cancer management."

CHAIRMAN MALMUD: So "oncology" should be replaced with "cancer management." That would include medical, surgical, and radiation oncologists.

MEMBER WILLIAMSON: I second.

CHAIRMAN MALMUD: It has been seconded by Dr. Williamson. All in favor of this change?

MEMBER NAG: Or any discussion?

CHAIRMAN MALMUD: Is there any discussion? Mr. Lieto? Okay.

(Laughter.)

CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: No opposition. Is there an abstention?

(Whereupon, there was a show of a hand.)

CHAIRMAN MALMUD: One abstention. Okay. Does that conclude it?

MS. TULL: No.

CHAIRMAN MALMUD: No. One more item.

MS. WASTLER: These are very quick.

MS. TULL: Yes. These are minor changes. If you guys don't even want to go over them, I mean, it's in there.

CHAIRMAN MALMUD: I think that --

MS. TULL: We added a paragraph for limited specific medical use licensees to state basically that notification does not apply. You've got to come in with a license amendment.

CHAIRMAN MALMUD: I didn't understand what you said.

MS. TULL: Okay. We added a paragraph to read, "An individual's qualifications to be an AU for Yttrium-90 microspheres at a limited specific medical use licensee site must be reviewed and approved by the appropriate regulatory authority." So this means you can't come in under notification according to 35.14. 35.14 would not apply.

MEMBER EGGLI: Only broad scopes can use notification.

MS. TULL: Yes.

MEMBER EGGLI: Okay.

MS. TULL: Donna-Beth?

DR. HOWE: Just a quick clarification. The broad scopes don't have to notify NRC because their radiation safety committee is the group that approves.

MEMBER EGGLI: Move acceptance.

MS. TULL: Say it again.

MEMBER EGGLI: Move acceptance of that provision.

MS. TULL: Okay.

CHAIRMAN MALMUD: Second? Any discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

MS. TULL: Next point on this slide is just waste disposal. There was an information notice, which I believe I sent to the entire Committee. It was talking about contaminants in the microspheres that cause problems with waste disposal issues.

So you either have to keep it for longer in decay and storage, send it back to the manufacturer if they'll take it back, or send it to a waste disposal facility.

There was an IN on that. We added a paragraph saying we issued an IN on this, that change, clarification, grammar, formatting, lots of that.

We have two discussion topics that we were going to ask for input from ACMUI. The first one is what Dr. Suleiman brought up earlier as far as dose versus activity. NRC's current guidance is written with dose to mean dose, absorbed dose, not activity, dose in gray.

Manufacturers currently use millicuries or gigabequerels in their inserts.

MEMBER NAG: I would like to table what is going to be a long discussion. And we can't do it now.

PARTICIPANT: I agree.

CHAIRMAN MALMUD: It has been moved and seconded to table it. And I would suggest that we adjourn for lunch.

Now I have been informed that our next two speakers, Drs. Katz and Ansari, have already been placed in a position where they have to change their flights out because they flew in expecting to speak this morning. So we will resume. And then they will be, obviously, the next two items on the agenda. And I apologize to them for the need to reschedule.

Be back here at 1:00 o'clock. Thank you.

(Whereupon, a luncheon recess was taken at 12:18 p.m.)

DR. MALMUD: We have with us today Drs. Armin Ansari and Luba Katz from Atlanta, and Boston, respectively, who will make the next presentation on the release of individuals containing byproduct material in the context of radiation monitoring at security checkpoints. And you're on.

DR. ANSARI: Thank you. Thank you very much. Just a little more introduction. I'm a health physicist with the Centers For Disease Control and Prevention in Atlanta, and Dr. Katz is a scientist with Abt Associates, who had the contract through Agency For Health Care Research and Quality, to do the survey that you will hear about today, and she analyzed all the data for us.

I'd also like to thank the NRC, and specifically Ms. Flannery, for the support that they provided for the project that you will hear about, and thank this committee for having us here to share our data with you.

I know Ms. Flannery, in the last meeting of this committee, briefly introduced the project, and I'll just take a brief moment to tell you why the interest in this topic and how we did the summary and the way we did it, and might also explain why the long title that we have for the presentation.

We have all heard about the patients having issues at security checkpoints. They are all anecdotal accounts, some news clippings here. We know how serious that problem is, how much of a nuisance it is, how frequent it is, and we also observed that there's a varying degree of being informed on the part of the patients. This is all again anecdotal, from what we heard, and some of our colleagues, friends, and family members.

So we knew about the issues about maybe unnecessarily alarming patients. We knew about the issues of providing documentation to patients as they travel. We knew about the NRC information notice of 2003, which we'll describe here. It was out there, and, you know, within that background, we thought it might be a good idea, since there was no other information out there, to go ahead and survey a number of health care providers and see what the actual practice is, how they actually handled this situation, get a range of practices and communicate that information, provide that information, perhaps a best practice can be identified and communicated.

So that was the intention of the project. Originally, there was some misunderstanding about what the project was about. Some folks thought that this

was looking at compliance issues of existing regulations, something that clearly is in the domain of the NRC and state regulatory agencies, but this was not at all the intention of the survey.

So that's part of the long title, in the context of radiation monitoring at security checkpoints. That's what the driver was.

So this is just to say that anything unintelligent you hear from me is not--you don't hold our employers responsible.

Just a few news clippings, just to show you the flavor of what's out there. This is last month, May of 2007, in the Seattle Times. "Bomb on board the ferry." This is a story about how Charlie was mistaken for a nuclear weapon and it begins during a trip to the cardiologist.

So sensationalized reporting. Another example from March, radiation data. This was in Connecticut. A lady was driving in a car and Connecticut law enforcement was passing her and they happened to notice the, it tripped the sensor, so they stopped her. This is a quote. She said nobody at my doctor's office warned me this would happen.

This was also in January, right before the Super Bowl, and what was interesting in this story, it

was warning fans going to the stadium to be prepared in case there's--well, they also mentioned an incident during a Christmas tree lighting ceremony in Rockefeller enter early in November, when the New York police had pulled six people and questioned them.

And what was interesting is two quotes in there of two people that they talked. One of them said it happens all the time. The other one says it had been infrequent. Different perspectives.

This one also was a Canadian gentleman, radioactive prostate, sets off airport alert, and what was interesting about here is iodine seeds in prostate, the patient stopped, and the patient knew very well why he set off the alarm and tried to explain it to the agent who stopped him. But the agent had not heard of such a procedure.

But fortunately for the patient, the agent's supervisor's brother-in-law had a similar procedure, so they let him go, indicating that there's also issues with people that are actually doing the screening, not perhaps being as knowledgeable as they should be.

This account was published by the patient's doctors in the Canadian Medical Association Journal, and they said in that article, the day after,

the state decided to actually go ahead and provide documentation to all of their patients from the on.

When we look at the literature, the earliest that we can find is something that was in a letter to the editor of New England Journal of Medicine 20 years ago, problems on Pennsylvania Avenue. Very interestingly, two of the patients from the University of Cincinnati Medical Center, a few months apart, thallium patients, they had gone to take the White House tour and were stopped by Secret Service.

And what was interesting about this recommendation is that the doctors thought, perhaps rightly so, that this was a very isolated--you know, only happens if you take the White House tour.

And because these radiation screenings were not as extensive as they are today. So they said, you know, issue one if they plan to go to the White House.

Two years later, a similar letter to the New England Journal of Medicine from Washington University School of Medicine. This was a patient who had actually gone to check his safety deposit box in a bank, and that tripped the alarm. Interestingly, the bank had installed this because they were

concerned about clients leaving radioactive materials in a safety deposit box.

So they also said it behooves all physicians ordering, or administering a thallium test, to warn their patients they may be radioactive. Of course we know that now they can even remain that way for longer than seven to ten days because the sensors are much more sensitive.

Then I didn't find anything in the '90s. What's in the literature now is actually post 9/11, and this is a sampling. Interestingly, these are in British journals mostly, Lancet and British medical journal. The Lancet article is about a commercial pilot who gets stopped, and the third item there is a gentleman with the seeds, the prostate.

The article in Nuclear Medicine Communications is this one, right here. One of the authors is actually a member of the Institute for Nuclear Medicine in Vienna, the Austrian agency, and what they provided in their report, which I've copied here, is actually a form, because after this happened to one of the patients, they decided to have this form and it actually has a lot of the information that we now see in some of the documentation for providers that provide them here. Even some of the language,

similar to the NRC information notice. I'm sorry you can't read this but it does say that dismissal of the patient is in agreement with Austrian radiation protection rules and regulations, similar to the NRC suggested language in their information notice.

And they also here say that if it trips the alarm, that this is not associated with any radiation hazard to others. So that's the example they provide.

Now this was another international who, at Orlando, was interrogated. The fact that he was strip-searched, dogs were brought in, kind of a, not a very pleasant experience, and so they also recommended that patients be warned about this, and they said that doctors show a worrying lack of awareness of such problems.

This is the NRC information notice I was talking about, came out in December of 2003, and what--I'm not sure if that's the incident that triggered it but the one incident that was mentioned in the information notice was the gentleman who had iodine-131, merely failed to follow the directions that was given to him.

The day after his treatment, he's going through Lincoln Tunnel on the way to Atlantic City.

So it prompted--I don't know if this was what prompted the information notice but the example that was given there.

And in that information notice, the doctors advise licensees to inform the patients about the importance of following the instructions they're given as they're released.

And two reasons were given for that. One is to maintain doses as low as reasonably achievable and the second is to reduce the probability of something like that, which would inconvenience not only the passenger but other people, and also law enforcement.

Some of the language in the information notice, if you look at the second bullet, it talks about authorized users are expected to evaluate the patient's capability to follow instructions before release, and stress the importance of them following the written instructions.

Even though the sentence starts with "when required to provide written direction," NRC acknowledges that even at levels below that, when written instructions are not required, they still have detectable radiation that would trip the alarms.

So then regarding all patients that have

detectible amounts of activity that could trigger alarms, they offer two voluntary actions. One of them is to provide all patients with an appropriate explanation on the potential for alarming radiation monitoring equipment and second is that to consider providing them with some kind of documentation and information for law enforcement they can contact and verify.

Later that December, American College of Nuclear Physicians had this press release, essentially saying what, the NRC information, and suggesting that documentation that is provided to the patients include that information.

This effort I believe was coordinated with the Society For Nuclear Medicine, because later on, they I believe asked the physicians to, if you encounter any--if you hear anything from your patients, please communicate that to us and let us know, and that e-mail was an SNM.org e-mail. So one thing is I'm going to follow up, actually, with Mike Peters, if he's here, with Society of Nuclear Medicine. We're going to move, follow up, and see if any information was provided--we kind of doubt it but we will see.

Speaking of Society For Nuclear Medicine

they most recently had a press release in November of last year, right before the holidays, asking the medical community to make patients aware of the security problems. Patients and health care providers should discuss. And then they also said patients should obtain a letter from their doctors that contains the following information.

And it stressed the after-hours availability of information, someone who has access to appropriate information if they are contacted for a verification.

So if all of that is not enough, I've got a sound clip, just two minutes long, maybe this will play, just as a last-minute thing. See if it plays. It was a Paul Harvey piece right before the Super Bowl, and was kind of just telling them that, people that, you know, don't be surprised, if you're going to the Super Bowl, get a note from your doctor. That type of thing.

Now with this, we wanted to see what, as I said, what kind of practices are out there. And this is our methodology of what we follow. NRC, you know, as I said earlier, was a tremendous help to get this project done, developed a temporary instruction for NRC inspectors, for the questionnaire Dr. Katz and

I assisted Cindy to come up with a draft of the questionnaire. Ms. Flannery sent that to NRC regions for comment. We got their input and we had many good comments from them.

And then this went into effect, temporary instruction went into effect in October of 2006 for three months.

Initially, we were hoping to---this was a small project--we were hoping for thirty, I think--well, we were--thirty minimum, and we were hoping for sixty and we got 66 facilities serving, and then NRC regional inspectors would send the data to headquarters and Ms. Flannery would then share the data with us, and Luba analyzed them for us.

Some limitations and advantages of this approach. Of course this was limited to nonagreement states, the way it was done. We also sort of, we had to be careful about recognizing the responder's candor. Has he been interviewed by NRC inspectors? Might be an issue. This was done not as part of the regular compliance type of inspection. It was done outside of that.

But, you know, you're talking to an NRC inspector, you want to put the, you know, present the best light. So we were aware of that and this was

certainly a limitation. And the third one, which is last but not least, was that the--we not being able to ask follow-up questions, because no matter how carefully we devised the questionnaire, there were some points, as we were reading them, that, I wish we'd asked that for clarification or I wish we'd asked that follow-up question.

So this was not possible to do. So these were limitations. The advantages was actually very valuable input that we got from NRC to draft the questions, we got very good input from them, and the kind of access that provided was very valuable.

In fact in several facilities, there was more than one person and NRC inspectors, who had access to those people to interview them, and the other was a 100 percent response rate. If we were doing it the original way, I know we were going to have issues with those facilities that would not participate, and therefore nonparticipating facilities would introduce some kind of bias.

And we didn't have that here. So we had a 100 percent response and that was an advantage.

The questionnaire had information about general facility information, about the individual being interviewed, and they were asked if they were

familiar with the NRC information notice, and we asked questions about how they do the informed consent, what kind of information they provide to the patient and who does provide the information.

We also asked them for copies, if they had documentation they give to patients, to give copies that we can see.

I think to go through these quickly, this will be in the report that we will make available, and so--but these slides are here just to show that even though our sample size was sixty facilities and 89 people, it did cover a wide range, communicative hospitals, number of beds, and also number of procedures that were done annually.

We did have a range. These are the type of procedures they do. This one just showing the experience of the people who were interviewed, also covered the range, people with 36 to 40 years of experience, or less than one year, either in facility or total experience. And also these are the people we talked to, nuclear medicine and medical physicists and RSOs and physicians.

A question with their familiarity with NRC information notice. 85 percent said yes, they were familiar with the information notice. This one, we do

wonder a little bit, if this might be an exaggerated number. Maybe we could have done the question a little differently or something maybe to minimize that but this was the answer we got. 85 percent said yes, they are aware.

Of the remaining that were not, ten of twelve were from outpatient diagnostic facilities. So this is something that, in fact, one of our observations at the end we talked about, this is a target audience that maybe we need a little bit more outreach with respect to this issue.

We asked them do you inform patients that may activate radiation detectors. The radiotherapy had therapeutic--we had these two sections, people who do only therapeutic and radiotherapy and radiopharmaceuticals. We separated those two. For the therapeutics and radiotherapy patients, the majority said yes, and the few that said no, one of the reasons, well, it unduly alarms patients. Four, diagnostics. It was sort of more said yes than no, and 15 percent of respondents recalled actually being contacted about a patient who was stopped, and some of the examples they gave was at the U.S.-Canadian border, two were nuclear power plants, and a landfill truck driver at an unspecified location.

And three of these, three of the facilities that were contacted about actual patients, still don't provide documentation.

The question, Do you provide documentation? 65 percent actually said yes, they do provide some sort of documentation, and pretty much the rest of them, they provided, on request.

What formal documentation? Of the 43 facilities, 35 shared their documents with us, and I will show you some examples of that. A few of them were handwritten notes on prescription pads or blanks pieces of paper, and this was generated during the interview, and--

DR. KATZ: It did not look very convincing.

DR. ANSARI: Whether to the law enforcement, or when we even questioned, they would--they did that for the inspector, we didn't know they would do that for the patient. So usually the information that's included is the radionuclide, amount of activity, half-life, and twelve of the 35 documents we got actually, verbatim, repeat what was in the NRC information notice, the suggested language, that this radiation poses no danger to the public and is allowed by the medical use regulations.

But in a couple of cases, we saw some text that really didn't, wasn't helpful to people who would be looking at it, and you can see the example down there. It was too technical. Most people looking at it, either the patient himself or the law enforcement, wouldn't know what that is.

Of the 27 respondents in a--this is for the facilities that do not provide documentation, two-thirds of them thought that what, the procedures they had was adequate, so they were not impressed. They didn't change anything.

And four of the individuals who do provide the documentation, there were some suggestions, when we asked could their procedure be improved, one of them said yes, the access to patient information during off-hours could be improved. We know that is a problem with most of the facilities. Offering documentation to all patients, other than just those who are planning to travel. This was actually something that was suggested in the NRC information notice.

And one individual said that this should be discussed at the regulatory level, which I know most of the people did not agree with that.

And then last was one they should, the

Government should install better equipment so they don't harass patients, and I think that view was shared by a lot of people too.

This is an example of one. Luba covered the part about the facility name, but that was also handwritten. The facility name was handwritten, and this of course I don't think will offer any value.

This is a much better example, CardinalHealth, but I want to pause on the last one, which is, we thought was the best example of the documentation we had. This is from the Barnes Jewish Hospital, Washington University in St. Louis, and Dr. Henry Royal provided this to us.

MEMBER SCHWARZ: Sally Schwarz.

[Laughter]

DR. ANSARI: Oh, okay.

MEMBER SCHWARZ: I am very definitely aware of. Yes.

DR. ANSARI: But we did get permission from Dr. Royal to publish this when we communicated this information, as a really good example. In fact I brought--David, you have three kinds. The one shown here is generic. Is there just wallet-size cards? Really convenient. One of them specifically for iodine. The other one was technetium and thallium.

But this one here is a generic one. It has everything you want in the card, just put it in your wallet, and the language and the instruction for patients is very well-written, and also to the security people.

It even says to the security, that you may be asked to let the patient confirm that the patient has given you permission to release this information. So it basically has everything in there, and when we write this up for publication so everyone can see, we plan to actually include this example.

We also asked some questions about how the patient is informed, who talks to the patient, and it really varied, about who gives this information to the patient and then they do it, administration, before the procedure.

One comment we included here was from an inspector and it says in his view very little information is provided regarding the nature of the injected diagnostic agent. Some patients were told it was radioactive or radiation, some were told it was medication.

We asked--really, not "we." The questionnaire included a question: How often do patients express concerns or ask for additional information? And this was a really broad range.

There are eight facilities, that patients apparently never ask questions, and in four facilities most patients do ask questions.

And Luba really worked this data to see-- she can identify what is the reason. This was not due to the staff years of experience. That didn't explain it. The type of facility didn't explain it, and whether or not the facility provides educational material couldn't explain it.

There was some data that weakly suggested that the training, communication training that the staff had may explain this. But it was hard to do this, statistically, with the numbers that we had. We couldn't show it was the same, but it was suggested that organizations that the staff had training in patient communication, they're more likely to get questions from the patient.

Now that would make sense, because when we read the literature, I mean informed consent actually says that personality and communication style of individuals makes a big difference. If patient regards the provider as approachable, they're more likely to ask questions. So that would be consistent with that.

Before we started doing this formal

questionnaire with help of the NRC, we did sort of a pilot thing, and this was Luba's introduction to health physics and community, and medical physics community, which was interesting. She will share that with you privately, later.

But one of the things, one of the interviews was actually really telling, and I don't want to repeat verbatim of what was said during the interview, it was a phone interview, but it was a children's hospital and the kind of comments that were made about patients asking questions about children was kind of a--represented a cultural issue, of how some people regard this issue, and I think it highlights some of the training that needs to be done, I think within this area. And this is the type of answers that we probably would have gotten more, if the survey was not done by NRC inspectors.

We were asked when the patients do express concern about following instructions, what is their number one concern. The number one concern seems to be minimizing time with children and pregnant women, maintaining distance.

Minimizing time in public was the least--only one facility mentioned that as a concern, and I think this also represents that, not that the patients

don't think they can follow it, it's just that patients are not concerned with that. They're more concerned with minimizing time with their children. They're not as concerned about being in public, so they're less likely to follow that piece of the instruction than the other.

We asked this question: Is it possible for a patient to leave your facility without the knowledge that they emit radiation?

The therapy, for the therapy in radiotherapy patients, the answer was absolutely no, it's not possible, and for diagnostic patients, 20 percent, 11 out of 54 who answered said yeah, it is possible for them to leave the facility without knowing. But the fault there is with the patient. Some of them said patients may not understand what we're telling them, they fail to understand instructions, and not all patients have the same knowledge, and not all of them retain information.

Specifically people with English as second language, or elderly patients were specifically mentioned there. But it was interesting that when they gave the possibility that they may leave without knowing, the fault was with the patient.

And this was also interesting. That 95

percent of the respondents considered the procedures adequate. And I think this might be also a side effect of being interviewed by a NRC inspector, because they're concerned, if we say it's not adequate, what's going to come down the pike. More, you know, more procedures, more regulations.

So this was understandable, that they would kind a say that yes, you know, things are fine and adequate.

We asked them, Do you have training in patient education? It was sort of half and half. Half of them said yes. This is self-proclaimed training in patient education. Half said yes and half said no. Then people who said no, we asked them, Do you think that training would be beneficial?

And the majority thought that it would be beneficial, but interestingly, a fraction of them, 28 percent, didn't think that it would be beneficial to receive the training.

Of the ones who did say they received the training, it was actually either by an RSO or authorized user, during in-service, or residency, or in a meeting. This was not very solid, even when they did claim training. So this I think presented maybe a need in that area.

So these are the observations and recommendations that we have looking at this data, is that first, even though our sample size was not very large, we think we captured the range of facilities and practices. Diagnostic patients are less informed than therapy patients.

And so in those facilities, the outpatient diagnostic things could benefit from an improved outreach. Staff may benefit from training in patient education and communication. Most standardized uniform documentation could be helpful, so we don't get the handwritten stuff, and providing documentation to all nuclear medicine recipients with potential to set off alarms, could be helpful.

I'd like to acknowledge again Cindy Flannery for her assistance and support, and all the NRC inspectors, seventeen of them who collected this data, and Ms. Palmer at AHRQ. And that's where we are, and Luba is still working the data, and there are some aspects of it that is in her report that's preparing, but this is the nuclear presentation.

CHAIRMAN MALMUD: Thank you. Are there questions? Comments?

MEMBER LIETO: So there's 78 total responses, is that--

DR. KATZ: Sixty-six facilities but each, some facilities had more than one person that inspectors spoke with, so it's 78 people.

MEMBER LIETO: Okay. Are you still gathering data at the regional level, or that's cut off? When was it cut off, date approximate?

DR. KATZ: It was between October and November and December, three months, starting in October.

DR. ANSARI: January. It was mid January, was the cutoff date. We were shooting for sixty and the temporary instructions had a provision for extending it three more months.

MEMBER LIETO: I was going to say, they're still handing that survey out.

DR. KATZ: They're still doing it?

MEMBER LIETO: They've been handing out during the first quarter of this year, cause I had a visit and I got one.

DR. KATZ: Okay. Well, that's good to know because we did terminate the temporary instructions. So obviously, someone didn't get the termination--

[Simultaneous conversation]

MEMBER LIETO: Are just trying to gather

information on certain--

DR. KATZ: Okay.

MEMBER LIETO: The inspector hands it right to you.

DR. KATZ: Yeah.

CHAIRMAN MALMUD: Any questions of us?

DR. ANSARI: Well, I think this was what we were thinking of doing with--and Mike, feel free to please speak up--as a next step for us was to maybe work with the Society For Nuclear Medicine, to see if we can give this issue a little bit more exposure. I think from our perspective, I think if recommendation came, perhaps even with a form--like the Austrians did--that was just a form. If a standard form was provided by the NRC, something on the model of what Washington University in St. Louis did, as an example, then it kind of--that would be very helpful because law enforcement are used to seeing and would be used to seeing that form. The same-looking form for everybody. And that would be really helpful.

The other thing that was helpful about that form is it had two phone numbers. One was off-hours, specifically. That would get them thinking, look, if we provide a phone number here, somebody on the other end, when they answer that phone, they're

going to have access to that information.

I think that would probably be something, if it came from a more authoritative source, providing that example, it would be very helpful.

DR. KATZ: So I guess another comment that we have is that we think the information which is, that was put out, misled people, because the specific example that was given was for iodine-131. So people who do not administer this type of isotope thought, oh, this has nothing to do with me, this is not my isotope. There were several studies published when people actually calculated for the modern detection equipment, how long thallium and other, you know, very prominently used isotopes, how long they are active in setting off this alarm. So it's quite a long time.

But I think the community sort of is not aware that this is the case, and that's why we notice the diagnostic facilities are less concerned than therapeutic facilities.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: So what are the threshold ambient exposure levels that tend to set off these devices?

DR. KATZ: There is a paper by Zucker, and, for example, a standard stress test, I think is

something like 30 days within a room.

MEMBER WILLIAMSON: No, I asked what is the exposure--

DR. KATZ: I don't remember the numbers.

DR. ANSARI: I think it sort of varies like the, because of how some of these folks are wearing it on their belt, and they are not as sensitive as the portal type stuff, but I think twice background is--

MEMBER WILLIAMSON: Yes. I think the detection sensitivities are getting better and better, so it's--I know 2mR per hour was the limit for one of the detectors out there, but they designed detectors to see almost anything.

MEMBER GILLEY: Twice background.

MEMBER WILLIAMSON: Yes.

MEMBER WILLIAMSON: But what was the most frequently-observed nuclide? Do you know, or--

DR. ANSARI: The unfortunate thing is about--and we tried to get data, nobody keeps that data, to our knowledge. We've tried to actually--and what we hear is anecdotal. Last week, I was at the Georgia Emergency Management Conference, talking to a gentleman who is familiar with Customs and Border Protection, telling me about lots and lots of thallium

hits. And I say, well, do they keep their data? Can I get the data? And he said no, they don't.

CHAIRMAN MALMUD: Yes. Dr. Fisher?

MEMBER FISHER: I recently served three years as science advisor at U.S. Customs and Border Protection, with a responsibility in this area. The sensitivity of the detectors is classified, of course, and can't be stated in public, for obvious reasons. The U.S. Customs and Border Protection has collected a lot of data on the radionuclides detected at U.S. border crossings, in terms of, you know, what's causing the alarms. A large body of data on the medical isotopes detected.

The agents are well-trained to recognize medical isotopes and distinguish those from nonmedical isotopes that might cause the alarms, and Customs also has extensive 24-hour reach-back through their Laboratories and Scientific Services Division, for transmitting spectra of radioisotope detection, using sodium iodide spectrometers.

And so that there's a 24-hour service, where a scientist is on duty, can interpret a spectrum, and quickly report back to the field if there are any questions, and this service actually works pretty well. At first glance, you might think

it doesn't work but there's an extensive reach-back to the field, and so we've seen a lot of examples where at least the well-trained CBP agents really know what they're dealing with when it comes to medical isotopes.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: I'd just like to say that this is an excellent study and important information If you are going to share this data with the Society of Nuclear Medicine, I might recommend that you also share it with the radiation oncology societies, ASTRO or ACRO, as well.

CHAIRMAN MALMUD: Thank you. Oh, here, a member of the public.

MR. WHITE: Gerald White with the AAPM. AAPM has previously commented to your organization and to the ACMUI about the inappropriateness of placing the burden of solving this problem upon patients and medical institutions, when the problem is really primarily that of the security staff who fail to adequately identify, as you seem to have solved, which patients have medical isotopes and which don't.

So I have two questions. One is formal and one is perhaps a bit more informal.

The first is, Do you plan to study the

feasibility of the ability of security forces to identify these isotopes, using commonly available spectroscopic instruments that are field grade, and the second question is there was a lot of discussion about the type of forms one might carry going into the Super Bowl, was it? some sporting event, post-medical procedure. How does a security person distinguish between a patient having a thallium scan with one of these cards from a hospital and a ne'er-do-well terrorist with dirty bomb material, carrying the same letter from Kinko's, from a hospital?

DR. ANSARI: The first question, the answer is no, we don't have any plans to do that. It's sort of I think outside the--I think there are other agencies who are addressing that topic and I think it could be done. I don't necessarily agree with you. And I also agree with you on the second point that you raise, that that would always be an issue. You always have to, for any counterfeit documentation that's produced, that will always be an issue. I agree with you.

The other thing that I'd like to say is that even though the law enforcement should try with better use of their existing instrumentation, or by

improving their instrumentation, to say that it's not mutually exclusive to do that and also to better inform the patient. Because I think some of the comments that came from AAPM, was, if I remember correctly, said that, it was something like they don't want to burden the patient with information.

We tend to look at it differently. We think a better-informed patient is a better thing. We don't think about burdening the--we don't look at it as burdening the patient with information.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: I would agree with your final statement, which was sort of the point I was going to make. In my practice, I tell every therapy patient, I need to think about telling diagnostic patients too--and what I tell them is this is no joke. They will treat you like terrorist and it will be unpleasant.

And I think the issue is to get patients to follow the restrictions. One of the things that will be helpful to the community practitioners is to understand how long specific isotopes are likely to be detected and what's a reasonable guideline.

I can give a patient 150 millicuries of radioactive iodine and release them because of the

exposures, but they are athyreotic and they will have it in their system for three or four days, and it'll be, it'll get fairly low level fairly quickly.

Likewise, I can give a hyperthyroid patient 15 millicuries of iodine, 10 percent, and that'll be in their system a whole lot longer cause their thyroid's going to hang on to that. So some practical guidance for practitioners on the recommendations that we should give patients with respect to duration of avoidance. I tell them avoid airports, avoid public transportation, avoid government buildings. Some guidance on also what should be avoided, and how long it should be avoided, would be very helpful.

MR. WHITE: Just to correct the record, AAPM did not object to burdening the patient with information. What we objected to was requiring the responsibility of the patient to educate security personnel on their medical condition. That was the objection we had. It was different than information to the patient.

CHAIRMAN MALMUD: Dr. Katz.

DR. KATZ: I actually have a comment about, sir, your last question. That was specifically asked, had a question on the questionnaire, How can

the respondent distinguish between a bona fide patient and a terrorist?, and apparently these cards include a phone number to call, and if the person who is on the other end of the phone is somebody who has access to the medical records and can check whether that name actually--I mean, perhaps it's still a system that can be broken, but there is some--

MR. WHITE: You should understand that a phone call to a hospital requesting information about a patient's medical treatment cannot be answered in the absence of a previously-signed release for that information.

If someone calls our hospital making that request, our people are forbidden to respond.

MEMBER EGGLI: Yes. This is a HIPAA issue. If a Border Patrol agent calls our hospital in the middle of the night and asks for information on a patient record, if I release that information to a Border Patrol agent, I'm violating a different federal law, which is called the Health Insurance Portability and Accountability Act. I cannot release that information.

I can put my phone number on a card, but it doesn't matter, because I can't release the information, unless I have specific written consent

from the patient to do so.

MEMBER NAG: Could I address your point? You know, when we have an authorization from the patient that allows us to release that information and technically, the phone number we gave was not the phone number of the doctor because he may not be available, and we give the phone number of the admitting supervisor who has the list of, you know, all patients, that they can at least--not know how many millicuries he was given, but they can say that this patient as a patient who had a prostate implant on such and such a date.

CHAIRMAN MALMUD: Dr. Schwarz.

MEMBER SCHWARZ: And I think, I'm not sure that we actually have signed sheets at Washington University, but certainly if we do something in combination with the Society of Nuclear Medicine or one of the oncology societies, too, that could be part of what you put in place, that they do sign the document that essentially allows information to be released when they get the card from the physician.

CHAIRMAN MALMUD: Dr. Fisher.

MEMBER FISHER: Just one more point of clarification. If the activity detected is internal to the patient, that's not of concern to the border

inspection people. That's not what they're looking for. They recognize that that's most likely related to a medical diagnosis or therapy. What they're looking for is suspect radioactive material and cargo that meets certain definitions. but they're not really interested in what isotope did you get. In fact they have very much difficulty identifying very low energy Auger emitters, palladium, iodine-125, cesium-131, because it's below the spectroscopic threshold of sodium iodide systems.

But they're not really interested in the isotope. They recognize it's a medical patient. What they're looking for is items in cargo.

DR. KATZ: Dr. Fisher, is it true to say that the experience is limited to Border Patrol, because there's clearly, you know, there's people who set them off who are at garbage dumps, you know, tunnels. So it seems like there is a group of people who are really well-trained but are there law enforcement personnel who are well-trained, outside of the Border Patrol areas?

MEMBER FISHER: I can't speak to that.

DR. KATZ: But your experience is about the border control; right?

MEMBER FISHER: Airports. Ports of entry.

DR. KATZ: Okay.

MEMBER GILLEY: But TSA is not U.S. Customs.

MEMBER FISHER: No. TSA is a separate agency, a part of Homeland Security.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: Yes. It's sort of a hodge-podge--I mean, some of our FDA inspectors in the field, because some of the products coming in have to clear Customs also, so some of them do have radiation detectors, and a lot of first responders, and whatever, and in some cases, a lot of these people are trained to detect the radiation but then they call in more expert people to help analyze and figure, but it's--you've got a whole multitude of agencies working at these things on different levels. There's not a simple--

CHAIRMAN MALMUD: Other comment from the public?

MR. PETERS: Yes. This is Mike Peters, SNM, just coming to answer Dr. Ansari's call for comment.

As you probably know, and you saw the American College of Nuclear Physicians slide, that showed a Web site article from 2003, SNM also had that

same exact article on our Web site, that we've had, actually, for the past five years, and we recently updated it last holiday season, as they said, with a press release, and it was well-accepted by the international trades as well as the normal press, and we feel an ownership over this issue, and that's why we've offered to help the CDC communicate with our community and our membership, and we're looking to do that.

We obviously have JNM, we have our press group, our communications team who can release press releases about this, and this is again an issue that we feel is our issue and we're really looking forward to working with the CDC to educate the community about this. That's all I have to say.

CHAIRMAN MALMUD: More comment from the public?

MS. FAIROBENT: Lynne Fairobent with AAPM. Just one thing I would like to caution, sitting here listening to the discussion. I think the cards, I think the outreach are great, but don't let anybody misbelieve that providing a card to somebody with a phone number, that they call back to a facility that verifies whatever name is asked of them, is anything to assure that that is a valid receptor call.

Terrorism organizations are very well adept at setting up this sort of a system. There is no verification that the number for the facility provided is a legal or valid facility, without any other documentation than a voice message on the other end of the phone.

CHAIRMAN MALMUD: Thank you very much.

MS. WASTLER: I believe Dr. Ansari has a second presentation as well.

DR. ANSARI: Yes. That one should be a shorter one, much shorter one.

CHAIRMAN MALMUD: We'll give you time to prepare it. Are you ready? Okay.

DR. ANSARI: Okay. This is now a major shift from minuscule doses and issues of convenience, and patient education, to some issues that are potentially life-saving situations and emergency response issues to nuclear radiological terrorism incidents.

This is a topic that I'm not sure that--I appreciate you giving me the time to share it with you. I'm not sure if it's a topic that this committee may or may not want to address directly, but since I was coming here for the other study, I asked for a few minutes to share this with you.

Again, anything stupid is just me, not CDC. Here's the issue. That availability of the medical community would be heavily involved in response to a nuclear radiological incident, and the hospital in-house radiation expertise. This is the radiation safety officers, may be physicists, nuclear medical technologist, will be the invaluable asset. This is considering that we have the human resource issues, specifically health physics support, radiation safety issued support at all levels of response.

This is really significant, and in our outreach to the hospitals in the training material that we prepare for emergency response for clinicians, emergency department clinicians, we stress to them to utilize their in-house staff of radiation scientists, technologists, to assist them in their emergency planning. So we stress this to them.

We think that RSOs, medical physicists and nuclear medicine technologists should be included in the hospital emergency response plan, should be familiar with their roles, what will be expected of them in such an emergency and they should be engaged before an incident occurs, to be most effective when it does.

We've done some focus group research with

emergency department clinicians, and these are the top concerns that they have expressed to us, that their hospital would be overrun. Actually, you're all familiar with these concerns, safety of their loved ones, lack of adequate staffing, preparedness, contamination of their facilities and self-protection.

And one thing that we told them is that their in-house expertise can address many of these concerns that they have, if they use them effectively in their planning.

If we look at the hospital incident command system, and there are some internal scenarios like bomb threats, hostage crisis, loss of power. There's some external scenarios that actually match the national planning scenarios, that includes nuclear detonation and RDDs.

And looking at the incident command flow chart, the structure, and the candidate positions for these command positions, for the radiation safety officer position, right here--there is another slide I didn't show--the radiation safety officer, the candidate position is specifically listed in the HICS as a radiation safety officer, with the primary duty of assessing the--to do a situational assessment and identifying issues of concern, and addressing them,

and responding to the incident commander, working directly with him.

The other position, medical technical specialists, specifically listed as potential candidates for this position of radiation safety officer are medical physicists and nuclear medicine.

And people that serve in this position have numerous roles. One of them is rumor control. This is rumor among the staff, making sure that the hospital staff get proper information, because if they don't, and the rumors spread, then the whole hospital response is going to get messed up.

So this is a very critical position, and for radiation scenarios, emergency response scenarios, this is what's actually right now listed in the hospitals, in the command system.

We have key roles in planning, training. In planning, just drafting, reviewing job action sheets. They need to be involved in doing that. They need to be involved in training, they need to be involved in exercises, and when it comes to the response, they would have input in the received treatment of patients, protection of care providers, providing screening for patients. This is for not only just external, like screening for internal

contamination, and also providing assistance in producing communication material, and many more functions.

And the question is that is the hospital emergency staff prepared to take on those roles? They have a certain familiarity with HICS. They need some familiarity with the relevant state and federal guidance documents. They also need to be familiar with the training material for clinicians.

The reason for that is that if they're familiar with the training material for clinicians, for radiation emergency response, they can anticipate what type of issues they may be asked to provide input for, what kind of assistance do we ask of them. They can at least be prepared for that.

Those are the type of technical consultations they might have to provide, not only the health and safety of the staff, interpretation of the guidance documents, dispelling rumors, screening criteria. This is the hospital staff, the radiation staff could really help their clinician colleagues in doing their job.

Sometimes they just need to function as translators, technical liaisons. And the good news is that the hospital radiation staff are highly-qualified

radiation professionals. They are highly-skilled professionals, they have a great interest in homeland security issues, we know that, and, for example, when the Nuclear Radiation Society tries to fill committees, there is no problem filling homeland security committees because there's no much interest in that.

And the specialized training that it requires is really minimum, because you don't--there's so much of it is radiation experts. So we just have to acquire very minimum emergency response training. And the problem is with some of the feedback that we have, is that the people we talk to feel they may not have the support from management, the management doesn't engage them in emergency response planning, and if they want to go and get the specialized training, they felt that if hospital management supported them more, if there was some, this training became a recommendation, or a requirement or recommendation, they could use that as an incentive to get their management to support them better.

So this is the feedback that we had, and the reason I wanted to--I knew that you were looking at training requirements, and so forth, in an entirely different context, but I just thought I'd share this

with you, that this is also an emergency response function, it doesn't have to do with license procedures but it's a real issue, and this is something we're going around the country telling clinicians and hospitals, to use radiation experts, but we do feel that those radiation experts themselves feel they need a little bit of extra training and support from the management.

CHAIRMAN MALMUD: Any questions or comments.

Dr. Welsh.

MEMBER WELSH: I think your presentation or overview was excellent; however, it did not include radiation oncology as one of the technical and medical specialists, and I feel strongly that where radiation oncology is available, understanding that many facilities don't have that, the radiation oncology physician is perhaps the one most familiar with radiation-related injuries and could be an invaluable member of this team.

And I strongly recommend that, where available, radiation oncology either lead that program, or be integrally involved in it.

DR. ANSARI: Thank you. Yes, definitely. This angle was formally health physics type of the--

but absolutely, yes. Thank you.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. In that same regard, ASCO is the national organization for radiation oncology and that that had radiation oncologists for, you know, similar incidents.

CHAIRMAN MALMUD: Most hospitals today do have programs in preparation for biologic, chemical and nuclear terrorism, or events. Sometimes they're simply events, a chemical plants explodes, etcetera, etcetera.

And the first thing a hospital does in a situation like this, with multiple potential injuries, is to slam the door shut to the entire hospital. The entire hospital has to shut down, no access, no egress, except through the emergency department, and the emergency department has to be separated itself, from the outside, with a system of tents, which are usually used to decontaminate, to undress the patient, decontaminate with fresh water, and then redress the patient, and then allow the patient, who's no longer contaminated, whether it's biological, chemical or nuclear, into the hospital. But not until then.

And having run a few hospitals for a while, when we had two situations, the first thing we

did was close the doors. I locked the doors of the hospital. Otherwise, the hospital gets flooded with people who come in and contaminate the hospital, potentially contaminate the hospital.

Most hospitals are waiting for federal funds in order to underwrite this effort, and while it is an issue of first responders, the community's first responders, and the hospital, they all seem to be sitting, waiting for federal funds to come through in order to underwrite this effort. And it's understandable considering the strapped funds that most hospitals in major urban centers face.

But we agree that this is an issue in which our radiation safety people should be intimately involved, and our hospital, which is the leading trauma center in Philadelphia, the leading penetrating trauma center in Pennsylvania, does have a plan, has instituted it through radiation safety, in fact, and we have been respirator-trained as well, those of us who wish to volunteer.

But I've watched the process from a distance now, and it's quite clear to me that there will not be an adequate response, which must be a local response, until there's federal funding for it, not diverted to some other purposes, and that is a

political issue which we don't have to deal with but we do appreciate your bringing this to our attention.

I'm certain that most radiation safety officers are already aware of the issue and their need to participate, are they not?

Dr. Williamson?

MEMBER WILLIAMSON: Yes.

[Laughter]

MEMBER LIETO: I had a question.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: Does CDC provide training for hospitals, medical physicists and health physicists?

MEMBER GILLEY: Yes.

DR. ANSARI: Training for clinicians or for--

MEMBER GILLEY: Yes.

MEMBER LIETO: I know they have for clinicians. I'm talking about like the health physicist, or a hospital are, so non-physician are, so medical physicists.

MS. WASTLER: Yes. There's a REACTS course that you can take.

MEMBER LIETO: Well, REACTS is in--

MS. WASTLER: Oak Ridge, Tennessee.

DR. ANSARI: REACTS. This is for radiation emergency--

MS. WASTLER: Medical personnel.

DR. ANSARI: Yes. The training is geared for a medical type of response. They have two forms. They have two levels of training. Both of them are already medical-oriented. But the type of training I don't think REACTS, addresses this type of training we're talking about, preparing the radiation, health physics support community in the hospital, preparing it for response, how they would be--there is no such training, to my knowledge. We have identified this at CDC as a target audience.

So, in fact, if there are partners that you can identify, that we could work with to develop such training material, this is on our, actually, radar right now, and identified as a need.

MEMBER LIETO: Thank you.

CHAIRMAN MALMUD: Member of the public.

MS. ROMANELLI: I'm Gloria Romanelli, American College of Radiology. Despite the fact that I don't want to be a "me too" organization, radiologists are also a key component to educating the public, and physicists who do not happen to be RSOs are also going to be very valuable.

The ACR, AAPM, and ASTRO, several years ago, put together a disaster preparedness primer for medical professionals, that essentially deals with the key components that those individuals might have to deal with in the event of a radiological dispersal device disaster, and that document is available and we'd be happy to share it with anybody who would like a copy.

DR. ANSARI: Actually, a very well-done document and in our outreach we always reference that.

MS. ROMANELLI: Right; right.

CHAIRMAN MALMUD: Thank you for bringing that to our attention. There is a rich literature on biological, chemical and nuclear terrorism. Something worth reading, if you have the time, is Dark Winter, which was a product of the Federal Government, it must be five years ago, which was a scenario of what would happen if there were a biologic event in the United States.

And then there are other documents which are mimics of other events. They're available on the Internet. They're federal documents. I suggest that you read them while you're not around your children, because you don't want them to read this as well. It's a very upsetting document, in which the federal

officers role-play other federal officers, and demonstrated our ability to respond to a major catastrophe.

Yes, Dr. Suleiman.

MEMBER SULEIMAN: Yes. I think one resource I hate to pass without mentioning is AFRRI, the Armed Forces Radiobiology Research Institute. They actually have quite a bit of good, useful documents on their Web site. I don't have their Web site memorized, but they're in Bethesda. But they've been doing this sort of thing for years.

CHAIRMAN MALMUD: Thank you. Oh, I'm sorry. Excuse me.

MEMBER THOMADSEN: REACTS does have a course for these people, not the physicians, and they recently brought a shortened version of it to Wisconsin, where they took it to several places in Wisconsin and put it on for local medical physicists, health physicists, and persons like that. So you can arrange to have it more locally.

DR. ANSARI: While we're going over resources, one other thing I'd like to mention is the REMM Web site that Department of Health and Human Services had recently--it went online in March. It's R-E-M-M, and if you type that, if you Google that with

National Library of Medicine, then the first entry will come up, actually, on their Web site. It's Radiation Event Medical Management, R-E-M-M. It's really rich with lots and lots of information.

MS. WASTLER: A very good site.

DR. ANSARI: Sorry?

MS. WASTLER: I said it's a very good site; very informational.

DR. ANSARI: Yes. It is also downloadable, so you can actually hit download and download everything on your desk top, so you don't have to have Internet connection to use it.

I just wanted to mention that. I do want to mention one example of the kind of training and education that I'm talking about, that is not covered by any of these resources. I will give you one example.

Screening for internal contamination. The guidelines are you look at the ALI. For example, if the decision is based on this number, based on this number of patients, it will treat, for adults, anything above 5 ALI of intake. And then they're going to use the thyroid optic scanners and screen patients at this distance to basically screen them out.

People we need to talk to are these radiation physicists, medical physicists, nuclear technologists, who not only understand ALI, and they also operate those machines and can read the instructions, and knew exactly what to do, cause they've done it before.

And this is the kind of thing that is not, right now, available. This is the kind of thing that we would be happy to prepare training material, and then provide that, and so this specialized training that I was talking about is this type of information that's currently not available.

It's the kind of issues that you need the best people in the hospital to address it, would be this group. That's it.

CHAIRMAN MALMUD: Thank you, Dr. Ansari. Any other comments?

[No response]

CHAIRMAN MALMUD: If not, I guess we need to move on to the next agenda item.

MS. WASTLER: Right. While we're switching speakers, I'd like to--one of the last questions that came up before we broke was to discuss how we can basically make up some time on the schedule. During lunch, I went back and reviewed the

schedule, and the last three items, the Elekta Perfexion, the AU approval for byproduct material by Dr. Welsh, and the NMED are three--well, the first two are informational, and my recommendation is that we basically we will hold those over to the next meeting. It's not necessary that they be discussed today.

The NMED presentation is also something that I'm going to recommend that we move over until the next meeting. This was issues that were raised by Mr. Lieto, and Michelle Burgess, who is my project manager on NMED, has met and had several discussions with him, and has answered his questions, and what we were proposing to do is just share that information with the full committee.

So from the full committee's perspective it's informational. So by eliminating--or not eliminating--but postponing those three discussions to the next meeting, it will free us up and we'll be able to make up the time. So I wanted to put that forward and make sure that that was agreeable to everyone.

MR. REED: Could you restate the agenda items. I didn't hear the numbers.

MS. WASTER: Item number 17, 18. What's the matter? You can't hear? Oh, the comment from the gentleman in the audience. Sorry, Donna-Beth. I

didn't get a chance to get back to you on that; but yes.

So if that's agreeable to everyone, we'll postpone 17, 18, and 19 and move them to the next agenda, they're informational, and that will allow us time to complete 14, 15 and 16, and the closing within the allotted time.

MEMBER NAG: You know, I think something longer than that, it still wouldn't fit in.

CHAIRMAN MALMUD: We've already taken time for lunch, so--

MS. WASTLER: We've shortened the lunch hour, so I think we've gotten--

MEMBER NAG: Are we going to eliminate the break also?

MS. WASTLER: No.

CHAIRMAN MALMUD: No. It's 2:15 now, it's two hours, so that's 4:15, fifteen minutes to close. We're okay.

MS. WASTLER: Right. And I would point out that I discussed with Dr. Eggli, the timing, and he feels that the sentinel lymph node can be done in a shorter period of time. So I think those three, postponing those--you know, you never know how discussions are going to go, but I think that's a

reasonable--at least those are things we can move, and we know, because they're informational at this point. We may have to make other adjustments. So that's my proposal.

If that's all right with you, Mr. Chairman, that's what we'll do.

CHAIRMAN MALMUD: It is; thank you. You cleared this before, so we're happy.

MS. WASTLER: Okay.

CHAIRMAN MALMUD: And therefore the next item is novel radiotherapeutics with Dr. Suleiman.

MEMBER SULEIMAN: Thank you. I'll try to circle this relatively smoothly. Even though the opinions expressed are those of--they're mine, and not necessarily an official endorsement or criticism by the department, Public Health Service or FDA, I don't think I'll make any intentional effort to bypass FDA policy. It's just that we are a pretty large regulatory agency, and sometimes we have different laws, and a whole variety of different regulations, and constantly changing policy.

So I'll try to best reflect that.

This will differ, just a little bit, from the handout, but basically, this is a question that's been bothering me for the last few years.

I come from a broad background, and I've only gotten involved with some of these therapeutics in the last few years.

The therespheres are medical devices, as Donna-Beth keeps on reminding me, but they're used as radiotherapy. The Bexxar and the Zevalin are monoclonal antibodies recently approved in the last few years, by FDA, actually, by the Center For Biologics.

They go after non-Hodgkin's lymphoma. One used an imaging agent, I-131, but delivers the dose with I-131. Zevalin uses indium-111 as the imaging agent but also delivers a dose of it with yttrium.

And there's some other therapeutics that have been out there for a while, and I-131 is sort of the decades-old classic. But even talking with a number of colleagues, I said how accurate is the dosimetry, or what are these therapies used for. It's obvious that they're basically used for, radiotherapy is basically used for refractory patients or late-stage disease, and so the state of the practice in terms of the dosimetry for these products is not as good as it is for some of the other dosimetry requirements.

Very briefly, and I'll discuss this a

little bit later too, but we have a lot of confusion out there.

I'm involved with a program where we require people to report doses and activities to us, and it just fascinates us, how inconsistent people are in terms of reporting dose. Administered activity clearly is a function of the calibration accuracy, and when I think of calibration, I always think of NIST traceability.

There is accuracy at the manufacturer and there's also validation or independent verification by the user. NIST does not always involved--NIST, the National Institute of Standards of Technologies--name is thrown around a lot.

I had the opportunity, recently, to talk with some of the people at NIST, and they're involved with some, and they're clearly not involved with others. So all sources are not traceable to NIST.

Radiation-absorbed dose, as most of the people here in this room know, is very much dependent on a variety of things in terms of how much activity's administered to the subject, to the patient, the pharmacokinetics or biodistribution, not only within the body but within specific tissue, and if you're thinking of therapy, you're thinking of what's the

target volume.

Also we all deal with risk, and so that gives us a little bit of latitude, in that if we talk about diagnostics, the risk really is the probabalistic, the chance of developing a cancer many years down the line, if at all. They're considered to be relatively safe. The uncertainty in dose estimation for diagnostics are very high, clearly, less than one significant figure but acceptable in practice.

When you get into therapeutics, and I'm not really sure if I've slighted anybody here, but my perception has always been that external beam therapy probably has very, very good precision and accuracy in terms of delivering radiation-absorbed dose to a target volume. I get a sense that brachytherapy isn't far behind but I've had to defer to my colleagues to tell me how accurate I am.

But I think I lump external beam and brachytherapy together, when you talk about internal lung sealed sources or brachytherapy devices, meaning the microspheres, the doses--and I use that term loosely--delivered, are probably acceptable for the clinical indications that they've been approved for and used, but these are not first-line therapies.

They're used for patients for which other therapies have failed. They're used for palliative purposes or they're used for humanitarian purposes.

I just threw these pictures in there to make the talk a little interesting, but when you talk about internal dosimetry, you talk about the old MIRD, Medical Internal Radiation Dosimetry, and this is the model that's been around for decades, and recently, there's a lot of exciting research, I'm not going to go into that, but you're seeing much more realistic, you know, models developed.

This is some work done at the University of Florida, and they're not the only institution doing research along this line. But you're seeing much more a set of realistic models for calculating dose.

The point I want to make here is that if you look at the axial image on the left of the mathematical, the old MIRD model, and the axial image to the realistic, it's obvious that organ geometries, and whatever, would clearly impact on dose.

And this is a little bit more dramatic. Here's your mathematical liver and your mathematical stomach, and you see how different they are, in fact, from a more realistic liver and stomach.

But the point I'm making here is depending

on which mode you use, and we've got three of the Oak Ridge models, these are, I think, the Christie pediatric phantoms and these are three of the University of Florida pediatric models.

The doses can be off by orders of several factors and how these relate to reality is also, you know, highly questionable in terms of the actual patient. Obviously for therapeutic, you actually do deal with patient specificity, but I'm concerned that a lot of people, in terms of some of the nuclear medicine type applications, may be applying diagnostic methodology and not appreciating the therapeutic needs.

This is an area that is so fundamentally simple, that I'm just fascinated, why there's so much confusion out there. But when you talk about administered dose, we're talking about activity, but is it the mass dose, the pharmacologic dose, and is it radioactivity? We still have, you know, a strong body of people out there who think millicuries.

Radiation-absorbed dose, we all learned this, and it's pretty straightforward, it's really a physical quantity, a 100 ergs per gram or joule per kilogram, and equivalent dose, we've sort of looked the other way over the years, because most medical

radiation, be it gamma, x-ray, electrons, have a quality factor of what's now known as radiation weighting factor of about one. So the term rads and rems, or grays and sieverts, are used extremely interchangeably.

I'm invoking a little bit of science here but there's some real fascinating research out there that's going to change this whole concept, in that we're going to have to pay a whole lot more attention to the actual equivalent dose.

There were some papers, recently--the work by George Saguros up at Hopkins, where he's been able to demonstrate, very exquisitely, that the radiation-absorbed dose, same physical-absorbed dose, but can demonstrate a dose rate effect just to tissue.

So, clearly, for particulate for electrons, and there are some alpha emitters, that are trials in Europe, where, clearly, the equivalent dose is going to be very dramatically different than the radiation-absorbed dose.

So what I'm getting at here is if therapeutics are eventually going to develop into a first-line therapy, then the dosimetry, in terms of determining the administered activity, be it NISt traceable, or some way that you can actually

standardize this activity, and how the absorbed dose to the patient is calculated is really going to have to improve over the current state of the practice. Clearly, standard reference models are not going to be acceptable, but they're a good first step in approximating the dose.

In addition to absorbed dose, as I said, the concept of equivalent dose I believe is going to have to come into much better use, because I think it's a much more accurate descripter. I had, as I said, in preparation for this over the last two years, it was an idea that's been in my mind, I've talked to therapists, I've talked to people from all backgrounds, and I've been surprised, basically for thyroid ablation, most people will give a set administered activity.

There was a presentation last week, where the physician said we give 150 millicuries. Now most of the people at this table represent the cream, and so you're not necessarily representative of what's going out there in practice, but I have a hunch that a lot of these therapeutics, the dosimetry is questionable at best. It does what it intends to do.

Tissue modifying factors, and I think I'm going to--that term I got from Saguros and his

presentation, where he's showing dose rate effects, and clearly, how you define relative biological effectiveness will become much, much more critical for radiotherapeutics in the future.

And the area that maybe we could have more impact, or at least awareness, is that doses are not always directly and independently verified or verifiable, and manufacturers make an effort, but sometimes, in some cases, the user has to trust what they have.

So why discuss now? My perception is that the state of the practice needs improvement and I think that the success and acceptance of some of these radiolabeled medical products, either in clinical trials or in clinical practice, and the ultimate efficacy of this class of radiotherapeutics, is going to have to depend on application of better science, be it radiobiology and some of the dosimetry.

So I just raise this to the committee and if everybody thinks I'm wrong, say Orhan, we've got this under control, we can deliver dose with this accuracy. Another presentation last week at the SNM basically demonstrated that if you knew the actual dose that was being delivered to patients, it actually improved outcome.

That's not a surprise but it's been a revelation to me, that basically, with radiotherapeutics, I don't think the level of precision and accuracy and dosimetry is anywhere near comparable to what exists with external beam and brachytherapy.

And I want to thank Wes Bolch for using some of his slides for the phantoms and the Agency for paying my salary.

CHAIRMAN MALMUD: Thank you. Yes, Dr. Nag.

MEMBER NAG: DR. Suleiman, I couldn't agree with you more. There are many of these where not sufficient dosimetry work has been done yet. However, for example, if they're microsphere with the AEM, we have formed a task force. The first one was to get a clinical guideline and now we are having a task force for dosimetry. Similarly, for many of the other new modalities, more work needs to be done in the dosimetry aspect, and I fully support you.

MEMBER SULEIMAN: Let me make a statement. This is my own opinion. I think there's a real potential for a very effective product here, and I'm afraid, you know, some of these products may not even clear clinical trials if the science isn't applied to

the way these things are conducted.

MEMBER EGGLI: I think the microspheres are unique in that you have more control over the distribution and therefore you can calculate the dose. In many of these unsealed systems, the biodistribution changes from patient to patient.

The MIRD equations that can be used to calculate the dosimetry make assumptions big enough to drive a Mack truck through and the small differences in quality factor between a beta particle and a gamma ray are totally lost in the assumptions of the MIRD equations.

The other thing to note is the benefit of the dosimetry attempt, in some cases is quite small. In high dose therapies, we try to do dosimetry, at least we try to predict the maximum safe exposure that we can give the patient's bone marrow, and try to maximize the amount of radiation that gets into the tumor.

In most of the cases, particularly post-thyroidectomy, the uptake is very low, so the amount of radiation you're delivering is actually fairly low to the volume, if you look at retained radiation iodine. In many of our goals in therapeutic iodine, which I'll have to disagree and say iodine is a

primary therapy in many diseases and it is not a salvage therapy, it is the primary therapy for most thyroid disease, and it's a first-line therapy and it's been a first-line therapy for more than 50 years, and the fact that our cure rate in thyroid cancer is in excess of 95 percent, says that the therapy is quite effective.

MEMBER SULEIMAN: No; no. I consider I-131 therapy as primary.

MEMBER EGGLI: Okay. But the issue is in cases where you cannot reliable predict a biodistribution, then you have to have some kind of a dosimetry experiment, and very sophisticated models that allow you to measure the biodistribution at dosimetry, and then I can tell you, a 100 percent for sure, based on looking at whole body disappearance of radioactive iodine, that what you did at dosimetry may bear absolutely no relationship to the biodistribution that occurs when you do your therapy, and that's a huge problem in trying to apply some of these dosimetric techniques to these unsealed sources delivered internally.

CHAIRMAN MALMUD: Dr. Williamson. Then a member of the public.

MEMBER WILLIAMSON: Yes. I just wanted to

simplify one point. I agree fully, with both speakers. I think there is, in theory, in principle, you know, the possibility of great gains by improving the therapeutic ratio through dosimetry but the challenges are formidable and sometimes escape, defy solution, even in principle.

Another area of uncertainty is target volume delineation and determining the pattern of uptake within an organ and what constitutes the target you're trying to treat. This is, you know, also, in many cases, a factor of two uncertainty, if you were to look. I would also decouple, completely, the concept of effective equivalent dose, which is a radiation protection concept that I think is intended to be a predictor of carcinogenesis for every low-level exposures, from the more sophisticated radiobiological and outcome models that are needed to predict therapeutic response, and I think it's very clear from the experience in radiation therapy, that the kind and nature of model that you need is highly dependent upon the target organ, the critical tissue being irradiated, and the particular clinical end point, and that it is not useful to confuse general radiation protection concepts with the quantities needed to score more therapeutic responses.

MEMBER SULEIMAN: I didn't use effective dose. I used dose equivalent.

MEMBER WILLIAMSON: Dose equivalent. I would say don't use that either. We use, for example, biologically equivalent dose, which can be defined in maybe a very customized way for a given organ end point. But I think the radiation protection quantities aren't useful for these purposes.

CHAIRMAN MALMUD: Thank you. We have a member of the public.

MS. WARBICK: Ann Warbick Cerone, MDS Nordion.

I just want to point out that our company does touch many of the products that are on your list here. The Y90 microspheres, the Bexxar, we manufacture that, we manufacture the Y90 chloride for Zevalin, and we have touched in the past Samarium, EDTMP. Just to let you know, too, that all these isotopes are cross-calibrated directly with NIST, from our perspective, and that many times customers will ask for secondary standards, and we do provide those.

And also there's a move now for customers to request an information or fact sheet that tells them exactly what's contained in the product vial. So that's an interesting move forward.

CHAIRMAN MALMUD: Thank you.

Dr. Fisher.

MEMBER FISHER: I appreciate the talk that you've given, Orhan, and we've discussed this a little bit previously, and he makes a good point. But I would differ with Dr. Eggli, that the problem is not the MIRD equations. I serve on the MIRD committee and have done so for more than a decade. It's perhaps in the way the recommended system is applied. The greatest source, really, of error is in determining the actual activity present inside the body, in any given organ, at any point in time, and that's probably the major source of error in internal dose calculations.

From a patient's right perspective, I think it's important that we improve this area, the state of the art. An analogy might be that, if I compare it to the airline industry, we have in the airline industry pilots who know how to fly the airplane and they know where the destination is, but in this particular case, they may not know how much fuel they have on board or how much fuel is needed to get to a particular destination.

And so dosimetry really is important for knowing how much energy is imparted, and I would kind

of agree with Orhan, that there is a lot of difference in the way units are applied, just to answer the rim-absorbed dose concept, question that came up. The MIRD committee is working on a better definition for applying a quality factor with alpha particles, and I think the concept that we're moving toward is the one proposed by the NCRP for dealing with space radiation, and that's to apply a gray equivalent dose in dealing with absorbed dose from alpha particles.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: I don't disagree that there's a need for improved dosimetry and that there is a role for understanding some of the things you've brought up such as dose rate, which is flat out ignored in many of these matters right now.

But the fact is that some of the studies that have been done, understanding the limitations of the models and the ability to estimate how much activity is within a particular organ, have not documented the correlation between tumor dose and response, which was very surprising to me, that's the way it came out, and true dosimetry estimates are going to be very challenging, for the reasons we've just discussed.

I think it would be perhaps a mistake to

hold up or slow down, or not promote the use of radiopharmaceuticals or radioimmunotherapy, in particular because of a perceived concern that the dosimetry is not state of the art right now.

The fact is that radioimmunotherapy and radiopharmaceuticals, in general, are grossly underutilized, and it has nothing to do, in my opinion, with the issue of dosimetry. It has to do with the gatekeeper mentality of those who manage these patients.

And as you mention, some of these are last resort therapies, when they should be first line or be tested in first line, and the fact is that right now it's not being done, not because of dosimetry.

I would ask if medical oncologists could tell me how much adriamycin or cisplatin really got to the tumor. With the limitations of the MIRD and what we have right now, we can get a much better estimate of how much radioimmunotherapy would get to the tumor, yet it's not being utilized.

And my point might be that if anybody needs to be educated or regulated, it might be our medical oncology colleagues about the value of this modality and that it needs to be thought of earlier rather than later, because it is perhaps the most

effective treatment there is for some of these conditions.

CHAIRMAN MALMUD: Any other comments?

[No response]

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. I thank Dr. Welsh also for his insightful comments with regard to the efficacy of this therapy versus others that are currently in use.

MS. WASTLER: Dr. Malmud, I would suggest that we are in a position where we could take our break, which was originally scheduled at 2:45 and come back for the final two presentations.

CHAIRMAN MALMUD: We will, and I just would like to remind the group an that prior to taking the break, would anyone leaving early please stop by and talk to Ashley.

(A recess was taken from 2:41 p.m. to 3:00 p.m.)

(Whereupon, the foregoing matter went off the record at 2:41 p.m. and went back on the record at 3:00 p.m.)

CHAIRMAN MALMUD: Ladies and gentlemen, can we begin? Dr. Eggli is ready. Dr. Vetter sends his regards.

MEMBER EGGLI: And his passion on this

issue.

MS. WASTLER: Yes. I was informed that if Dr. Eggli doesn't make this presentation there could be dire consequences from Dr. Vetter.

CHAIRMAN MALMUD: All right.

(Off the record comments.)

CHAIRMAN MALMUD: Three of our members are actually getting their photographic I.D. badges. So we also celebrate that with them.

MS. WASTLER: A monumental occasion.

CHAIRMAN MALMUD: Yes, it means they can get through the front door without a 20 minute delay.

(Off the record comments.)

MEMBER EGGLI: Dr. Malmud, should I go ahead and start?

CHAIRMAN MALMUD: We are ready. If you would begin, we would appreciate it very much.

MEMBER EGGLI: Thank you.

CHAIRMAN MALMUD: If you would like, I can introduce you.

MEMBER EGGLI: Okay.

CHAIRMAN MALMUD: This is Dr. Eggli.

(Laughter.)

MEMBER EGGLI: I'm going to try to represent some of Dr. Vetter's passion on this issue

and the impact on the medical community. I was going to put some graphic slide pictures in my presentation, but I thought for the sensibilities of the audience I would leave them out. But I will talk about the graphic consequences of not being able to perform this procedure as we go.

We have a number of objectives here this afternoon to describe the current practice, to demonstrate the safety of the practice, to identify inconsistencies in guidance and to propose a consistent application of Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials.

Lymphoscintigraphy is a several step process. Typically, less than a millicurie of sulfur colloid either specially filtered or not is injected into a patient to identify the lymph node drainage of a tumor system. In step two, the patient is released by the nuclear medicine department per Reg. Guide 8.39 and then step three, the patient has surgery to remove either just the lymph nodes or sometimes the lymph node and the primary tumor in the same setting.

This is sort of an image of what goes on and I don't know if this will give me a -- there we go. I have a pointer here. This is one of my

favorite old gamma cameras and I don't know where Dick got the picture of this but possibly at the Smithsonian.

Yes, XRT-3000. We have radioactivity injected either subcutaneously or subareolarly in the breast shielded with a lead shield with the activity subsequently draining to an axillary lymph node. Although we inject in the order or the neighborhood of approximately 1 millicurie or less, less than one percent of that injected dose ends up in the lymph node.

And here you can see we can often define both the lymphovascular pathway and the lymph node itself and the definition of a sentinel lymph node is the first lymph node in any lymphovascular drainage pathway. The significance of analyzing the sentinel lymph node is that if it is tumor-free, that the lymph nodes upstream are also tumor-free. The point of this is to limit the magnitude of the lymph node dissection that has to be performed to adequately stage the patient's tumor. This is most commonly used in two tumors currently in breast cancer and in malignant melanoma.

So after imaging, a patient is released and, in general, based on the Regulatory Guide 8.39,

other medical procedures including surgery may be performed, and there's additional guidance provided under NRC Health Physics Position Statement No. 156 which is this whole long statement here which says "If our licensee administers a radiopharmaceutical for a licensed authorized procedure, it may conduct any number of additional procedures whether they are authorized or not provided that additional administrations are not performed for the purposes of the unauthorized procedure (although additional authorized administrations may be needed for other authorized procedures). The basis for the above is that once a dose is administered to a patient for a procedure that is authorized no additional harm from radioactive materials can result to the patient during the conduct of other medical procedures."

And if you look at other medical imaging procedures that routinely are followed by other medical procedures, myocardial perfusion imaging is often followed by angiography, angioplasty or open heart surgery. It is not uncommon that in the middle of our procedure if we see a severe perfusion abnormality that the patient goes directly to the cardiac cath lab for intervention.

Thyroid scans are often followed by

thyroidectomy. Tumor scans are followed by tumor resection and lymphoscintigraphy is followed by lymphadenectomy. This can be done in a variety of settings. It came be hospital/same hospital, hospital/different hospital, outpatient clinic/hospital and mobile imaging center/hospital. The bottom line is there is sort of a disconnect between localization of the sentinel node and the subsequent surgery that removes it.

And the people who are exposed are typically the operating team and the pathologist, the surgeons and the pathologist and if you look at some data on the exposures and there's not a lot in the literature and when you see these "less thans" these less thans are the lower limits of the detection systems in play, so that when we say less than 1.6 mR or less than less than 2.2 mR that was the lower limit of the detection system and so that a dose less than that could be in the order of magnitude of Morton's study where they were actually able to detect fairly low levels and get 0.2 millirem or 0.25 millirem. So that the radiation exposures to the other personnel are really quite small.

The new NRC guidance from March, from the quarterly newsletter in March of 2006, states that

"Surgical removal of radioactive tissue and its biopsy constitute the medical use of byproduct material in imaging and localization studies and must be performed at a licensed facility under the supervision of an authorized user."

The consequences of the new guidance are fairly significant particularly for rural medicine outside of major metropolitan areas. Local nuclear medicine service now can no longer provide lymphoscintigraphy if the follow-up surgery is planned at a hospital that is not licensed to handle the radioactive material. And now you ask "So why would anybody use a mobile nuclear medicine imaging service?" It's probably because they are very small volume and, in fact, the hospital doesn't have a license. So these mobile imaging services are the only access to these procedures that these patients have.

And then we have the problem of money. You know, "Money is the root of all evil" and certainly the root of all insurance. A lot of insurance requires that patients have their procedures done in-network and if the in-network means a hospital that does not have a license, the patient will then have to be subjected to a radical lymphadenectomy

which I'm going to talk about and which I did not bring pictures of because of the sensibilities of the audience seeing very swollen extremities with surgical wounds that won't heal because the lymph can't drain from the extremities.

There is significantly increased patient morbidity if image guided sentinel node biopsy cannot be performed and a formal axillary or inguinal lymph node dissection has to be performed and let me explain to you what a formal dissection is. That is the effort to remove every single lymph node in that basin and as a result, the lymphatic fluid does not drain from that extremity. The wound may not heal. If it heals, the patient has a problem with extremities swelling for the rest of their lives. Every time they have an injury to the extremity, they run the risk of infection and they wear these both expensive and uncomfortable garments that try to squeeze the lymphatic fluid out of the extremity back into the body without the benefit of a lymphatic drainage pathway.

In addition, the cost of the operative procedure, the operative risk and the recovery time are far greater for a formal lymphadenectomy which keeps the patient in the hospital two to three days as

opposed to a sentinel node biopsy where the patient leaves the hospital on a same day basis. And again, the persistent lymphadema is a very difficult to manage medical problem that is unnecessary to have to manage and what it does is it subjects these patients who do not have access to sentinel node localization and image guided biopsy to a substandard care of medical practice. So the regulation is now condemning these patients to substandard care.

Hospitals not licensed to handle radioactive materials then would either have to purchase a license and then contract for services with an authorized user, an RSO, which again unnecessarily increases the cost of delivery of health care. This guidance is inconsistent with Regulatory Guide 8.39 which allows the release of patients that contain less than 150 millicuries of technetium and directly contradicts the Health Physics Position Statement No. 156.

So the recommendation is that to facilitate best practices of medicine and put the needs of the patient first, lymphoscintigraphy should be allowed. The patient should be released unconditionally. The surgery of these released patients at hospitals that do not contain materials

licenses should be allowed.

However, it is reasonable to require hospital, clinics or mobile services to education applicable surgical and pathological personnel at the unlicensed hospital. I don't know if the article was distributed, but there were recommendations for handling radioactive specimens obtained by sentinel lymphadenectomy published by the Surgical Pathology Committee of the American College of Pathologists and the Association of Anatomic and Surgical Pathology Directors in the year 2000, and I have a copy of that article with me. I can provide the reference if we didn't distribute that. And then I promised I would take less than 15 minutes. Have I done that, Sandi?

MS. WASTLER: Yes, you have.

MEMBER EGGLI: Hot dog.

MS. WASTLER: Fourteen minutes.

MEMBER EGGLI: Any questions from the audience for me?

MS. WASTLER: Boy, talk about a person on a mission. Very good.

I would ask though that one thing that we were going to do. Donna-Beth is going to talk about the basis for our position, and so it might be good or I would suggest that it might be good for Donna-Beth

to give her presentation and then open up the entire discussion.

CHAIRMAN MALMUD: Sounds good.

(Off the record comments.)

MS. WASTLER: They have the slides. Why don't we go ahead just rather than to hold up because of the technical difficulty. Let's talk from the handouts and then we'll see about getting the technical difficulty fixed.

DR. HOWE: Okay. We had a technical assistance request from one of our regions. We had a licensee that requested the surgical part of sentinel lymph node biopsy to be done at one of their hospitals that was not licensed. We evaluated the request, and essentially we're in agreement with Dr. Eggli's presentation that technetium is used with the localization and surgical removal of radioactive tissue, but our position is that the technetium that is used for the localization and surgical removal of tissue is not exempt from the requirements for a license, that it is regulated right now under 10 CFR 35.200 and that the surgeon using the radioactive materials in the patients to localize the radioactive sentinel nodes. So we considered the surgical removal to be completion of the procedure of the original

image -- of the imaging and localization procedure.

And the material, that it's a medical use for the byproduct material and it needs to be performed in a licensed medical use facility under the supervision of an authorized user and in an operating radiation safety program under the supervision of radiation safety officer. What we have done in a number of cases in various regions is that we have licensed the surgical suite area which may be in a different facility as a satellite facility to a larger licensee that provides the nuclear medicine.

MS. WASTLER: Go ahead, Donna-Beth.

DR. HOWE: Okay. The third slide essentially shows that there is the injection of the radioactive material. There are several components versus the injection of the radioactive material. The second is the biopsy and surgical removal of the radioactive lymph node. The third is the pathology laboratory and the fourth would be the disposal of the radioactive material.

If you look at the injection part, the injection is performed under the supervision of an authorized user. The authorized user in this case, this is -- I have a 920 on there because I picked it up and didn't edit it quite right. The authorized

user meets the training and experience requirements of 35.290 because it is imaging and localization.

We believe the surgical part of the biopsy is the medical use of byproduct material. Currently, we consider that to be completion of the procedure. It would be covered by 35.200, Imaging and Localization. I'll talk to you later about another possibility.

The biopsy materials are radioactive material whether they are licensed radioactive -- and this is assuming that the material goes to a pathology department that is not licensed. If the material contains 100 microcuries or less of technetium-99m it can go to an unlicensed pathology lab and it can travel under an exempt quantities provision in 10 CFR 30.18. And the pathology lab is exempt from licensing. If the tissue, however, contains -- so there is a need to assure that the material in the tissue contains less than 100 microcuries of technetium.

If the tissue contains over 100 microcuries of technetium-99m, then it can only be transferred to another licensee. In this case, the pathology laboratory needs to be licensed and the licensee needs to ship the radioactive material in

accordance with DOT requirements and verify that the recipient is authorized to receive the material. The remaining material in lymphoscintigraphy needs to be disposed of radioactive waste. We think the preferred method of disposal is decay in storage so that once it is held, it can be thrown away as regular waste.

Okay. When we answered the TAR, we were asked, "Can we do this in an unlicensed facility?" We said, "No." We offered them a mechanism that we have used before to license the facility as a satellite. The next question is "Can the surgeon become an authorized user" and, "If so, would the surgeon need to meet the requirements of 35.290?" If we break the imaging and localization procedure into its two component parts, it's very clear that the injection part of the procedure would come under the nuclear medicine physician that meets the requirements in 290. When you look at the surgical requirements, it's pretty easy to see that the surgical requirements from a radiation safety point of view are not as extensive as the overall training and education mode a 200 physician would need.

So we could handle a surgeon becoming an authorized user under 35.1000. We would probably put it under 35.1000 because our position would be that he

did not require the full 700 hours of training and experience and all the imaging and localization for the 290 but would require some lesser amount of training and in tasks that were specific to his use of the material, his identification of the tissue as either being radioactive or exempt from licensing to go to a pathology lab.

And so far, we haven't received another request for that, but I think that's the position that we would take is that we can license the surgical suite independently under 35.1000.

CHAIRMAN MALMUD: Thank you, Dr. Howe. Dr. Nag.

MEMBER NAG: I am wondering if the two components can be separated because if the injection was done, for example, in a mobile facility or in a different hospital and the surgical portion of the removal was done in a different hospital, that can be handled in a separate manner from one where the injection and the surgical are done in the same place because the risk of doing the injection and so forth. So that component I think has to be under some type of licensing, you know, 219 and so forth.

However, I think to extend and say because that tissue is radioactive and it is in a different

hospital because it is radioactive, although very low amount, now you want to apply all the rules for radioactivity, I think, is extending far beyond NRC law. For example, we do radiation implants, permanent implants. Those patients once in a while, some of them may die and then you have to do an autopsy and they are not subjected although the amount of radiation is far higher.

So I think you are extending the role of NRC beyond what is required, at least in my opinion. I would like to separate the two, the injection and the surgical part. So if the injection is done in a center that has all the licensing information to do the injection, that could be done and then the surgery could be done in a place that doesn't have a license.

DR. HOWE: Dr. Nag, that's almost the proposal we have and that is we would consider licensing the surgical area separately from the injection, but it is still license material and needs to come under license. There is an assumption and the licensee made the same assumption that 10 CFR 35.75 sets a limit in which NRC considers the medical use to be a licensed activity. But, in fact, you're still using this licensed material for its one intent, imaging and localization, and you have not completed

the procedure. It's not that different from many of our other procedures where you have bone scans where you release patients because you don't have to hospitalize them. But you expect them to come back to the licensee for the completion of the procedure. In this case, you're working on completion of the procedure.

We also looked very carefully at 35.75 and determined that the assumptions that you're basing your release in 35.75 are that the patient will resume normal activities and with some restriction on close contact to others and that the radioactive material and the radiation sources contained within the subject are released primarily to the sanitary sewer through normal biological processes. We did a careful look at our regulation and our indications for use and there is no indication that the regulation or the regulatory history in 35.75 was intended to encompass surgical excision of radioactive material that was implanted for that particular surgical excision and so it is a completion of the procedure and 35.75 is not the applicable part of the regulation.

MEMBER NAG: I think that is why we keep on saying that there should be some judgment exercise about how much do you want to stretch a rule versus

what the relative medical importance, what is the radiological risk. Because if the risk is that therefore that patient will now undergo a radical surgery of the node, I think that's far worse than whatever risk you may place by having 100 millicuries of radioactive material.

MEMBER EGGLI: Microcurie.

MEMBER NAG: Microcurie. I'm sorry.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: I have to disagree with staff's position on the procedure is not complete. The procedure is complete when the patient leaves my department. I have taken images. I have made a mark on the skin which localizes the node and from that point of view, this procedure is complete. The Standard Medical Terminology Committee defines these as separate and distinct medical procedures. So NRC is changing that definition as well.

And then what we're talking about is for a couple of microcuries of radioactivity, you are going to subject patients to a very morbid procedure or deny them health care which is now the standard of care over a couple of microcuries of technetium, and I think that's a very difficult position to support, and I would like to see if our patient advocate would

have a comment on that.

DR. HOWE: We are not denying the --

MEMBER EGGLI: Yes, you are because if the insurance company requires the procedure done in-network to pay for it and the hospital is unlicensed, you are de facto denying the patient standard of care. There is no other way to interpret that.

CHAIRMAN MALMUD: If we may get to the heart of the matter. Why can't the two procedures be considered separate procedures? It's unclear to me why they are not separate procedures. When we do thyroid imaging or parathyroid imaging with specific radiopharmaceuticals, it's with the intention of removing the tumor when it's found or the organ and the patient may have more than a few microcuries of the isotope on board at the time of the surgery. These are two separate procedures done by two separate departments and often not even done in the same hospital.

Why is it that we see the lymph node in the breast as part of a procedure when the parathyroid in the neck which is imaged with technetium sestamibi is not seen as part of the procedure? Isn't there a precedent already? What I'm trying to do is see if there's a precedent within the NRC practices which

would encompass this and the two that I can think of readily are thyroid imaging and parathyroid imaging when the adenoma takes up the technetium-99m sestamibi and is removed surgically.

DR. HOWE: It's also our understanding that you use the radioactivity that's in the lymph node to identify the sentinel lymph node with probes and you're measuring the location to ensure that the surgeon is removing the right lymph node with the radioactivity.

CHAIRMAN MALMUD: So do we with the parathyroid.

DR. HOWE: And you're using radiation.

CHAIRMAN MALMUD: We actually would do that with the parathyroid also. The surgeon is given a probe to identify it intra-operatively. So it's not unique. I'm trying to help us, all of us.

MEMBER EGGLI: It's the fortuitous consequence of an imaging procedure.

CHAIRMAN MALMUD: There may be a precedent that exists clinically that the NRC could see as an example of how this particular study could be encompassed in the same kind of thinking and I think parathyroids in particular are a better analogy even than thyroid because in the case of thyroid, the tumor

itself, the initial tumor, is cold, whereas with parathyroid the adenoma is lighting up.

So the precedent does exist if we can somehow say we are already doing something like this and this is another example of it. It is true that the woman would be subjected to a more radical surgical procedure and a worse outcome without this procedure than with it. So in a sense, we are part of a system that would be denying the advantage of that care and it's also true that the insurance companies now direct the patients to specific institutions, some of which may not be licensed to do the nuclear medicine procedure preoperatively. But the removal of a couple of microcuries of technetium-99m is really a very minimal thing and one for which there is a precedent.

DR. HOWE: Now when you do your parathyroid removal, do you send your patients to another facility?

CHAIRMAN MALMUD: No, we're at a university hospital. We do the whole thing internally.

MEMBER EGGLI: But the answer to that -- is the answer to that could be yes?

CHAIRMAN MALMUD: The answer --

DR. HOWE: How often is it yes?

MEMBER EGGLI: I'm not here to talk about that today, but the answer could be yes.

CHAIRMAN MALMUD: There is no reason why it couldn't be, why the answer couldn't be yes and it may be that the patient's surgeon is at an institution that doesn't have the nuclear medicine facility available to do this and therefore it's done elsewhere and then the surgery is done in the smaller institution.

I'm sure there must be somewhere examples of this that might be useful in figuring out how we overcome what appears to be a regulatory impasse.

DR. HOWE: And then when they pull the radioactive parathyroid tissue out, do they send it off to pathology or --

CHAIRMAN MALMUD: It goes to pathology.

DR. HOWE: -- or does the fact that it is already radioactive is enough that --

CHAIRMAN MALMUD: The amount of radioactivity is quite trivial. I mean we handle more radioactivity than that on a daily basis in patients who undergo technetium-99m imaging for bone scans and so on and at the same time, they may have a blood specimen drawn that day and they have technetium-99m

in that blood tube that's being sent off to the lab to be processed for chemistry. There is technetium floating around the place all day long.

DR. HOWE: I understand that.

CHAIRMAN MALMUD: Not to mention urinary excretion of radioisotopes which are a sore subject for all of us in terms of the patients who may be incontinent or catheters that are leaking. Dr. Fisher.

MEMBER FISHER: Thank you. It has been my perspective that in most cases the Nuclear Regulatory Commission tries to come up with rulemaking and decisions that are in the best interest of society and the best interest of not only radiation protection but also in the best interest of the patient in terms of clinical benefit. Otherwise, you would be outlawing all radionuclide procedures and all uses of radiation. Clearly, there's a medical benefit.

My concern here is that the NRC may be looking at the regulations a little bit too closely in terms of the letter of the law while ignoring the benefit to the patient in use of what really is a very trivial amount of a very safe radionuclide. Among all radionuclides used in medicine, I can't think of one that is perhaps more safe and effective than

technetium-99m in terms of what is the risk of a misadministration or a risk of a spill. It's really a very good choice.

And I would urge the Nuclear Regulatory Commission to very seriously consider the proposal from Dr. Eggli and the rest of this advisory committee that there are cases where patient benefit may be more important than letter of current law, and the NRC has the ability to change its regulations to take these important factors into account so that the benefits of a treatment outweigh other considerations. So I would very much support this.

CHAIRMAN MALMUD: Thank you. Ms. Schwarz.

MEMBER SCHWARZ: And I wanted just to add the fact of being a woman on this committee and I think that I'm speaking for women. This is certainly something that should be considered. It's a very benign procedure and the people who would benefit typically would be a very small community or an insurance issue and maybe possibly poorer people that couldn't afford to go to a different institution that could accommodate the type of procedure. So again, we have to think that it's a limited number of people that will be in this position but certainly would be tremendously benefitted by the availability of being

able without regulatory constraint to actually obtain this procedure.

CHAIRMAN MALMUD: Thank you. Dr. --

MEMBER WILLIAMSON: Yes, I would just say that my own immediate family has been a beneficiary of the fact that this procedure has not been policed in this intrusive way as you propose, that in case in point the patient had the outpatient administration -- nuclear medicine imaging done in one outpatient facility and had the surgery done in a different outpatient facility and would not have been able to have the choice of surgeon had this rule been imposed in this way.

So I think I, too, would urge the staff to consider the merits of Dr. Eggli's procedure. Perhaps if you can't make it fit the letter of the law what you should do is put it in 35.1000 so that you specifically can relieve the surgeon from the burden of having to become a licensed personage and the surgical facility from having to become a licensee or satellite licensee.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: I am kind of opposed to adding things to 1000. It just seems like we're setting up a bureaucracy that's really totally

unnecessary.

It seems like one driving philosophy that is being missed here is ALARA. This is totally -- what's being recommended here is not reasonable and there's not any health or safety issue that this whole additional mechanism that's being proposed here is addressing. What we're doing is we're setting up a whole set of rules and requirements on surgeons because he takes a node out and puts it in a tube and hands it to a pathology tech just so that this procedure can be done.

At our health system, we're actually kind of affected by this directly. The issue that goes on is not so much the surgeons. It's that in larger systems pathology services are centralized for economic reasons and so forth. So where the node is removed has to be sent, maybe sent, via -- is taken out in a hospital that's not licensed and sent to another pathology area where it's analyzed. We had to set up a whole mechanism for transport just simply because the fact that we are putting radioactive materials on public roads.

But the point is that there's not any health or safety -- especially in an OR environment. The biohazard environment of that surgical procedure

so far exceeds the radiological it's not funny and so what we're doing is we're creating a whole set of requirements where again I think keeping things as low as reasonably achievable is kind of being lost in this procedure.

And the other thing that I wanted to point out was a follow-up to Sally's statement. This is going to increase. Sentinel node procedures are now or have within the past year or two become the standard of care in the management of patients with breast cancer. So this is going to become a greater procedure or a procedure of greater need in rural areas than it is even now and I think setting up something like this just -- you are going to prevent patients because surgeons will not go through this process. Okay. They're just not going to become authorized users or ask to be named on a license because they're doing surgery in Hospital X and Hospital Y and so forth and you're going to set up a whole system of license amendments just because of a couple of microcuries of technetium, and it just doesn't seem reasonable.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes.

DR. HOWE: I think there's one thing the

ACMUI needs to recognize, and that is that NRC doesn't have a lower threshold of radioactivity which you can use byproduct material that doesn't require a license unless it comes under a very narrow set of regulations and 30.14 through 30.21 and this is not in that category right now. We don't have -- at one point, we had something that the NRC had proposed. It was called below regulatory concern and that went out on a Friday and died on a Monday.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: I have been very much impressed with the Commissioners that whenever the ACMUI has met directly with the Commissioners, the Commissioners always say that the overriding factor should be the access to care, the availability of good care for the patients and therefore, if something is said just purely because of a regulatory issue but not a safety issue, those should be overridden for the overall benefit. So I would definitely bring this up directly with the Commissioners.

MS. WASTLER: I don't think we even need to go to that level.

CHAIRMAN MALMUD: If I may --

MS. WASTLER: What we're here for is to raise an issue. When we did this, I mean, it wasn't

with the intended consequence of keeping patients from getting treated. I mean, this was an unintended consequence, and we're here to discuss it, and we will go back and relook at the situation because that's not what we intended.

CHAIRMAN MALMUD: Yes, and I fully agree with your statement and that's why I made the point that I did earlier. It's been my experience that when these kinds of issues arise that staff, that NRC staff, tries to reinterpret within the law the regulations to allow for this kind of humane practice to exist in various situations and there has been flexibility and that's why I think that if you and the staff look, you'll see that there is precedent and there are many examples we can cite of organs that are imaged and then promptly removed which have far more radioactivity in them and are then processed. Besides blood, there are other organs that we look at. There's a kidney scanning for tumor and then a nephrectomy is performed promptly while the kidney still has some residual activity in it I'm sure and urine and blood.

MEMBER NAG: Liver scans.

CHAIRMAN MALMUD: Liver scans, generally the liver remains in, but there are some situations in

which it may not.

Biopsies, malignant bone lesions which are promptly operated on. Fractures which are operated on. They are picked up because the other imaging techniques don't detect them and the nuclear medicine technique does. Then they go to surgery. They're still slightly radioactive. There isn't that much activity there. So I think that there is precedent in the practices over the past decades that would allow some flexibility if your staff is given time to look for them.

MS. WASTLER: And I think -- I would just say for my benefit I don't recall -- I mean, the consequences that Dr. Eggli brought up with regards to the mobile nuclear option and the insurance restriction option were not issues that we were aware of. At least, I personally wasn't aware of and I don't think my staff was. So these are additional pieces of information that I think we need to consider and see what we can do with regards to --

MEMBER WILLIAMSON: Also choice of practitioner and facility. There are patients' wishes to be honored here and I think there is no safety issue at stake.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: How does this fit into the risk-based paradigm because clearly we're not dealing with a high level of risk here? So how did this get into the --

DR. HOWE: We regulate many things with very, very low risk. Our level of when we regulate does not come into play with risk but the amount of regulation that we apply to things we try to apply in a risk-based manner.

We do have persons that are exempt from licensing. We have very specific uses of material and types of material that can be used by persons exempt from licensing. Those are our lowest risks and we go through extensive review of that for setting that up and then we have general licenses which don't require much more regulation. Then we have specific licenses. But if you also look at Part 35, you'll see that we do have regulations in place for 35.100 uses which are very low risk.

MEMBER SULEIMAN: My concern in this case would -- how much radiation could the surgeon received.

DR. HOWE: The estimates we have, it's pretty low, but we don't have a regulation that says if you get below a 100 millirem in a year then you're

not regulated. We --

MS. WASTLER: You did some calculations.

DR. HOWE: We did some calculations.

MEMBER. SULEIMAN: Clearly, that's an indicator of risk, obviously, if you've been picking up very little quantities.

DR. HOWE: We have policy that was below regulatory concern and this was a number of years ago and that was risk-based and that did not last more than a few days.

CHAIRMAN MALMUD: I think Dr. Zelac was next and then we'll --

DR. ZELAC: I think we're moving in a direction for the entire issue, but there is one aspect of it that I would like to bring up for possible further consideration and that's the mention that Dr. Eggli made of specific coding require hospital, clinic or mobile license to perform lymphoscintigraphy to educate applicable surgical and pathological personnel at unlicensed hospital, etc. Now I think for us that becomes an issue to try to accomplish the objective of having people in these facilities, handling these materials, that have an awareness of what it is that they're doing. Because I know that at least in some facilities, there is

apprehension and concern because it's radioactive. It doesn't matter the amount. It's radioactive. I'm concerned working in the facility, handling these specimens. These people need to be educated, but I'm not sure that this suggestion is the way that it can be accomplished.

CHAIRMAN MALMUD: Dr. Welsh and then Dr. Nag.

MEMBER WELSH: I have a quick comment from the perspective of the clinician who practices in the rural areas and the practice, the standard of care, two years ago was not inclusive of sentinel lymph node biopsy because the surgeons were not trained in that. So when a patient who presented with a breast tumor and had a lumpectomy was now given the option of axillary lymph node dissection which we heard from Dr. Eggli carries significant morbidity versus radiation therapy to the axilla empirically because that patient might have a 20 percent risk of having a node involved, it must be kept in mind that axillary radiation carries significant morbidity, too. So the patient was initially told from the surgeon "I don't know how to do a sentinel lymph node biopsy. So you won't have that, but you won't have an axillary lymph node dissection because that's a very morbid procedure

and your risk of having a node that's involved is small."

But when I met with the patient and calculated the risk, it might be about 20 percent and the patient elected to go ahead with axillary lymph node radiation. This could simply have been avoided by a sentinel lymph node biopsy and it needs to be kept in mind that the alternative to axillary dissection which is radiation therapy to the axilla carries significant morbidity itself, potential morbidity, and sentinel lymph node biopsy is a medically simply way of avoiding both of those morbid procedures in appropriate clinical context.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: And again if you go back to the slide that references the little bit of data on exposure to surgeons and pathologists, virtually with the exception of Morton who measured very low, they are all off the bottom end of the detection system. So the radiation exposure the individual surgeon received or the individual pathologist received is somewhere off the bottom end of our ability to measure it. These are again very, very low exposures.

I understand what Dr. Howe says that in regulatory space there is no lower limit. But again,

if you look at risk versus benefit, there is virtually no risk and the benefit is staggeringly high.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. May I offer a motion?

CHAIRMAN MALMUD: Certainly.

MEMBER NAG: I'll make a motion that for sentinel lymph node biopsies the injection of the radioactive material be done under the supervision or under someone with certified 290. However, the subsequent surgical procedure does not need to be performed under any other licensing procedure. I mean the wording can be manipulated, but the idea is that the injection has to be under 290 but then not the removal. Up to after the injection and the imaging has been done, that's considered the end of the procedure.

CHAIRMAN MALMUD: That's a motion.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER NAG: I mean you can modify the second -- reword as needed, but that's the --

CHAIRMAN MALMUD: The motion is that the injection for a sentinel lymph node biopsy is a procedure unto itself. The surgical removal of that

node later on is a separate procedure which is not a part of the nuclear medicine procedure and should not be regulated. That's your suggestion.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: And do you want to add a correlate if there are existing precedence for this in other organs and other tissues?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: That is the motion. Is that acceptable?

MEMBER EGGLI: I second it. I was the second. I accept that.

CHAIRMAN MALMUD: Any discussion of that motion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: So it's unanimous.

DR. HOWE: Thank you very much.

CHAIRMAN MALMUD: So that's a recommendation to decouple the two. The surgical removal is no more significant than the surgical removal of any other tissue specimen in a body that

has had any kind of diagnostic imaging, nuclear medicine procedure done within a day in advance.

MS. WASTLER: Thank you.

CHAIRMAN MALMUD: And therefore, there's precedent for it. I'm trying to help you out with the precedents since I know that's the basis on which you --

MS. WASTLER: As we look into this more, we may be contacting you to try to get some additional information on similar precedent.

CHAIRMAN MALMUD: Sure. Okay. Great. Thank you very much. The next item on the agenda is?

MR. METZGER: So far 100 percent of them are able to do it.

MS. WASTLER: Dr. Nag.

(Off the record comments.)

MEMBER NAG: I have the slides submitted in hard copy; you may want them. Basically disclosure that I have obtained slides and information about some of these new emerging technologies from Isoray, Xoft and Neovista, but I do not have any financial interest in them.

The things we'll talk about are cesium-131, the electronic brachytherapy and a strontium eye applicator. Now for low energy nuclides like a

cesium-131 it's not new. The idea of having low energy soft x-ray, short half-life isotopes have been there even before I started with my residency because they have a limited depth of penetration, minimal damage, ease of shielding, and at that time in 1958, three isotopes were talked about. One was iodine-125, palladium-103, and cesium-131.

Although from a radiobiological view point cesium-131 as I'll show you later is probably the better one, the one that was marketed first was I-125 because it was easy or had a lower cost and easy to manufacture. This was done by Donald Lawrence and then a few years later, Theragenics produced the palladium-103 seed that was actually approved in 1987.

What are some of the problems with these seeds? I-125 had a relatively long half-life of 60 days. So what's the big deal? Two problems. One is that if you have a long half-life in a permanent implant, the initial dose rate is low. If the initial dose rate is low and you have a fast or rapidly proliferating tumor, you may be ineffective. So I-125 would be effective in a slow-growing tumor like most prostate cancer. However, if you have a rapidly growing tumor, it may be ineffective and because the half-life is 60 days, you have to have radiation

protection to some extent for ten half-lives.

But palladium-103 has a much faster or much shorter half-life, therefore, has a higher dose rate so it's more effective theoretically. However, the energy is much lower, 21KeV, which means that if the seeds are very far apart, more than 1.5 cm apart, you have may have cold spots in between.

A chemist at the Pacific Northwest National Lab, Lane Bray, had the process of economically separating and purifying cesium-131 in 1998 and therefore founded with Don Lawrence the IsoRay Medical and the seeds were approved in 2003. From the outside, the cesium -- I'm sorry, cesium-137, the cesium-131 not 137, the cesium-131 is identical with iodine. So from the outside, it's the same. The same equipment can be used and so forth.

So what are the -- where are they used? Like other iodine, it's used mainly for permanent prostate implants. We've had about 500,000 cases worldwide. You can use it for permanent implant at other sites, for example, breast. Apparently very few people are using permanent implant in the breast, but you could. You could also use it as a removable implant for eye plaques or even in breast implants.

But what are the differences between these

three? Well, cesium-131 has the shortest half-life, nine days, as opposed to 17 or 60 days. Therefore, it has the higher initial dose rate and most of the dose or 90 percent is delivered within one month as opposed to two months or ten months for pallidum and iodine.

The other thing is biological effectiveness. For most tumors, you need a half-life for a permanent implant, a half-life of four to 17 days for the optimum half-life. If a tumor is fast repopulating or highly proliferating, you need something with an even shorter half-life. So from a theoretical standpoint, cesium-131 would probably be most efficacious of the three for the fast repopulation tumor.

And because of the short half-life, most of the radiation is delivered in one month. So you don't have to worry about radiation safety after that period. There are a couple of other things because of the short half-life. The tumor, there are two things you have to think about. (1) If you are implanting in a tumor as opposed to prostate which is a normal organ, if you are implanting an organ that is principally made of tumor, the tumor may regress very, very quickly which means the seeds can come closer together very rapidly and that may even deliver a

higher dose than what you're projecting.

In the prostate, it may be the reverse because in the prostate when you implant, there are very few tumor cells, it's mainly a normal organ and initially prostate expands because of edema and then slowly comes down and if you are giving the radiation very fast, you may be giving most of the radiation before the prostate has a chance to resolve the edema. These are things you have to keep in mind.

The other thing you have to keep in mind is because the half-life is so short, you have to use it within two or three days of delivery as opposed to iodine where if you cancel the case, you can reschedule it for next week. A slight difference. Of the three the cesium-131 is having very little anisotropy. Anisotropy means if you can see the dipping in, there's relatively little dipping in on cesium-131 seeds when compared to palladium or iodine. So technically or theoretically, it's much better. However, from a practical viewpoint or pharmaceutical viewpoint, it really may not make much difference because there are so many seeds that the anisotropy cancels each other.

Now the energy, the energy of cesium is higher than that of palladium and very similar to that

of iodine and therefore the inter-seed spacing may not matter too much. So even if you are more than 1.5 cm apart, you may not have a cold spot.

Now history of what the current state is. As of October 2004, that's about three years ago, the first patient was treated with cesium-131. About 1200 patients have been treated so far in about 45 centers and perhaps another 25 centers are about to use I-125. So we may have about 60 centers by the end of the year.

What are the concentrations from a radiation safety and regulatory standpoint? Size-wise it's similar to I-125 or palladium, similar in energy to iodine. The only difference is that you need a shorter time for storage until decay and therefore there may not be major differences in terms of the regulatory standpoint.

The clinical future, I think, radiobiologically it's a better isotope than iodine or palladium from a radiobiology standpoint, however, we don't know if this radiobiological advantage would translate to better clinical outcomes. This remains to be seen in a few years. Practically, the shorter half-life may present a problem if a case is postponed. However, you have to remember that

nowadays we order the seed per patient. So it's not that we order a lot of seeds and keep them on-hand. So it may or may not present too much of a problem.

I think -- should I go onto all the treatments and cases and then have questions?

CHAIRMAN MALMUD: Yes.

MEMBER NAG: Okay. The next one is the new technology called Xoft Axxent Electronic Brachytherapy System. Now what is brachytherapy? We are coming to the heart of a definition. Brachytherapy, the strict definition, is the treatment of neoplastic disease by radioisotope placed inside or close to tumors because brachy means close distance; therapy means treatment. That's the definition currently. However, if you just use the words "brachy" and "therapy," it means treatment from a close distance and therefore, in the broad definition of brachytherapy you can have treatment of disease by sources, not necessarily radioactive, by sources placed inside or close to the tumor. If we use the broad definition of brachytherapy, what I'm going to present to you is brachytherapy.

Now what is an ideal brachytherapy system? Well, you want something that will penetrate to the desired depth ideally and then -- very rapidly. High

energy gamma will be like that. Low energy gamma drops off very rapidly and a beta penetrates and then drops very rapidly but may not penetrate enough in certain circumstances.

What about dose rate? Well, you know the cobalt has a long half-life, five years. So the dose rate is almost constant, dropping very slowly. Iridium, then iodine, palladium and cesium drops off very fast. But the ideal would be if when you are implanting it it's not radioactive. Then suddenly it becomes radioactive and then it gives a lot of radiation and then when you want it it drops automatically to zero. That is the ideal radioisotope. So far, we haven't found any ideal radioisotope.

Let's see what this Xoft system is. The Xoft system includes an x-ray emission controller, some applicator and a disposable x-ray source. The x-ray controller delivers the power, the electricity, and then it can spread the source to wherever you want. So it can pull itback and forth and then you use the output from conventional brachytherapy planting systems to do your planting.

So what is the source? The sources is an x-ray source. But rather than a big x-ray source,

it's a very miniature x-ray source as seen, this is my finger, and it's much smaller than my finger and therefore it can go into a narrow needle. So it's 2.2 mm in diameter and it's disposable and it can give up to 50 kV x-ray. So it's not the radioactive source, yet the designed is such that it will closely mimic a -- iridium-192 high dose rate source. The output is 0.6 Gy/min and the treatment time will therefore also be comparable to iridium-192 high dose rate.

Currently as the system is being used, it is only being used with the -- so right now, it's very similar to using a mammosite balloon except it has the integral drain and the balloon is radiolucent. So you have better visibility.

You have a flexishield. So you can put a temporary shielding over the tumor area and you can -- everything is disposable at the end of treatment.

I'm not going to go into details of spectral characteristics, but basically you are having x-ray emitted with decay very similar to iridium-192 and radiobiological effectiveness or RBE is similar to that for iodine.

Here is a very primitive dosimetry of a source from a radiochromic film during -- the dose is

very high at the center and rapidly goes down as you go further from 100 percent here to 50 percent within a couple of -- I think a centimeter and a half or so.

Now how do you do it? It's done very similar to those who know mammosite, very similar to the way you do mammosite. The surgeon will put the applicator or the mammosite balloon into the tumor. The only difference is instead of attaching the HDR catheter, you attach the Xoft or the Axxent catheter. You localize the balloon with ultrasound or x-ray and then you treat.

The treatment times and the fractionation are exactly the same as that for HDR. Right now, you're giving about 34 Gy in ten fractions, similar to that for breast and right now, it is FDA approved for treatment of mammosite of breast. So the treatment is similar to HDR. The source will step like HDR source. It has a stepping source of 5 to 10 drill positions and takes about 5 to 10 minutes.

CHAIRMAN MALMUD: What type of anesthetic is used?

MEMBER NAG: You can do it in -- it's the same as mammosite. Some places do it under local. Others will do under general. I mean that part doesn't changed at all.

The treatment control is again very similar to the HDR. It shows where the source is and how many seconds is left and so on.

What are some of the radiation exposures? It doesn't require a shielded room because of the low energy x-ray. You can have some type of shielding. At a typical operator's location, it's getting only 15 mR without the shielding and when you are applying for the license, you have to provide what your exposure rate is.

Quality control. Again, they really have not been totally developed, but they are in the process of being developed using AAPM brachytherapy guidelines.

Now the FDA status from FDA, it is "to deliver intracavity or interstitial radiation to the surgical margins following lumpectomy for breast cancer." So right now, the FDA approves only for the use in breast cancer.

It is not regulated by the NRC because it's non-radioactive source. There are no special QA guidelines as of now, but they are in development.

Some of the advantages of this system is that you can switch it on and off. So remember, I told you that the radioisotope where the isotope has

no radiation suddenly gives a lot of radiation and then stops. Here you have something very close and you are able to mimic that. You can adjust the radiation output. There is very little shielding required. So you don't need a shielded room. You don't need to eliminate any radioactive disposable material. The dosimetry characteristic is similar to iridium-192 afterloader and there is no NRC requirement or there is no consequence of this medical event.

What is the clinical future and summary? The non-radioactive source is a major advantage from a radiation exposure standpoint. Currently, this has only started recently, and only two sites have started. They are hoping to have about 30 centers by the end of 2007. Right now, it's approved only for breast and so far as we know there has been no off-label uses. However, I can very easily predict or see that there would be either off-label users or potential for use at other sites. For example, vaginal applicators are being planned. Right now, the sources, the entire system is disposable. If they were to build a reusable source, I think the price would come down even more. But right now, each applicator is per patient.

What are the NRC implications? I would like to compare this system to what existed in external beam with the cobalt-60 external beam linear accelerator, one was radioactive and one was not, and one possibility is that if we make the regulations for radioactive materials too burdensome, very onerous, the licensing too difficult, radiation oncologists may decide not to do brachytherapy if you have a very similar alternative which is less cumbersome. And therefore, we now have something that is a very similar alternative. This had happened before with external beam for cobalt, teletherapy versus linear accelerator and also it is slowly happening that many people are abandoning the possible advantages of brachytherapy by using IMRT which is an external beam which has less regulation. So from the NRC viewpoint, you have to strike a balance between how much regulation you want to do and whether by having too much regulation you are pushing some people out of doing this thing at all.

The next applicators I would like to talk about is a new thing called Strontium-90 Ophthalmic Applicator with a disclaimer that I'm not an ophthalmologist. I'm a radiation oncologist. So I'm not going to go into details of ophthalmology. I'll

talk about the details of the radiation component of it.

But before that, I must say a few words about what it is used for. So you have to know a few things about what is Age-Related Macular Degeneration or AMD. It's a disease associated with aging which affects the part of the eye, the macula, the central part of the retina in the back of the eye, and because there's a gradual destruction of this, you can end up with losing vision especially in people who are 60 years of age or more. And there are two types. One is the dry form and the other is called the wet form.

In the dry form which is an early stage, you slowly lose some of the retinal function because the cells in the retina break down and so your central vision is affected. You are able to see the periphery, but not the center. There is really no treatment for that and about ten percent of those patients can go on to what's called wet AMD.

In the wet AMD, it's neovascular due to formation of vessels and then there is the abnormal vessel that is growing in the back portion of the retina and that's what's called choroidal neovascularization or CNV and these new vessels, they leak out. Because they leak out, they form fluids

which therefore raise the macula and therefore you cannot see anything at all and then a rapid loss of vision.

So with this short introduction to ophthalmology, how can we treat this? There are many ways of treating it, laser, photodynamic therapy, injection of drugs in the eye. I'm not going to go into those details because none of these treatments really cure these patients. They may slow it down, but then they continue to lose the vision.

Now why would you want to use radiation in the eye? What is this choroidal neovascular cell? In many ways, they are similar to cancer cells because they rapidly proliferate. They are similar to things like neointinmal hyperplasia in coronary artery or pterygium in the front part of the eye, and ionizing radiation has proven beneficial in keloids and pterygium and in the intracoronary sight and therefore, if you can destroy these newly forming blood vessels you may be able to stop wet AMD.

So Neovista came up with this strontium applicator which basically, I think is an offshoot of strontium-90 intracoronary techniques. There used to be intracoronary strontium-90 for the heart. It's a handheld device, very narrow, and it delivers the

radiation directly to the macula by surgeons who do surgery and place the tip of this right at the site where there is the neovascular formation which will push the strontium into the area, tip it for the required amount of time and pull it back.

Technical details, you don't need to know except that it's the source of 357 megabecquerel. Treatment time is on the order of four to five minutes. The dose in the center of that area is 24 gray and by the time you go to about 5 mm, you're down to about 7 gray.

Radiation protection, you have a rapid fall-off and it's a beta emission so there's very little radiation to the operator.

There is a multi-channel tester where you place the applicator before you place it on the patient so it can be verify what the dose rate and so on is.

In case you are interested, here is the dose rate profile, 24 Gy given to the center and then 16 Gy and 12 Gy and by the time you come to about 5 cm you are getting down to 4 Gy.

It's a minimally-invasive, out-patient procedure done by an ophthalmologist. They do a partial vitrectomy under local anesthesia, give 24 Gy

and you are radiating in about four to five minutes, and the whole procedure takes about 20 to 30 minutes.

Clinical trials have been started, and about 90 patients so far have been treated in Brazil, 30 in Mexico. They have had some improvement which has been comparable to that by some drugs like Lucentis. If you are adding anti-VEGF, you may even get better results. But they are now entering into phase 3 trial.

With the prospective randomized phase 3 trial, I think, because they are in California, they are calling it the CABERNET from the wine growing there, Central Neo Vascularization secondary to AMD treated with Beta Radiation Epiretinal Therapy.

(Laughter.)

MEMBER NAG: And they are randomizing Arm A with the Neovista and Lucentis versus Arm B with the active control, Lucentis alone. They are expecting about 450 patients and there will be about 30 sites worldwide, 20 in the U.S., 10 outside the U.S.

Summary, I think this represents a new use for strontium. The technology from what I understand, the technology is very similar to the use of technology of strontium-90 for intracoronary brachytherapy for prevention of restenosis that

Novoste was using. It is a handheld equipment and potentially can be useful for a large segment of patients who have wet AMD.

Some of my concerns. Right now, it is in use by ophthalmologists who have very little or no radiation training. There has been very little or no radiation oncology input, and this is similar to intracoronary brachytherapy in the early days when the pathologists were doing it without any input. But then once they sought the help of the radiation oncology and the physics team and the dosimetry and so on, the understanding rapidly multiplied and intracoronary brachytherapy flourished.

The other concern I have is that the radiation is almost used like a burning tool because in ophthalmology they are more used to using the laser. So they are using it more like a burning tool rather than a radiation tool. The dosimetry right now is very primitive and it is, I think, a very useful technology that may die away if there is inadequate multi-disciplinary input.

So my recommendation is that we need to develop a team approach with ophthalmology, radiation oncology, radiation physics and radiation safety being involved. We need to develop guidelines for written

directives, regularly prescribe the prescription points, the dosimetry. And in terms of regulation, I would say it's similar to strontium-90 for intravascular brachytherapy. Therefore, at least, initially regulate under 35.1000 and that the T&E should be similar to that for 35.490. And an authorized user should provide written directive before the use of this teletherapy material.

I think with that I'll stop.

CHAIRMAN MALMUD: Thank you.

MEMBER NAG: I think I finished in about 12 minutes.

MS. WASTLER: You did very good.

MEMBER NAG: Within my time.

MS. WASTLER: You're keeping us right on schedule.

(Off the record comments.)

CHAIRMAN MALMUD: You're on.

DR. HOWE: Dr. Nag, when you're looking at this device, do you see it in training and experience to be a three year residency program type of training or do you see it more on the training that we hour-wise --

MEMBER NAG: I need to know which of the three things you are talking about.

DR. HOWE: The last one, the strontium-90.

MEMBER NAG: Yes, I would say as I said from my standpoint I would think this is similar to the use of strontium-90 like the Novoste. What were you requiring for the use of the Novoste? I think the parallel is the same.

DR. HOWE: So you don't see a parallel with the current ophthalomological radiotherapy?

MEMBER NAG: No, I should have added that. I'm sorry. It is not similar to the strontium-90 applicator that is placed on the surface of the eye. That's entirely different. I think the parallel is to strontium-90 intracoronary application in the heart where, I think, the best way you can develop this technique would be to have a multi-disciplinary team that would include radiation oncology who would be the authorized user, the ophthalmologist who would be the surgeon putting it in, the radiation physicist who would do the dosimetry and radiation safety.

CHAIRMAN MALMUD: Other questions or comments? I'm sorry.

MEMBER THOMADSEN: We're in the process of putting together our team and getting people educated for this.

MS. WASTLER: For which one?

MEMBER THOMADSEN: For the last one. The one the discussion is about right this second.

MS. WASTLER: Okay.

MEMBER THOMADSEN: And as we're doing so, it's not entirely clear what the radiation oncologist is going to be doing here since the prescription doesn't change. They aren't really in a position to evaluate whether the patient is a good risk or not since it really doesn't have to do with the system such as with the liver and the microspheres.

I mean, we're definitely having the radiation oncologists involved, but they're asking what are they going to do. What is their point in all this? So the authorized user is actually a bit superfluous in this whole process.

MEMBER NAG: Actually, that was similar to what intravascular cardiology what's happening. They said "Well, you are giving 8 Gy and that's all you need to do." However, I think it requires someone with understanding of different dose, different dose rates. How do you know that 24 Gy is the right amount? Where do you prescribe it to? Is this too much? Is this too little?

This fine-tuning, I think, is where you are going to need the radiation oncology. I don't

think you necessarily need the radiation oncology just to be present and give out 24 Gy for every case, but in terms of understanding. Most non-radiation oncologists do not necessarily understand the nuances of what's happening with the dose follow-up, where is the dose, what does the epithelium need and, you know, the dose. The three dimensional dosimetry is something that needs to be worked upon.

CHAIRMAN MALMUD: Follow-up questions? Dr. Thomadsen.

MEMBER THOMADSEN: I was going to agree. During some sort of clinical trial and the research fine-tuning, you do need everybody on the team and certainly you need somebody who knows something about dosimetry to figure out what's actually going on here. But in equilibrium once people know what the dose should be, it doesn't seem like they're going to be using different doses based on anything with the patient presentation. At that point, it's not clear that the team is all that necessary anymore than it was clear that team was necessary who was intravascular at that point which we never got to that point with the intravascular.

MEMBER EGGLI: The question you might ask is why you never got to that point with intravascular

brachytherapy because the interventional cardiologist didn't really like this team approach and they found something else they could do and not have to use the team and they used drug-eluding stints instead and intravascular brachytherapy died very quickly because the interventional cardiologist found this team approach to be cumbersome and if this is a good therapy, I think that your point is well-taken that we should determine what is the role of the various team members for what fraction of time and if it's a valuable therapy you don't want to see it wither on the vine because, in fact, the team approach is cumbersome.

CHAIRMAN MALMUD: Donna-Beth.

DR. HOWE: Just two quick points. One, intravascular brachytherapy may be down, but it's not dead. The Novoste product was bought by Bess Intravascular. So they are still in the market.

And I guess the issue in here is, and we're very interested in hearing the debate between the ophthalmologist with a small amount of radiation training because he's the one that understands the eye and the radiation oncologist who has the extensive training but is not fine-tuned on the very minute places where you have to treat within the eye. So

we're very interested in hearing this discussion to figure out what to do with it because it is coming down now.

MEMBER NAG: I think that was very similar for eye plaques. In eye plaque, you don't need a radiation oncologist to place the eye plaque in. There are manufacturers. But for the eye plaque to have come up for treatment of choroidal melanoma by radioactive eye plaque it needed that team approach between ophthalmologists, radiation oncologists and radiation physicists. So I think you need that team approach to be able to understand the whole gambit.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: I think there are with different types of brachytherapy procedures the different team members have varying levels of importance and dominance. I think the eye plaque is a very good example where the dominant team members are, in fact, the ophthalmologists and the physicists who puts the thing together and works with the ophthalmologist to interpret the imaging information. There is still, I think, though a role for the radiation oncologist in evaluating the dose distribution and arguing with the ophthalmologist about using it to treat tumors too close to the optic

nerve. So you miss and there are judgment issues where the radiation oncologist can be involved.

I think a more nuanced approach than that developed by the FDA for intravascular brachytherapy maybe needs to be considered for this therapy where the level of involvement is more proportionate to the contribution. So I should think that we shouldn't reflexively insist that the radiation oncologist be physically present at every one of these procedures. I'm not sure that played a very useful role in intravascular brachytherapy for coronary restenosis except maybe early on in the first few procedures, but I think that was a major issue in preventing the cost-effective dissemination of the treatment because radiation oncology really wasn't staffed to provide the instant service that was needed to make this be useful on a large scale. So I think one can have the team approach and do it in a way that respects or is proportional to the -- specifies the roles of the individuals in a way that is proportional to their potential contribution.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER. SULEIMAN: I think the team approach can only work as well as the team members can get along.

(Laughter.)

MEMBER. SULEIMAN: I found the presentations all fascinating. I found the x-ray source interesting. I think, the CRCPD and the agreement states, I don't think you are going to go unregulated, but I think how it all plays out. Clearly other factors like reimbursement will play into this, but I have no clue how -- I think you sort of see how this thing is going to play out clinically, but it's interesting technologies.

CHAIRMAN MALMUD: Let's see. I think next was Ralph.

MEMBER LIETO: I actually just had a question for Dr. Nag or Dr. Thomadsen. Does the dose vary per patient or is it just a set absorbed dose that's given for each treatment?

MEMBER NAG: Right now, this is a starting technology. I don't think anyone knows what the different doses are. So right now, for starting off, they are giving 24 Gy for all comers. But I think that is where you need someone who understands the differences and therefore for further development 24 Gy is what we are doing today. That may not be the optimum dose.

So I think you need somebody with more

detailed understanding of the radiation part. The ophthalmologists are great at localizing, knowing, where the different layers of the eye. That's why I was talking about a team approach.

MEMBER LIETO: How is this physically placed?

MEMBER NAG: Yes. It's like a -- needle.

MEMBER LIETO: -- needle.

MEMBER NAG: I think it's 20 to 22 gauge needle.

CHAIRMAN MALMUD: We have a member of the public who wishes to say something.

MS. FAIROBENT: Lynne Fairobent, AAPM. I just want to follow up a little bit on the Xoft System just to make sure the record's complete, although it's not going to be an NRC regulated device. There are actually two systems. There is the Xoft Axxent System and then the Intervene by MediTech is also out there and the Intervene System actually has already been used in over 1,000 cases worldwide, whereas the Xoft System is truly just coming to fruition, I will put it that way, in this country.

AAPM recently did provide to CRCPD officially draft suggested state regs. that does cover the QA/QCs, and CRCPD is now working on incorporating

AAPM's recommendations into suggested state regs. and, Orhan, just on your point of whether these will play out in the financial world, Xoft already has a CMS reimbursement code.

MEMBER NAG: You are correct, having both the Xoft System and the Intervene System. The reason why I chose not to present the Intervene System is twofold. One, Intervene has been around for awhile and secondly, Xoft is very similar to the HDR. It has a stepping source. It means it goes through a very, very narrow needle. So for all practical purposes, it's in parallel to HDR, whereas the Intervene System doesn't have that much of a similarity to the HDR. X-ray shows it doesn't step in one place.

MS. FAIROBENT: Right. I just wanted to be sure they realize there was also a second device that is on the market and is being used in addition to the Axxent System.

CHAIRMAN MALMUD: Yes. You were next.

MS. FLANNERY: Okay. Thank you. Dr. Nag, going to the strontium-90 ophthalmic device, your presentation was very timely because we do now have two licensees that are interested in using this device.

I guess just for the benefit of the ACMUI

I just wanted to quickly read. We do have a section of the regulations that address the other types of ophthalmic devices and as far as the regulations, it's 35.491 and there are three sections. One of them is the training which requires 24 hours of classroom and laboratory training and it lists the topics. The other part is the supervised clinical experience and the regs. require five cases and then there's a written attestation.

I guess my question for you is would these regulations be applicable to this new device and be specific to that device or you were talking about 35.1000. I'm just really interested in ACMUI's input if we had to just sort of start from scratch in developing regulations specific to this device and what kind of training and experience does ACMUI think is necessary for this new device?

MEMBER NAG: I think I should have given what a strontium superficial eye applicator is. 491 refers to the use of strontium-90 as a surface applicator on the eye. So I don't think the two have any parallel. I think the two -- the word "strontium-90" is the same and using the eye the same, but the technology is so far different from each other, I do not think that the strontium-90 Novoste should be

regulated under the 35.491 because it's so different. That is why my suggestion was to put it under 35.1000.

MEMBER EGGLI: What is the --

CHAIRMAN MALMUD: I think Dr. Welsh was next.

MEMBER WELSH: I would agree that perhaps the best category for this at this time is 1000, and I would also state that I think a team approach is justified here and radiation oncology does have a role at this early stage.

The dose is quite large. We're not talking about a few cGy. We're talking about 24 Gy and that dose may change with the clinical experience. As was mentioned, right now it's a single dose, but I would not be surprised if next year some patients would get 20 Gy. Some get 24 Gy. Some might get more. Similarly to vascular brachytherapy, right now there's one isotope. Next year, there might be another if this proves to be of clinical benefit.

Overall, it seems that with greater radiobiological understanding, dosimetry understanding, the role of the radiation oncologist is going to be more important.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: What dose rate and distance is the 24 Gy administered?

MEMBER NAG: Okay. The 24 Gy is administered in about four minutes, within four and five minutes. So you can divide it to be about 6 Gy per minute. At the center, it's like about -- I had it in one of the earlier slides. So it's within like about 1 cm or so and then by the time you come to 5 cm, it's down to 4 Gy.

CHAIRMAN MALMUD: Sandi.

MS. WASTLER: I think while we've heard from you that at least Dr. Nag believes that 35.491 is not applicable to the training and experience for that, it's not applicable to the new technology, what I didn't hear was any views with regards to what the committee believes would be applicable. Is it comparable to any other procedure? Would we compare it to a 290? A 490? A 690? I mean, where should we go?

MEMBER NAG: My suggestion was the intravascular strontium-90 for Novoste. I think there are so many parallels.

MS. WASTLER: Similar to the dose.

MEMBER NAG: Similar to the Novoste was my suggestion. But I would like to hear the other

people.

CHAIRMAN MALMUD: We have a member of the public.

MR. METZGER: Yes. Bill Metzger. I happen to be from the company that made the strontium-90 devices and we are working with the radiation oncology community right now in answering a lot of these questions.

But when this was first envisioned, it was actually considered to be close to the pterygium device mainly because the thing that the ophthalmologist is adding is the surgical technique to get it to a different surface. They're not adding anything in the way of application of radiation. But they are adding the fact that it's direct visualization while it's in place which is very accurate. I mean, they're holding this device in the exact correct position for a non-cancerous lesion for exactly four minutes, and we have ways of measuring whether or not they are capable of doing it.

CHAIRMAN MALMUD: Two.

MR. METZGER: One hundred percent of them are able to do it.

MEMBER THOMADSEN: Despite my disparaging the role of the radiation oncologist in this in

equilibrium, I would in answer to your question in the beginning until the questions are answered and this comes into equilibrium, I would say the suggestion for the qualifications would be just the same as any brachytherapy. That is being a regular radiation oncologist having gone through --

MEMBER NAG: 490 basically.

MEMBER THOMADSEN: Yes, all the residency and everything. That may be subject to change once all the questions have been answered.

MS. WASTLER: And that's the, I should say, the advantage of making it a 1000 where we would --

(Telephone interference.)

MS. WASTLER: Okay. Reference back to the 490 and then as the procedures advance or more experience is gained then we can go back in and say, "Okay, we found out we were too restrictive" or maybe we'll find out we're not restricting them enough. But we can change it as we move forward and get more experience. But as a starting point, you would recommend the 490.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: I'm wondering if because we do have another authorized user and that's in ophthalmic

therapy that if we put it in 1000 we consider two training paths. One is something similar to the 491 which may take over in the end and then the 490 would then be part of a team.

It is a high dose rate type of device and so in our model in high dose rate is that the authorized user has to be physically present and that there is an authorized medical physicist physically present. So if you provide training and I don't know if the hours but the actual training may be slightly different for 491 could eventually take the place of having to have a radiation oncologist physically present during the entire procedure if we used an HDR-type of model where this is my dose rate. I'm just throwing that out as a thought.

(Telephone interference.)

MEMBER NAG: If the 690 had a few other things in it so, although you could use some of the things from 690, you can't use 690 whole scale.

DR. HOWE: That's true.

MEMBER NAG: Because of all the calibration of HDR, blah, blah, blah. So I think for the time being my suggestion of using intravascular, everything that you did for intravascular brachytherapy strontium-90 of Novoste, if you apply it

here, you don't have to reinvent the wheel at least for the time being.

DR. HOWE: We had the physical presence of the authorized user and the medical physicist for the intravascular brachytherapy.

MEMBER NAG: For the time being, I think you can do that.

CHAIRMAN MALMUD: Dr. Thomadsen.

MEMBER THOMADSEN: Was that not changed so that it had to be either at one point, that they both did not have to be present anymore?

MEMBER GILLEY: Yes.

MEMBER NAG: Yes. It started with one and then as --

MEMBER THOMADSEN: It started with both of them having to be and then one or the other.

MEMBER NAG: And then once there was more experience gained and people had a comfort level it became either or. I mean, I think similar things could be applied here. You start with both. Once the team has enough experience, you can decide whether you need both or not.

DR. HOWE: But it sounds to me like we might have a third person and that would be the ophthalmologist.

MEMBER NAG: Yes.

DR. HOWE: Getting training and experience to eventually become an authorized user.

CHAIRMAN MALMUD: We have another member of the public with a comment as well.

MR. REED: I'm Craig Reed. I'm a health physicist and I was involved with the intravascular brachytherapy development and I'm listening to the discussions about qualifications of users and I look back on our history with the team approach and other things and discussions of people being present or not present and I think this is an early technology and it's going to go through its clinical trials and it's going to go through a very rigorous review process, both with regulators, FDA and NRC. I think we should take the opportunity to learn and see during the clinical process who adds what to the procedure.

And certainly to Dr. Nag's point early on, we need to involve everybody who has the most information about all potential effects of the radiation, not just the primary effect of treating this disease, but what are the secondary effects. So I think it's kind of early to decide what the final authorized user will be because we don't really know even really the final outcome and what the potential

side effects are.

But what I would say is that I think if I had to make an evaluation of what's an adequate training for an authorized user, I don't know that anybody in 24 hours or 24 days would take in the full scope of the regulations and their impact of everything you need to do be an authorized user especially if you're at a single facility.

But with respect to simply using a device that's very precise and very specific in its positioning and localization and how it's used according to a very specific protocol and in a clinical trial or even after a clinical trial, I don't think it's too difficult to imagine that an ophthalmologist who already positions needles and applicators and things at a very precise distance couldn't do that on a regular basis even with a radioactive source.

So I think we have to look to the basis for why there are regulations for ophthalmologists using sources close to the eyes that involves 24 hours of training and when that was promulgated years ago, is that still applicable to what we know today. So I also don't think necessarily the training experience we put on an oncologist who treats so many different

diseases throughout the body in so many different organs, that that's appropriate. So we have to find a middle ground and I don't think we want to start necessarily at the most extreme, at least anticipating what would be the final user. Maybe in the clinical trials there's one thing, not in the final end analysis.

There was also a comment about having an authorized user present. Well, I assure you that the ophthalmologist is immediately present and can withdraw the source immediately if there's an issue. So there is somebody there who is authorized to put it in and take it out. I'm not too concerned about that type of scenario.

Let's assume for a minute that one physician will be treating this patient in the end. All right. What does that physician need to know to do it completely and adequately? Early on, we can consider the team approach, but we have to look towards this being a successful procedure and what's adequate for the full scope of one procedure.

CHAIRMAN MALMUD: Thank you. The hour being what it is. I think the next item on the agenda is Ashley Tull and thank you again, Dr. Nag.

MS. TULL: Okay. The first thing I want

to go over is the proposed meeting dates for the next meeting, and I have two weeks proposed, October 23, 24, 25 and the second one is November, 6, 7 and 8. Does anyone know of any conflicts right now with those dates? Sally.

MEMBER SCHWARZ: Sixth, 7th and 8th.

MEMBER NAG: Can you give those dates again? October?

MS. TULL: October 23rd, 24th and 25th. So we could either do it Tuesday/Wednesday or Wednesday/Thursday.

MEMBER FISHER: November 6th.

MS. TULL: Yes. November 6th, 7th and 8th is the second set.

MEMBER SCHWARZ: That's the one I have a conflict with, the November 6th, 7th and 8th.

MS. TULL: What was that?

MEMBER SCHWARZ: I won't be available.

MEMBER FISHER: I have a conflict also.

MS. TULL: Okay.

MEMBER EGGLI: I have a potential conflict on the November date.

MS. TULL: So three potential conflicts on the November date?

CHAIRMAN MALMUD: Any conflicts in

October?

(No response.)

CHAIRMAN MALMUD: Go for October.

MS. TULL: Okay.

MS. FLANNERY: I just want to remind everybody that there is the ASTRO meeting to consider.

MEMBER NAG: ASTRO is from 27th through 31st of October. So it's immediately following the meeting.

MS. TULL: Right. I've gotten around that and I also based on the availability of this room. So we don't get bumped to NIH or the Marriott.

CHAIRMAN MALMUD: And so Tuesday and Wednesday of that last week in October?

MS. TULL: So October 23rd and 24th.

CHAIRMAN MALMUD: Okay.

MEMBER NAG: I would suggest earlier in the week because if you're having it the 23rd and 24th, people cannot finish up the backlog and then go to ASTRO because ASTRO will be starting on the 27th.

CHAIRMAN MALMUD: You prefer Monday/Tuesday?

MEMBER NAG: Yes. So that it gives you a couple of days to catch up on your work.

CHAIRMAN MALMUD: Monday/Tuesday okay?

MS. WASTLER: We checked availability for the room.

MS. TULL: Room conflict is fine. So I'll come in on Sunday.

(Off the record discussion.)

MS. TULL: Starting on the 22nd. Okay.

(Off the record comments.)

CHAIRMAN MALMUD: Monday/Tuesday.

MS. TULL: Monday/Tuesday, October 22nd and 23rd.

MS. WASTLER: Okay.

MS. TULL: Okay. That takes care of the first thing. Next, I'm going to go through the recommendations that I was able to take notes of. So hopefully, I captured all of them. If you think of something else, feel free to stop me.

Dr. Williamson, let's see. The first was with regard to Air Kerma Strength versus activity and ACMUI recommended that the NRC draft an information notice.

MEMBER WILLIAMSON: In collaboration with the AAPM.

MS. TULL: In collaboration with the AAPM. Okay. So draft an information notice in collaboration with the AAPM.

The next that I have are the 11 issues that were documented during the T&E discussion. Four of those the ACMUI made a recommendation on and the remaining seven will be discussed at a future telecon.

Quickly, the first issue was a preceptor statements and the recommendation was to remove the attestation from the board certification pathway.

The second issue was impasse to the effective date for previously board certified to be grandfathered and the recommendation to fix that is previously board certified members be grandfathered.

The third one is 200 hours of radiation safety training for 390 users under the alternative pathway and the recommendation is to change 200 hours to 120 hours.

The fourth issue is the Canadian issue and no recommendations for anything else that I'm going to list here, but the Canadian issue, compatibility, grandfathering, diplomates, preceptor not being available, RSO requirements, seven year recency of training and the unintended consequences of prescriptive requirements and increased complexity with no additional benefit. Those would all be discussed at a future meeting.

MS. WASTLER: It would be a teleconference

meeting?

MS. TULL: A teleconference.

MS. WASTLER: And we will have to get back to you on setting up a date for that.

CHAIRMAN MALMUD: Yes.

MS. WASTLER: And finding appropriate times.

MEMBER SCHWARZ: Can you send a summary of what you've just said?

MS. TULL: Sure.

MEMBER SCHWARZ: Email?

MS. TULL: Yes. Actually, the way this is done, there is an official memo that goes to Dr. Malmud with all of this. It's something that's always been done for the meetings. I don't know if everyone gets a copy.

CHAIRMAN MALMUD: No, we don't.

MS. TULL: Okay. Would that be something we can do?

MS. WASTLER: We could easily send you that.

MS. TULL: Yes. I mean --

MS. WASTLER: For every meeting there's a summary.

MS. TULL: Yes, I did the last one.

Basically, it's just action and then what the NRC is doing or has done.

MS. WASTLER: It just goes through a list either motion or action or commitment that's been made.

MS. TULL: If you'll look in your binder, the one from the previous meeting is there. So you would see something similar to that.

CHAIRMAN MALMUD: I thought the whole committee was getting that.

MS. TULL: I think we just sent the memo from Sandi to you, but I can send it to the entire committee.

MEMBER WILLIAMSON: I think we only see it in the packet when we come to the meeting.

MS. WASTLER: Right.

MS. TULL: Correct.

MS. WASTLER: Okay. We can send it, but it's under the tab of meeting summary and action items.

MS. TULL: Yes.

MS. WASTLER: And basically that's --

MEMBER WILLIAMSON: As well as a summary, it's a meeting minutes as well. Right?

MS. TULL: Correct. There are meeting

summaries and there's the transcript. But as far as action items and motions, there is a specific memo that I will draft that will go from Sandi to Dr. Malmud.

(Off the record comments.)

MS. WASTLER: Yes. So we will make sure you get that.

MS. TULL: Definitely.

MEMBER EGGLI: We had a long discussion about the use of the word "competence" in the preceptor in the alternative pathway which the preceptor isn't drafted. Did we make a recommendation on that or did we just have a long discussion and not make a recommendation on that?

MS. TULL: Preceptor, remove.

MS. WASTLER: It was remove attestation from board certification pathway and change competency to has met the minimum training and experience requirements.

MEMBER EGGLI: Okay. So there is a comment for the alternative pathway on competency.

MS. WASTLER: Yes.

MEMBER EGGLI: Okay.

MS. TULL: Sorry. I'm trying to very briefly summarize.

MS. WASTLER: She's trying to summarize them very quickly.

MEMBER EGGLI: Yes, I'm just thinking about putting my name on the line again.

MS. TULL: And all of these can be discussed again at the future team meeting discussion.

MS. TULL: Okay. So moving on past that were potential changes to 10 CFR 35. Five motions were made and all of these were tabled. So if you want me to go through them I will.

CHAIRMAN MALMUD: No.

MS. TULL: But I feel like they're tabled. Okay. Next, allowing multiple RSOs on a license, ACMUI recommends --

MEMBER WILLIAMSON: Wait a minute. Excuse me. I don't think that all the motions were tabled. We passed several of them and then tabled the remainder.

DR. HOWE: The first one, they did not pass. Most of the others they passed and then we started tabling.

MS. TULL: Donna-Beth, you're not on the microphone.

CHAIRMAN MALMUD: The court transcriber is rising his hand and asking us to identify ourselves.

Am I correct?

DR. HOWE: Yes. Dr. Howe.

MS. TULL: Microphone.

CHAIRMAN MALMUD: Microphone.

DR. HOWE: Dr. Howe. The first one the ACMUI did not support. Then they supported and I don't have my notes in front of me.

MS. WASTLER: 35.2.

DR. HOWE: And then they tabled.

MS. TULL: I have it in front of me, but if we want to go through them we can.

MS. WASTLER: We do. 35.2 motion was leave as is. All right. 35.12 was moved and approved. 35.50(c)(2) moved and approved. 35.50(d) moved and approved. 35.57(a), hang on, tabled.

CHAIRMAN MALMUD: Tabled. That's where we got --

(Several speaking at once.)

MS. WASTLER: And then 35.75 was tabled.

DR. HOWE: Tabled.

MS. TULL: And then there was a final recommendation.

MS. WASTLER: Everything else was tabled.

MS. TULL: And then Dr. Nag made a recommendation to table all of the issues so that

ACMUI could gather --

CHAIRMAN MALMUD: No.

MS. WASTLER: Only those left.

CHAIRMAN MALMUD: Only those remaining issues.

(Several speaking at once.)

MS. TULL: Sorry.

MS. WASTLER: No, that's fine. That's why we go through the action items.

MS. TULL: Okay.

MS. WASTLER: So we make sure that we have those clear and understood.

MS. TULL: Yes. This will be much easier to put together once I have the actual transcript.

CHAIRMAN MALMUD: Sure.

MS. TULL: To see what the wording of the motion is.

MS. WASTLER: Right.

MS. TULL: Okay. So moving on past Donna-Beth's presentation to microspheres.

MS. WASTLER: Did you do the RSO?

MS. TULL: I started the RSO.

MS. WASTLER: Yes. Go through that.

MS. TULL: Okay. So there was a recommendation from ACMUI to allow multiple RSOs on a

license and one RSO can be identified as the one in charge. ACMUI recommended that NRC publish an RIS after receiving input, review and comments from the agreement states and ACMUI. Does that sound acceptable?

MS. WASTLER: Okay.

MS. TULL: Next is the microspheres. As far as written attestation, there was a motion to delete the paragraph and add "and provide documentation" to the second paragraph of the guidance.

Team approach, there was a motion to replace the term "oncology" with "individual with expertise in cancer treatment or management."

MS. WASTLER: There was also a motion under the written attestation to add the requirement -- I'm trying to remember it.

MS. TULL: From 690.

MS. WASTLER: For 690.

MS. TULL: The wording from 690.

MS. WASTLER: The wording from 690.

MS. TULL: Correct. Okay. On the other slide that I had which was specific medical use, licensees and waste disposal, approved both of those changes. ACMUI recommended to approve both of those

changes and then the dose versus activity was tabled for further discussion at the next teleconference or future meeting and then there was also one thing on the slide that we didn't get to and that was a clarification that we're asking for as far as end of the treatment, end of the procedure. We need a recommendation from you on that as well.

MS. WASTLER: We didn't get to it.

MS. TULL: We didn't get to it, but it's tabled.

MS. WASTLER: Okay. Next. Sentinel lymph node. A recommendation was made that after injection and an imaging is done, the subsequent surgery should not be regulated by NRC.

CHAIRMAN MALMUD: I think we were a little more specific than that. We were indicating that we felt that they were two separate procedures and therefore, we didn't feel that was within our purview.

MS. TULL: Okay. I will go back to the transcript and pull the wording from that.

This wasn't a motion but this happened. We moved items 17, 18 and 19 which was the Elekta Perfexion, Dr. Welsh's AU approval for byproduct material and Michelle Burgess' NMED presentation to a future meeting.

And on -- I guess that's it. There was no formal recommendation from Dr. Nag's presentation.

MS. WASTLER: But we will go back and double check the transcript for any additional action items.

MS. TULL: Yes, once I get that.

MS. WASTLER: And we will -- As Ashley noted, we will put that together and we'll make sure that all members get a copy of that.

MEMBER SCHWARZ: Great.

MS. TULL: Okay. Next on my list, time and travel. If you haven't already turned it in to me with signatures, please do.

Self-evaluations are in the front of your binder. Please fill those out. Give those to me as well.

CHAIRMAN MALMUD: I'll have to mail those to you.

MS. TULL: Okay. You can mail them to me or if you would like, I can send you the Word version and you can just respond electronically.

CHAIRMAN MALMUD: Yes, can you send the Word version?

MEMBER WILLIAMSON: That would be good.

MEMBER EGGLI: That would be excellent.

MS. TULL: I'm all about electronic.

(Off the record comments.)

MS. TULL: I have been sending everything in Word. So I think that that's -- We're transitioning in our office.

MS. WASTLER: We're actually transitioning to Word. We're finally coming into the 21st century.

(Off the record comments.)

MS. WASTLER: It's going to be traumatic for all of the staff.

MS. TULL: If you want to leave your name tags, I'd appreciate it because then I wouldn't have to reprint them. It would save me some time next.

MS. WASTLER: And I would just like to say on your desk you will find copies of the most recent regs. Those are yours, should you chose to carry them back. That is your copy to take with you.

And I think last I just wanted to thank everyone. We really appreciate your contribution and I just wanted to again extend Janet's apologies for not being here, though I'm sure you all understand. She had a medical treatment that she's trying to recover from was not able to be here, but she just wanted us to extend her -- Yes. She had a myelogram and was not, shall we stay, has had a whopping

headache and if it didn't stop, I think she went back in to get it, I guess, redone so it would -- leaking. Not pleasant at any rate. So she's been not feeling well.

MS. TULL: 5:01 p.m.

CHAIRMAN MALMUD: One final word. I want to thank --

MEMBER WILLIAMSON: 5:02 p.m.

MS. WASTLER: Okay.

CHAIRMAN MALMUD: I'm sorry. I wanted to thank all of you, all the members of the committee and all the staff for two very intense days with lots of very animated and robust discussion. I think that everyone here certainly has exhibited their commitment to getting this done in the best interest of patient care and we appreciate the effort. Our opinions may vary at times, but our goal is the same and it's wonderful to work with you all.

MEMBER NAG: And we survived.

CHAIRMAN MALMUD: We survived. Yes.

MEMBER WILLIAMSON: I think we respect the way you've run the committee.

CHAIRMAN MALMUD: Thank you very much. And we're going to miss you, Jeff.

MEMBER WILLIAMSON: Yes, maybe things will

be less robust.

(Laughter.)

CHAIRMAN MALMUD: There may be fewer words, but also you have done some yeoman's work for us in various presentations that you've made which represent an extraordinary amount of effort and I don't want you to think that we don't remember that don't appreciate it because we do and you will be missed.

MS. WASTLER: I would second that. Thank you very much.

(Applause.)

MS. WASTLER: And with that, we close the meeting, Dr. Malmud.

CHAIRMAN MALMUD: Safe trip everybody.

MS. WASTLER: Thank you.

CHAIRMAN MALMUD: Off the record.

(Whereupon, at 5:02 p.m., the above-entitled matter was concluded.)

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