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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TUESDAY

MAY 23, 2006

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OPEN SESSION

TELECONFERENCE

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The meeting convened by teleconference at 3:18 p.m., EDT.

MEMBERS PRESENT:

LEON S. MALMUD, M.D.	ACMUI Chairman
EDGAR BAILEY	Member
DOUGLAS F. EGGLI, M.D.	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member
SALLY WAGNER SCHWARZ	Member
ROBERT E. SCHENTER, Ph.D	Member
WILLIAM VAN DECKER, M.D.	Member
RICHARD J. VETTER, Ph.D.	Member
JEFFREY F. WILLIAMSON, Ph.D.	Member

NRC STAFF:

THOMAS ESSIG, Designated Federal Official,	
	NMSS/IMNS/MSIB
CYNTHIA M. FLANNERY	NMSS/IMNS/MSIB
DONNA-BETH HOWE	NRC
ANGELA MacINTOSH	NMSS/IMNS/MSIB
MOHAMMAD SABA	NRC

C O N T E N T S

P R O C E E D I N G S

(3:18 p.m.)

MR. ESSIG: Okay. Dr. Malmud, if I may, let me open the meeting with my --

DR. MALMUD: Please do.

MR. ESSIG: -- Designated Federal Official's opening comments.

As the Designated Federal Official for this meeting, I am pleased to welcome you to this publicly noticed conference call meeting of the ACMUI. My name is Thomas Essig. I am Branch Chief, the Material Safety Inspection Branch, and have been designated as the Federal Official for this Advisory Committee in accordance with 10 CFR, Part 7.11.

Present today as the alternate Designated Official is Cynthia Flannery, Team Leader for Medical Radiation Safety within the Material Safety and Inspection Branch.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the May 9th, 2006 edition of the Federal Register, 71 FR 26994.

The function of the Committee is to advise

the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the views of the Committee and values them very much. I request that whenever possible you try to establish a consensus on the various issues that we will discuss during this conference call, but I also value minority or dissenting opinions. If you have such opinions, please allow them to be read in the record.

As part of the preparation for this meeting, I have reviewed the agenda for members and employment interests based on the general nature of the discussion that we're going to have today. I have not identified any items which pose a conflict for the members.

If, however, during the course of our business other members determine that they have a conflict of interest in mattes before the Committee, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point I would like to perform a roll call of members who may be participating today.

Dr. Malmud, Health Care Administrator.

DR. MALMUD: Yes, sir.

MR. ESSIG: And Committee Chair.

Dr. Douglas Eggli, nuclear medicine physician.

DR. EGGLI: Present.

MR. ESSIG: Dr. David Diamond is not present. Dr. Subir Nag, radiation oncologist.

DR. NAG: Yes.

MR. ESSIG: Dr. William Van Decker, nuclear cardiologist.

DR. VAN DECKER: Yes.

MR. ESSIG: Ms. Sally Schwarz, nuclear pharmacist.

DR. SCHWARZ: Yes.

MR. ESSIG: Dr. Richard Vetter, Radiation Safety Officer.

DR. VETTER: Present.

MR. ESSIG: Dr. Jeffrey Williamson, therapy physicist.

DR. WILLIAMSON: Present.

MR. ESSIG: Mr. Ralph Lieto, nuclear medicine physicist.

MR. LIETO: Present.

MR. ESSIG: Mr. Edgar Bailey, State

Representative.

MR. BAILEY: Present.

MR. ESSIG: And Dr. Robert Schenter, Patient Advocate Representative.

(No response.)

MR. ESSIG: And Dr. Schenter has not made the call yet.

And Dr. Ohran Suleiman, Center for Drug Evaluation and Research, USFDA.

(No response.)

MR. ESSIG: Dr. Suleiman was not able to attend.

Dr. Leon Malmud, ACMUI Chairperson, will conduct today's meeting with discussion of each agenda item. The Chair, at his option, can entertain comments or questions from members of the public who are participating with us.

I will turn it over to you, Dr. Malmud.

DR. MALMUD: Thank you, Mr. Essig.

I notice that in the agenda it says "Opening Remarks by Tom Essig." And you have 35 minutes for remarks.

MR. ESSIG: Yes, yes. And that was a typo. It should have been five minutes.

DR. MALMUD: So it is 3:00 to 3:05.

MR. ESSIG: Yes, sir.

DR. MALMUD: And at 3:05 we begin the meat of the meeting.

MR. ESSIG: Yes, and since we started the meeting actually at 3:15, it is now 3:20, and it is time to start the meeting, and Dr. Howe is poised at the phone here ready to roll on 535.

DR. MALMUD: In that case I'll be happy to open the session with the introduction of Dr. Donna-Beth Howe of the NRC, who will present to the ACMUI the potential changes to 10 CFR 35, which is an unfinished item from the April '06 meeting, and you should have with you the PowerPoint presentation from that meeting.

Dr. Howe.

DR. HOWE: Yes, and we're going to be starting on Slide No. 8 because we successfully got through Slides 1 through 7.

I would like to reiterate that this is potential changes to 10 CFR Part 35. The internal procedures at NRC are for us to submit a memo to the Regulatory Guidance Branch on changes we believe need to be made to the regulations, and they are the ones that will decide whether and when any changes are made. So this is preliminary to any changes.

But I do need the ACMUI to approve or disapprove or give me changes to things that I'm proposing at this point.

So without any further ado, Item No. 8 or Slide No. 8 is supervised work experience, and this is to bring 10 CFR 35.190(a) and 290(a) into conformance with the language in 10 CFR 35.390(a). And in 190 and 290, the text in the existing regulation says that you must have training and experience to cover the topics in the alternate pathway, and it has been interpreted by some people that does not include the hours or the requirement for the work experience to be under the supervision of an authorized user.

And so the recommended change is in conformance with what we have in 390(a), is the change alter hours of training and experience to as described in Paragraph C(1)(i) through C(1)(ii)(g), and so that would include the introductory text at the beginning of Paragraph (i).

Do you have any discussion?

DR. MALMUD: Is there any discussion?

MR. LIETO: This is Ralph Lieto. I'm still not quite sure in reading this. What is it that is not being covered? Because it seems like the training and experience topics, the alternate pathway

are reference to those sections or am I off base here?

DR. HOWE: The interpretation is that the topics are, indeed, included, but what is not being included is that introductory text on C at the beginning that says the supervised work experience. "The work experience under the supervision of an authorized user who meets the requirements in" and then the appropriate section is not being picked up because they're only picking up the topics, and the topics would be that text that's in the capital letters for 190 and then in 290, I believe it's also in the capital letters.

DR. WILLIAMSON: This is Jeff Williamson.

I must confess I'm a little confused as well. I'm looking at Paragraph 35.290 in the --

DR. HOWE: Yeah, let's focus on one of them.

DR. WILLIAMSON: -- printed edition, revised as of January 1st, 2006, to make sure I understand what language is changed, and I'm not sure where in the -- perhaps you could read the paragraph, the full paragraph, and tell us exactly where the insertion occurs. Maybe that would help. It would help me.

DR. HOWE: Yes. In Paragraph A(1) of 290,

it says, "Complete 700 hours of training and experience in basic nuclear handling techniques of radiation safety applicable to the medical use of unfilled byproduct material for," and we've revised this to say, "imaging and localization studies that includes the topics listed in Paragraph C(1)(i) and C(1)(ii)."

And by saying C(1)(i) and C(1)(ii), that when you read it, you skip right down to the topics, and so you're not necessarily kicking in the supervised work experience text that starts at the beginning of C(1)(ii). It says only the topics.

DR. WILLIAMSON: All right. So the change is not the 35.290(a) but 35.290(a)(1).

DR. HOWE: That's correct.

DR. WILLIAMSON: Okay. That's one.

DR. HOWE: Sorry.

DR. WILLIAMSON: The way I'm confused here. So the motion isn't quite complete.

DR. HOWE: Okay. And so what I'm recommending saying is that instead of saying the training that includes instead of saying the topics, I would say "as described in" and then I would start the beginning of the description at C(1)(ii), and I would conclude it at the bottom of C(2)(ii).

So I would go C(1)(ii) through C(2)(ii)(g), and that leaves out how the hours are split up in C(1) for the Board certification pathway, but includes the work supervision under supervised authorized user.

MR. LIETO: Dr. Malmud, this is Ralph Lieto.

DR. MALMUD: Yes, Ralph.

MR. LIETO: You know, Jeff's direction here has kind of helped out a little bit, but I think that really this change would need to be tabled. I would like to see this with the strikeouts and the additions because from what I'm hearing, it's almost like we're adding something here rather than clarifying, and I'm really reluctant to have any change in this rule that's going to potentially be interpreted as an added requirement.

DR. HOWE: The intent was not to have it be an added requirement, but just to bring in conformance with the text in 390, which is clear that you start at the beginning of a section and you end at the end of the next one. So all of the text in between is captured.

DR. WILLIAMSON: Somehow there are two things you're changing. One is you're arguing that

the current text -- this is Jeff Williamson, by the way -- states topics listed in Paragraph C(1)(i) and C(1)(ii) of this section, you believe that it is not clear that this includes all of the subsections in C(1)(i) and C(1)(ii). So that's one problem.

And another problem is you are also changing the phrase from "includes the topics listed in Paragraph" so-and-so to "training and experience as described in Paragraph."

So somehow it seems like we're making the word "certification requirement" more prescriptive now.

DR. HOWE: Okay. I can table this and bring it back in a longer red line strikeout.

DR. WILLIAMSON: It is very subtle, I must confess. I'm trying to --

DR. HOWE: If you look at --

DR. WILLIAMSON: -- understand what's missing from the current text.

DR. HOWE: The attempt originally when they revised the regulation for the board certification was to make sure that the number of hours required under the board certification route was not split into specific hours for training and experience as specific hours for work experience. So

it was supposed to be a total number of hours, and you could sort the hours out however was best for the individual for the board certification route.

And then the alternate pathway, you had to have specific hours and training and experience. And so when they rewrote it, they used two different approaches, one approach in 190 and 290, and then another approach in 390.

And I believe the approach in 390 is much clearer, and so that's why I was recommending that this be revised to be in conformance with 390, but I can table this if you want.

DR. WILLIAMSON: May I ask one last question of clarification? So is the intent that under the board certification route that 80 hours must be classroom and laboratory and no more than 620 can be practical training and experience, or is it intended that this more prescriptive split as opposed to just 700 hours total be implemented only for the alternate pathway?

DR. HOWE: The split, let's say, on 290 between 80 hours for training and experience and the rest of the hours in supervised work experience was intended only for the alternate pathway. The board certification route is supposed to be just a total of

700 hours.

And so there was a little bit of tricking writing in how to get there.

DR. WILLIAMSON: I see, and I'm worried that your phraseology make the board certification have to divvy it up in prescriptive ways.

DR. HOWE: No, by starting it C(1)(ii), you have skipped Paragraph 1.

Do we have some kind of phone call going on?

DR. MALMUD: Is there someone else engaging in another call?

DR. HOWE: Okay. When you look at the text in 290, you'll see that Paragraph A(1) starts with C(1)(ii).

DR. WILLIAMSON: I see.

DR. HOWE: By starting at C(1)(ii), you have skipped the preliminary information in C(1).

DR. WILLIAMSON: I see.

DR. HOWE: And the preliminary information in C(1) is what splits the hours. So the board certification doesn't split the hours. It just has total hours.

DR. WILLIAMSON: Okay. Makes sense.

DR. HOWE: And if you looked at the

wording in 390, you would see that the way it's written in 390(a)(1), and it says as described in Paragraph B(1)(i) through B(1)(ii)(e), you skip B(1) which has the hours breakdown. You go directly to B(1)(i), and then you continue all the way till you get down to the clinical case work so that you've included the text at the beginning of (ii) that says "work experience under the supervision," and that makes it very clear that this work supervision is under an authorized user as opposed to just having to cover the topics.

MR. BAILEY: Dr. Malmud.

DR. MALMUD: Yes, sir.

MR. BAILEY: This is Ed Bailey.

I'm going to have to drop off the line.

DR. MALMUD: Did you have a comment, Mr. Bailey?

MR. BAILEY: Not on this issue. Okay?

DR. MALMUD: Thank you.

MR. ESSIG: And did someone else join while in the last few minutes or so who hasn't been recognized?

DR. SCHENTER: Bob Schenter.

I just joined.

MR. ESSIG: Okay. Thank you.

DR. MALMUD: Now, Dr. Williamson, this is Malmud.

DR. WILLIAMSON: Yes.

DR. MALMUD: Dr. Williamson?

DR. WILLIAMSON: Yes.

DR. MALMUD: Did Dr. Howe's explanation satisfy your concern?

DR. WILLIAMSON: For one part of the change, yes. I think that it's changing it from Paragraph C(1)(i) and Paragraph C(1)(ii) to Paragraph C(1)(i) to C(1)(ii)(a) through (f) I agree is a clarifying change. I see no harm in that.

DR. MALMUD: Thank you.

DR. VAN DECKER: Dr. Malmud.

DR. MALMUD: yes.

DR. VAN DECKER: This is Bill Van Decker.

DR. MALMUD: Yes, Bill.

DR. VAN DECKER: I have to say that when I initially looked at this my belief had been that the intention had been as has kind of been brought out by the current verbiage that the goal here was to make sure that the clinical training and experience part was not wrapped into being a didactic experience and that it was under the supervision of an authorized user who was capable of doing that.

I think that that as a gestalt is probably what we're looking for.

I would also agree with Mr. Lieto that as the conversation has gone on and the rulemaking language has gone, I'm starting to feel uncomfortable about making sure we don't get unintended consequences in this, and as such, I would probably prefer personally to see this thing out in long hand with all of the rulemaking language, although if what I've said is the concept, I don't think that I'll have any personal problems with it.

DR. EGGLI: This is Doug Eggli.

DR. MALMUD: Yes, Dr. Eggli.

DR. EGGLI: I actually have the printed version in front of me since I printed it out and I am looking at it, and I think Dr. Howe is, in fact, accomplishing what she has set out to do, and I do not believe with the printed copy in front of me that the prescriptive piece of C(1) is included. It just simply adds that it has to be under the supervision of an authorized user.

So I believe that, in fact, the intent has been accomplished.

DR. MALMUD: Thank you, Dr. Eggli.

Do we need a motion to approve this?

MS. FLANNERY: Yes.

DR. MALMUD: Is there a motion to approve this?

DR. EGGLI: This is Eggli.

So approved or so moved, rather.

DR. MALMUD: Eggli makes the motion. Is there a second?

DR. VETTER: Dick Vetter seconds it.

DR. MALMUD: Vetter seconds it.

Any further discussion?

DR. WILLIAMSON: Jeff Williamson here.

Now having understood one part of this rulemaking proposal, I'm having difficulty understanding why the language as written doesn't obligate, you know, the board certification to having training carried out under the supervision of an authorized user because it basically says -- oh, I see. You want to replace "includes the topics listed in Paragraph C(1)(i)" with "as described in Paragraph C(1)(i) through" whatever.

That is the major change; is that correct?

DR. HOWE: That's correct.

DR. WILLIAMSON: So you believe that currently this makes a loophole in 290 where someone could have the 700 or some board could come along and

700 hours of training and experience supervised by short order cooks instead of authorized users, for example, is theoretically possible.

MR. LIETO: This is Ralph Lieto.

Let me take a look from your side of the fence here, you know, not being on the side with the short order cook. What is being recommended would preclude, say, radiation safety being done and provided under a medical physicist or an RSO because it says it has to all be done under an authorized user.

So if someone went to someplace and had didactic work done or even some type of a training course where you're doing hands on work under the auspices of a medical physicist for an hour or so, that wouldn't be recognized the way the rewording would occur.

DR. HOWE: Mr. Lieto, the intent is that the work experience for everyone in 190, 290 or 390 be under the supervision of an authorized user. That doesn't necessarily mean that the authorized user has to, you know, provide or be supervising directly all of the work experience, but the work experience should be under the authorized user.

We're not talking about the didactic

classroom training because that can be provided by anyone.

DR. WILLIAMSON: Well, I think that to answer -- this is Jeff Williamson -- to answer Ralph, he raises a good point. What they're trying to exclude is forget the short order cook, which was intended to be amusing and not serious, but I guess you could sort of imagine a nonclinical facility staffed by physicists and radiopharmacists that would do everything except prescribe and deliver treatments to patients, but receive radionuclides and, you know, do all of these tests and so on. That's what they're trying to exclude.

They want this to occur in the context of a clinical operation, I think. Is that the intention?

DR. HOWE: That's correct.

MR. LIETO: Well, I guess I still feel that this should be tabled so that we can see it all laid out in the language. I see feel uncomfortable with approving a change without seeing how this wording is exactly going to be fitted into the proposed rulemaking.

DR. HOWE: Now, I would also remind you that this is a potential. So we would send this as a memo to the Rulemaking Branch, and so if they elevate

it to actual rulemaking, you will see this many times before it becomes a proposed rule or a final rule.

So this is not your one and only opportunity to comment on specific words.

MR. ESSIG: Yes, this is Tom Essig.

Just to remind us what we're discussing here, as Dr. Howe just articulated, the process is that my branch would send what we call a user need request to the Rulemaking and Guidance Branch. They would prioritize in the other rules that they have in front of them. This may, depending on the basis that we articulate, the safety basis, that will kind of determine where we are to rank priority-wise.

If it's merely a clarification and doesn't have a strong safety basis, it may be ranked in the medium to low priority, and if it has a strong safety basis, it could be elevated, but even then, it is pitted against those rules that have already been prioritized as having a high safety basis, and that would probably impact the timing that the Rulemaking and Guidance Branch would undertake it.

But as Dr. Howe noted, you will have definitely, even if it gets through those wickets, you will have many more bites at the apple.

PARTICIPANT: This is (unintelligible).

So let me ask you this. Is this going to be sent out; after we approve this, is this going to be sent out as being endorsed by the ACMUI or recommended by the ACMUI?

DR. MALMUD: For those that we agree on, yes. I mean, if the committee, as we did in the meeting last month, we had the first seven items. I believe we moved and passed on all of them.

MS. FLANNERY: A minor change to one.

MR. ESSIG: With minor changes, and we just wanted to pick up where we left off, and that's the purpose of today's call. So if there are changes that the members wish to offer, modifications, clarifications or just outright tabling of it, certainly we'll be responsive to that.

DR. WILLIAMSON: This is Jeff Williamson.

I think with the discussion and the combination of this nice, yellow/white book, Code of Federal Regulations, I am able to agree with it. I would offer a friendly amendment that we change the slide to read "35.190(a)(1)" and "35.290(a)(1)" from its current reading of 35.190(a) and 25.290(a).

DR. HOWE: That's okay.

DR. MALMUD: That's a motion from Dr. Williamson.

DR. WILLIAMSON: It's a suggestion to modification of the motion on the table, which is Dr. Eggli's motion.

DR. EGGLI: Yeah, this is Eggli.

I accept the modification.

DR. MALMUD: All right. The motion has been made. Is there a second to the modified motion? Dr. Eggli?

DR. WILLIAMSON: I will second it.

DR. MALMUD: All right. Any further discussion?

DR. EGGLI: This is Eggli again.

Again. to reassure the people who don't have the printed copies in front of them, I also now have a printed version of 390 in front of me, and the language change that Dr. Howe is proposing is completely consistent with the language as exists in Part 390.

DR. MALMUD: All right. All in favor?

(Chorus of ayes.)

DR. MALMUD: Any opposed? I'm sorry.

MR. LIETO: Ralph Lieto, opposed.

DR. MALMUD: Ralph Lieto opposes. Any other opposed?

(No response.)

DR. HOWE: Abstentions?

DR. MALMUD: Sally Schwarz abstains.

DR. SCHWARZ: No, I was for.

DR. MALMUD: I'm sorry.

DR. HOWE: I was just asking. I was just asking if there were any abstentions because I hadn't heard any.

DR. MALMUD: Oh, I'm sorry.

DR. HOWE: Sorry, Dr. Malmud.

DR. MALMUD: I apologize. All right. So there's one who is not in agreement. No abstentions. The motion carries. Thank you.

Dr. Howe.

DR. HOWE: Okay. Slide No. 9 is a problem that has been identified to us, and we're bringing it to the ACMUI to see if you think it's something that we should pursue. It's not something that would happen overnight, and that is we have been told that it is and we also know that most facilities use unit doses, and that very few facilities will elute generators. Even broad scopes will use unit dosages, and in 290, we require each authorized user to have supervised work experience under a 200 authorized user in eluting generators, and we are asking the ACMUI whether it believes it would be a good idea or not to

explore the idea of possible two training and experience pathways for 200 physicians, one for physicians that can only administer unit dosages and the other for physicians who are permitted to prepare radioactive material.

So this is more of a concept type of thing that we're asking you for versus specific rule language.

DR. EGGLI: Mr. Chairman, this is Eggli.

DR. MALMUD: Dr. Eggli.

DR. EGGLI: We actually discussed this topic at the last ACMUI meeting, and again, commercial pharmacies are generally willing to help it in that line and provide that generating elution experience. I do not believe here is any real difficulty in obtaining that particular experience.

DR. MALMUD: Are there other comments besides that of Dr. Eggli?

DR. VETTER: This is Dick Vetter.

How would the NRC track these two different means of training?

DR. HOWE: I think that would depend upon how a rule language change came about. We might have something that indicated that you had training experience up to a certain point, and if you had up to

that point which didn't include generator elution, then we would authorize unit dosages only.

So I'm not sure how it would work out, and so I did not provide specific rules, potential rule text for it.

DR. VETTER: This is Dick Vetter again.

What I'm envisioning is a physician who would train under the route where he or she received permission or has the training for unit dosages, and then one day moves to a facility where they have a generator, and they're not using unit doses. As a matter of fact, the physicians aren't going to be administering anyway. It's the technologists who administer the dose, but the physicians are the authorized users. The technologists work under the supervision of the authorized user.

So I envision that down the road a ways it could get a little bit complicated.

DR. HOWE: It could.

DR. SCHWARZ: I'm Sally Schwarz.

I have a comment, a question also in regard to this. If you eventually are establishing two different physician authorizations, one that uses unit doses and one that elutes generators, will you then similarly change the requirements for training

for these physicians who are only going to be using unit doses?

Because it seems that essentially what you're saying that they most likely wouldn't be preparing radiopharmaceuticals, which then it seems like the amount of didactic training maybe could drop down significantly for the group only using unit dosages.

DR. HOWE: Those are the kinds of things that would be discussed in detail if you decided that it would beneficial to go and explore this as a rulemaking option. And how that would come out I don't know at this point. It's just way too early.

It would also affect how we have authorized, the authorizations we have in 35.100, 200 and 300 that allows physicians with 290 physicians to prepare radioactive drugs. So there are a number of interacting part that would have to be worked out, length of training and experience, how we would designate between the two, and then how it would affect 100, 200 and 300 materials.

So there are a number of issues that would be discussed if it went to rulemaking.

DR. WILLIAMSON: This is Jeff Williamson.

Could I ask a question, namely, because I

think the nuclear medicine experts in our group? This seems like it's a lot of additional complexity to create another two tracks within 35.200 and 300, and does the experience eluting generators really contribute materially to patient safety and quality treatment or, you know, as an alternative to leaving it alone?

Simply dropping it from the regulations, would that substantially diminish or jeopardize public safety?

DR. EGGLI: This is Eggli.

Let me speak to that issue if I might. When we reviewed iodine incidence, two or three of those errors were committed by central pharmacies, and I think if the authorized user doesn't really have a feel for what goes on in a central pharmacy, they're less well prepared to catch the errors that are made in a central pharmacy.

I would personally be reluctant to remove that requirement, and again, I do not believe there is a serious burden trying to achieve it.

DR. WILLIAMSON: I guess my question is: does eluting a generator, which seems to me has nothing to do with Iodine 131, which is the issues you address, it has to do with technetium based agents; am

I not correct?

DR. EGGLI: We get wrong things out of our central pharmacy all the time that we catch. I think the comment is generally extendable to technetium labeled radio pharmaceuticals as well.

DR. WILLIAMSON: So what does the rating the generators have to do with learning the category and modes of failure of a commercial pharmacist? That's my question.

DR. MALMUD: That's your question, Doug, to you from Dr. Williamson.

DR. EGGLI: Yeah, I know. I need to think about that a little more. I guess I think that it's in general a useful experience, and I would be reluctant to remove it.

DR. WILLIAMSON: I think that my advice, just my suggestion for you guys, for the nuclear medicine part of our community, is this is a lot of complexity for a very indirect way of getting at something that, you know, I have no basis for disagreeing with you on that it's important to understand the failure modes upstream of product cycles when you buy something.

But maybe it would be better to modify the regulation in a more straightforward way that gets at

what your concern is that wouldn't be so complex and clumsy as creating this very artificial two track pathway.

Because even if you get unit doses, you know,, it just seems very strange. That's all.

MR. LIETO: this is Ralph Lieto.

To answer Jeff's question, one thing that needs to be understood is that everything that happens in that department is under the auspices of the authorized user and that includes all of the formulation of kits that go on, the distribution, the quality control and so forth.

And so they should have an appreciation and a good basic understanding of what those operations entail, and like Dr. Vetter indicated earlier, you know, they may learn it, and if they were not required to learn this and go into a setting where you do have like a pharmacy operation and they are an authorized user, they need to understand what types of problems will arise from that. And so I would support keeping it in there.

The other point I wanted to make is that unless there is a specific request from a professional society to change this, I think the NRC ought to just, you know, run as far away from this as possible.

Leave things as they are because I think you're just going to open up a hornet's nest trying to come up with some type of rulemaking language that's going to create this second track and then expect that from state to agreement state to NRC state that these credentialings are going to follow this person. I think it's just a very, very large problem.

My question to NRC staff is that at the last meeting we had, I thought, agreed that there were other opportunities by which individual physicians could get this training which would be going to centralized pharmacies, also getting what was called dummy or dead generators and practicing on those.

It has come to my attention on this issue since the last meeting that some licensees that provide training on this topic have been told they have to be done with live generators that elute activity. And I don't know if that's just a misunderstanding or maybe a regional interpretation, but I think that really needs to be addressed from headquarters down to the regions.

DR. SCHWARZ: Sally Schwarz.

Since I'm a nuclear pharmacist and have been involved in eluting generators and training residents for about 30 years, I think that certainly

it's a process to understand as far as nuclear medicine is concerned. I don't know that you necessarily need to perform the elution. You can observe the elution. You can use the dummy generators and Rob was pointing out.

I know Mallinckrodt will provide those dumb inflation generators to us, and that might be a route to go that even observing the elution of a generator would be useful in terms of training. The fact that you elute it one time is maybe explaining techniques to learn, but I don't know. I mean, observing might be satisfactory as well or at least the use of the nonradioactive generators, I mean, that certainly could be something that's allowed as opposed to a radioactive generator.

But then if you're using non-radioactive generators and you're talking about training for radionuclidic acuity analysis, you don't have really any way to do that step. So the observation of the procedure is, again, maybe sufficient as well.

But I think two pathways probably becomes more problematic than it's worth.

DR. HOWE: This is Dr. Howe.

Just a clarification. Our requirements in 290 is that the applicant have work experience under

supervision of an authorized user, and it's eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies.

Also measuring and testing the eluite for radionuclide purity and processing the eluite for reagent kits to prepare labeled radioactive drugs; so that is not watching somebody elute a generator, and that's not a generator with no radioactivity. That certainly could be an old generator that doesn't give a lot of activity, but there's supposed to be the performance part of that is that they have experience eluting the generator under supervision and that they have experience in measuring and testing for the radionuclide purity and processing for radioactive drugs.

DR. MALMUD: Thank you for clarifying that, Dr. Howe.

This is Dr. Malmud.

There is a discussion ongoing then regarding this issue. Any other comments regarding the issue?

DR. VAN DECKER: Yes, Dr. Malmud. This is Bill Van Decker.

Let me weigh in.

DR. MALMUD: Doctor.

DR. VAN DECKER: I also would agree with just about what everyone has said so far, that creating two tracked categories in 200, which is a diagnostic radioisotope category is going to create tremendous difficulties as far as people changing sites, and I think that it adds tremendous complexity to something that does not need to be there, and that there are other ways to go about making sure that people have experience, even if they are going to unit does sites.

And I think that having that flexibility allows us to create access for studies and it brought a variety of venues, and I think that that's important for the patient population in the country.

DR. MALMUD: Thank you, Dr. Van Decker.

Is the feeling of the Committee therefore that we should not alter the current regulation with regard to this issue?

DR. EGGLI: This is D. Eggli.

That is my feeling.

DR. VETTER: This is Dick Vetter.

I agree.

DR. SCHWARZ: I agree.

Sally Schwarz.

MR. LIETO: Ralph Lieto.

I agree.

DR. WILLIAMSON: Jeff Williamson.

I agree.

DR. HOWE: Dr. Malmud, has someone made a motion?

DR. MALMUD: No. I was just asking what they were thinking. I will ask for a motion now and the motion would be presented by whom? Dr. Van Decker?

DR. VAN DECKER: Well, I thought Dr. Eggli would take the lead, but I would say that my motion would be that although some of the statements here about unit dosing being most common are all true, that we believe that attempting to create artificial categories within diagnostic 200 would add a tremendous level of complexity that is not necessary for safety and would limit access to patients and, therefore, we would not recommend this situation.

MEMBER EGGLI: This is Eggli. Although I would have made the motion, I could not have done it as eloquently as Dr. Van Decker. But I will certainly second it.

CHAIRMAN MALMUD: This is Malmud. May we abbreviate the motion to simply state that the

committee reaffirms its commitment to the regulation as it exists?

MEMBER EGGLI: It's not nearly as eloquent as Dr. Van Decker.

CHAIRMAN MALMUD: I understand. But I thought that brevity might prevail.

MEMBER VAN DECKER: Dr. Malmud, which one of us is from New Jersey?

(Laughter.)

CHAIRMAN MALMUD: You're from Jersey.

(Laughter.)

Is that acceptable to you, Dr. Van Decker?

MEMBER VAN DECKER: That is acceptable to me, Dr. Malmud.

CHAIRMAN MALMUD: And then, the second to the motion would be Dr. Eggli?

MEMBER EGGLI: Acceptable.

CHAIRMAN MALMUD: All in favor of the motion?

(Chorus of ayes.)

Any opposed?

(No response.)

It carries unanimously.

Thank you, Dr. Howe, for bringing the concept before us. May we move on to the next item?

DR. HOWE: Yes. On slide number 10 -- actually, slide number 10 and 11 are interrelated. One addresses supervising authorized users, and the other addresses the preceptor authorized user. So the concepts are essentially the same.

And the issue is that in 390, you have the board certification pathway, and then you have the alternate pathway. And when you get to the person that is -- is supervising the work experience in paragraph (b)(2)(i), you end up with -- let me see. The basic element is if you're coming to the board certification pathway, which is 30 -- 390(a), you go into the -- the critical experience is not included in the board certification pathway. It's something that is attested to after the certification part.

And if you look at the clinical part, you'll see that instead of 390 requiring all four types of clinical experience, it has an and/or at the end. And so you could come through 390 with less than four of the clinical experiences, and the board certification pathway could also come through with less than four of the clinical types of casework.

And when you get to the alternate pathway and you have the supervising work experience, you read that the supervising work experience -- only the

person coming through the B pathway has to have the same experience in dosaging as the person they are training. And they do that by coming through the board certification pathway -- for people that have come through the board certification pathway.

So I am recommending that the text in 390, which very similar but not quite the same text shows up in 392 and 394, be revised so that regardless of how you get your authorization, if you're the supervising authorized user you have to have clinical experience in the same type of administration that you are providing training for. That's the bottom line.

And so it's to rectify that, where it says, "The supervising authorized user who meets the requirements in 390(b) must have the experience in administering dosages," I would recommend taking out the letter B, so that anyone coming through the 390 process, whether it's A or B, the supervising authorized user has experience in administering dosages of the same dosage category as those required in the regulation.

CHAIRMAN MALMUD: Thank you, Dr. Howe. Is there discussion? Is that a motion, Dr. Howe?

DR. HOWE: I can't make a motion.

CHAIRMAN MALMUD: Yes. Is that something

you want to have presented as a motion?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Does anyone care to make that a motion?

MEMBER EGGLI: Sure. This is Eggli. I'll do that.

MEMBER VETTER: I'm Dick Vetter. I'll second it.

CHAIRMAN MALMUD: So Eggli makes the motion, Vetter seconds it. Now it is open for discussion. Does anyone wish to discuss the motion?

MEMBER LIETO: This is Ralph Lieto. I think this is getting overly prescriptive. What this is saying is that if you have an authorized user who, let's say, may have experience in doing I-131 and I-131 monoclonal antibodies, they would not be qualified to supervise somebody doing a Zevalin administration.

And I think that if you are an approved user under 390 that, you know, there is just I think a level of prescription that we're creeping into that just makes this I think totally unnecessary. What is -- I guess my question would be: what is the problem that has been presented that we're trying to fix?

DR. HOWE: Just to clarify, Mr. Lieto, the

types of clinical experience that are required are two different activity levels for oral I-131 and then two different types of parental administration. So if the drugs were in the same group, the I-131 monoclonal antibody would come under group number 3.

So if you were giving a Zevalin versus a Bexxar, and you were still in group 3, that would be considered okay. So we're not going any deeper than the types of clinical experiences that are in subparagraph G in 390.

What we're saying is that we would -- in one case you're expecting -- you're holding the alternate pathway user to a higher standard than you're holding the board certification supervising authorizing --

MEMBER WILLIAMSON: But that is built into the structure, certainly, of 35.400 and 600, and we agreed a long time ago that 300 was kind of in the middle where, you know, there had to be kind of a transition from the 200 style of doing things to the radiation oncology style of doing things, and that, yes, board certification should count for something as a -- you know, kind of a national seal of approval that this person has generalizable clinical experience and judgment and is able to do something a little bit

different than they were exactly trained for.

So I agree with Ralph. I think this is a mistake.

CHAIRMAN MALMUD: Any other comments?

(No response.)

All right. A motion has been moved and seconded. All in favor of the motion?

(No response.)

All opposed to the motion?

(Several negative responses.)

Any abstentions?

(No response.)

The motion is defeated.

Thank you. May we go on to the next item?

DR. HOWE: Item Number 11 is similar to Item Number 10, and that says that the preceptor authorized user should have the same qualifications as the person that they are precepting. And the difference, once again, is that the clinical experience is not required. All the elements of the clinical experience are not required in the board certification route.

The clinical experience is attested to outside of the clinical -- outside of the board certification route, and so the change would be to

ensure that the preceptor authorized user, regardless of the route they came through, has the same clinical experience as the person that they are supervising -- the person that they are attesting for.

So that would ensure that if you have a person that wants attestation for parental administrations, they are a preceptor authorized user, would have experience in parental administrations and not just I-131.

CHAIRMAN MALMUD: Does anyone wish to make a motion, so that we can discuss this issue?

MEMBER LIETO: This is Ralph Lieto. I would move, based on the same arguments as before, that this not be -- that the NRC not proceed further with this suggested recommendation.

CHAIRMAN MALMUD: Is there a second to Mr. Lieto's motion?

MEMBER SCHWARZ: I second the motion.

CHAIRMAN MALMUD: Dr. Schwarz seconds the motion. Any further discussion?

(No response.)

All in favor of the motion, which is not to make the change?

(Chorus of ayes.)

Any opposed to the motion?

(No response.)

The motion carries unanimously.

Next item?

DR. HOWE: Good. The next item is 35.396, and we have had a number of people that have erroneously interpreted 396(d) as standing alone. And what we are recommending is just rewriting 396 so that it is perfectly clear, that all of the text in paragraph D is included -- is part of the requirement for C1 or C2 -- B and C -- and that the current paragraph D does not stand alone, and a person has to have the experience in radiation oncology before this paragraph comes into effect.

Now, our General Counsel has determined that D does not stand alone, but we're just trying to make it perfectly clear to people in more of a plain English if that's possible, that the information in D is part of the requirements in B and C, and doesn't stand alone.

CHAIRMAN MALMUD: All right. Would someone care to make that motion?

(No response.)

Would one of the radiotherapists or physicists care to make the motion?

MEMBER WILLIAMSON: Jeff Williamson here.

So moved.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER VETTER: Dick Vetter. Second.

CHAIRMAN MALMUD: It has been moved and seconded. Is there discussion of this motion?

MEMBER LIETO: I feel, without reading this very carefully, which, you know, this is a long section in the -- on page 589 and 590 of the Code of Federal Regulations, I feel unable to discuss this issue without it being explained in far more detail and having an opportunity -- you know, an opportunity to really study this.

DR. HOWE: Okay. Essentially, what I've done is I have taken paragraph D1 to the end, renumbered that C2. So all of that text in D1 is now called C2. Okay? And the paragraph that was C is now -- because Part J is no longer in the regulation, so that simplifies the text a lot. That is now called C1. Therefore, you see C1 and C2 are combined together, and you need to meet those criteria.

And then, I went up into paragraph B, which is where you are already an authorized user under 400 or 600 uses, and I made it clear that those individuals have to meet the requirement in C2, which

is the 80 hours of classroom; C3, which is the work experience; and C4, which is the attestation.

MEMBER LIETO: I have to, you know, understand the basic purpose of the 35.396. So this is a special pathway for -- I think that lets either authorized users under 35.400 or 600, regardless of how they got there, or those who are board certified according to a board recognized by the Commission for 35.400 or 600, to let them use a single class of photon-emitting radionuclides, radiopharmaceuticals, you know, essentially any beta emitter or low energy radionuclide -- so, for example, strontium-89 -- for example, metastron. Is that correct?

DR. HOWE: That's correct.

MEMBER LIETO: Okay. And so the concern is that once somebody -- some physicist or fry cook out on the street could come and say, "I have completed 80 hours of training" and not even have an M.D. and apply to be an authorized -- what is the concern exactly?

DR. HOWE: The concern is the interpretation of the rule. We have had people that have mistakenly interpreted that paragraph D1 and -- let me see if I've got -- flip the page here. D1, D2, D3 are stand-alone requirements and are not tied to

paragraphs A, B, and C. Well, they're not tied to A, because A, you're already authorized under 390 for it. But that they are not tied to paragraphs B and C, and --

MEMBER LIETO: This is Ralph Lieto. Why not just put the word "and" after paragraph C?

DR. HOWE: When you do that, it sounds as -- that changes the regulation. That does not fix the problem.

MEMBER WILLIAMSON: I'm not sure I see there's a problem. This is very clear. It says that -- if you read it from the beginning, it says you can be a B or a C, and then do this different activity that's not allowed directly under 35.400 or 600, if you comply with D. And I would assume -- you know, it doesn't say just D, but, you know, I would assume all of the subparts of D, depending upon how they're connected with -- strung together with conjunctions or disjunctions, you know, would apply as specified, not just the top part of D.

DR. HOWE: If this is the top of D, it's -- our Office of the General Counsel says this is the way -- you have to start at the beginning of this paragraph, up at the top, and read. And when you read, you essentially quit reading when you get to the

period at the end of C. So D cannot stand alone.

But we have people that don't interpret it that way, and so we were just trying to write it in a -- in a way that is easier to see that there is no part of it that stands alone.

MEMBER LIETO: This is Ralph Lieto. I would disagree with making these suggested changes, because you're renumbering paragraphs, reordering them. I -- you know, I would either at a minimum table any action on -- by the committee on this specific item, and at best I think we should just leave it alone.

MEMBER NAG: This is Dr. Nag. You are saying that there has been problems, that people were saying that D was a stand alone. I mean, has anyone really -- has anyone analyzed it based on only the 80 hours without having 490 or 690 training?

I thought it was quite clear they put 490 or 690, and then you have to have the extra 80 hours. That's the way I have been telling the Radiation Oncology Committee -- I mean, community anyway.

DR. HOWE: When you come into the NRC we very clearly -- if people have the wrong interpretation of this, we straighten them out fairly quickly. But we have had -- we have seen a lot of

discussion on RADRAP where people have interpreted it wrongly, and they haven't been in NRC jurisdiction.

MEMBER NAG: Yes. Also, when you said that, I think I do remember seeing some ads basically from some people who are offering an 80-hour training to allow them to use yttrium and, you know, any of these other things. So I guess -- I guess some people are not clear.

DR. HOWE: That's our problem; some people are not clear.

MEMBER WILLIAMSON: This is Jeff Williamson. I think it reads pretty clearly to me. And since the Office of General Counsel has given you a -- told you basically that the interpretation is sort of the obvious one, and, moreover, an interpretation that adheres to the underlying intent, I would not support the proposal, because I think it's a lot of trouble and we'll probably make some other mistakes which may have unintended consequences.

CHAIRMAN MALMUD: Is there any other discussion of this?

MEMBER LIETO: Dr. Malmud, this is Ralph Lieto. I don't know if we want to make this a recommendation, but I think we should defeat this. And I think using the current NRC information avenues

of their FAQs, the newsletter, and if staff feels appropriate that this is something that licensees need to be made aware, maybe an information notice, or all three, that addresses this. But I think we should stay away from rulemaking.

MEMBER NAG: This is Dr. Nag. Can we do it in guidance, so that we make it clear that this paragraph means you have to have 490 or 690 plus the 80 hours? If we can do it in guidance rather than rulemaking.

DR. HOWE: Yes, we can.

MEMBER NAG: I would support to have it done that way.

CHAIRMAN MALMUD: Dr. Nag, would you make a motion that this be achieved via guidance?

MEMBER NAG: This is Dr. Nag. I make a motion that the paragraph about 490 and 690 users needing or requiring a further 80 hours training in isotopes be clarified under guidance rather than having a separate rulemaking.

CHAIRMAN MALMUD: Thank you. Mr. Lieto, would you care to second that?

MEMBER LIETO: I will second that. And, Mr. Chairman, just a point of order -- I think we had a previous motion to approve this. So I think we

would need to maybe -- I would like to urge my committee members to defeat the first motion, and then we could vote on the second one.

CHAIRMAN MALMUD: All right. I'll call the vote on the first motion. All in favor?

(No response.)

All opposed?

(Several negative responses.)

Any opposed to the opposition?

(Laughter.)

So it's unanimous. We oppose the first motion.

And now the second motion was to request that Dr. Howe achieve the same goal via guidance. All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

So that there is approval of Dr. Howe's recommendation, but that it be achieved via guidance.

Thank you. Next item?

DR. HOWE: Thank you very much. Okay. The next item is also -- 13 and 14 are related, and they are dealing with medical physicists, authorized medical physicists, specifically for 35.433 users,

which is the strontium eye applicator.

Slide number 13 is -- we brought this issue to the ACMUI before in requesting exemptions for individuals that don't meet the criteria for authorized medical physicists that want to do the strontium eye applicator decay corrections and other activities that would be associated with this, and we've had differing opinions on the ACMUI.

And one thing was the ACMUI indicated they'd like to reexamine this issue and possibly come up with a clear description of what the tasks are for the medical physicist that is associated with the strontium eye applicator use.

And so Item Number 13 -- or slide number 13 would be a recommendation to revise 35.433 to expand the description of tasks responsible for -- the responsibility for the medical physicists prior, during, and after use of strontium eye applicators, so that we have a clear understanding of what this individual needs to do and what his credentials ought to be.

MEMBER NAG: This is Dr. Nag. Has anyone written up any drafts of what these new things would be?

DR. HOWE: No. This is something that we

would -- we would work on at a later date. I mean, this is just saying this is an area that ACMUI would like to move forward on with a potential rulemaking.

MEMBER NAG: I would support that. Do you need me to make a motion?

CHAIRMAN MALMUD: Yes, thank you, Dr. Nag.

MEMBER NAG: Okay. I make a motion that 10 CFR 35.433 be revised to expand the description of the tasks and responsibilities.

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

MEMBER WILLIAMSON: Second. Jeff Williamson.

CHAIRMAN MALMUD: Dr. Williamson seconds it. Any further discussion?

MEMBER WILLIAMSON: I think that I would like to just ask a question of clarification. Is the concept to develop a definition of AMP for manual brachytherapy, not just strontium eye applicator?

DR. HOWE: That might be part of what would happen. There may be a recognition with other modalities also that there's a possibility we need another medical -- another description of a medical physicist that would get down into the manual brachytherapy.

But I suspect that if this motion carries, this is an item that will have a lot of debate with the ACMUI, and it's not something that's going to be fixed overnight.

MEMBER LIETO: This is Ralph Lieto. I totally echo Dr. Howe's comments. I think this is going to be a very, very large task, probably maybe something needed in terms of a designation of manual brachytherapy versus the old teletherapy designation for medical physicist.

MEMBER NAG: Yes. I think -- isn't it restricted only to strontium-90 eye applicator? It may be a little bit easier to do that than to do the whole manual brachytherapy. I think the whole manual brachytherapy is going to be a far more difficult task, and I would suggest restricting it only for the I-plat.

CHAIRMAN MALMUD: Thank you. With that discussion, may we move the motion?

MEMBER LIETO: I would like to respond. You know, I think that there are many more challenging roles for the physicist, medical physicist, in manual brachytherapy than performing decay corrections for strontium-90, which, you know, I certainly don't wish to minimize their significance.

But I think that it is a fair observation that the regulations as currently written kind of marginalize or, you know, don't appreciate I think the contribution that the qualified medical physicist does play in manual brachytherapy, and there are many forms of manual brachytherapy which are extremely complicated. It is not just high-dose rate brachytherapy which presents a risk to patients and members of the public if not properly performed, and if there is not a coordinated effort between the authorized user and authorized medical physicist.

So I would recommend, in fact, you know, generalizing this to consider the -- you know, some regulatory mention of the more general role of the medical physicist in manual brachytherapy.

MEMBER VETTER: This is Dick Vetter. I just wanted to point out that paragraph 433 deals only with strontium-90.

MEMBER NAG: Yes. I mean, that is something that I -- I think that was my intention. I was not trying to marginalize the manual brachytherapy or criticizing manual brachytherapy. I was just talking about only the I-plat selection, which is under 433.

So I agree with you about the role in

manual brachytherapy, and that's why I was referring not to manual brachytherapy under this item.

MEMBER WILLIAMSON: So I would just propose changing your motion to 35.400.

MEMBER NAG: 35.433.

MEMBER WILLIAMSON: Yes, I would have proposed changing it from 35.433 to 35.400, so they --

MEMBER NAG: Well, no, that is not my intention. But then, you are trying to embark on a much bigger task that will not -- we won't complete in a few months. It will take probably years.

MEMBER WILLIAMSON: Maybe so, but perhaps it's more worthwhile than this. You know, essentially what they're asking -- the problem is they would probably like undergraduate degree people to be able to do decay corrections, because it causes problems to have an authorized medical physicist do this one duty.

But I think that actually Dr. Howe has brought up the larger problem, and it's -- so I would suggest maybe it should be a different motion that the, you know, NRC and ACMUI should give some future consideration to the role of the physicist in manual brachytherapy generally.

MEMBER NAG: That is fine, but I think that should be a separate item, separate from the much

simpler task of doing the 35.433.

CHAIRMAN MALMUD: Thank you, gentlemen. We do have a motion on the floor. May we move forward with the motion? I think you had seconded it, Dr. Williamson.

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

The motion carries.

MEMBER WILLIAMSON: I abstain.

CHAIRMAN MALMUD: Dr. Williamson abstains.

MEMBER NAG: Dr. Williamson, if you want to make a separate motion that the role of medical physicists in manual brachytherapy be sort of reexamined and categorized, you can make a separate motion. I have no problem with that.

MEMBER WILLIAMSON: Well, that's up to the Chairman to allow that It's not part of the intent.

CHAIRMAN MALMUD: I would suggest we bring that up at a regular meeting. It's a significant issue.

DR. HOWE: I think what I'm hearing is that if -- the next time I bring up potential changes

to Part 35 I include that as one of the items of interest to the ACMUI. That would be the appropriate time.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

DR. HOWE: Okay. Have we finished with Item 15?

CHAIRMAN MALMUD: Yes, Dr. Howe.

DR. HOWE: Okay. Item 14 is an extension of 13, and that is that if we have additional -- the tasks described in 433, then we would have an easier time to permit medical physicists with training and experience in those specific tasks to use the manual brachytherapy sources for 433. So the two are kind of interrelated.

MEMBER LIETO: I'm really confused what the intention of both this motion and the previous motion are.

DR. HOWE: The first one was we have had a number of requests for exemptions. And as we have brought exemptions to the Board, to the ACMUI, one of the concerns that came up was that 433 did not adequately describe the tasks that were really expected of the authorized medical physicist.

And then, 14 is kind of going into the idea that once we describe those tasks you may decide

that you don't need an authorized medical physicist, and it opens up the door to the other concept of studying -- do we have a medical physicist for manual brachytherapy?

MEMBER LIETO: This is Ralph Lieto. This issue kind of strikes close to home here. This should not be up here, because what is intimated by this slide is that if you're an authorized medical physicist, okay, on a license you are not authorized to do strontium-90 decay corrections, which I totally disagree with.

If you're an AMP, period, you're authorized to do this. It doesn't state that you have to be the AMP on that license. Okay? So, for example, Jeff Williamson, as an AMP, if he got asked to do decay corrections for strontium-90 for a hospital in, say, Hawaii, okay, he could do that, because he's an authorized AMP. It doesn't say he has to be on that license.

What this is seeming to indicate is that you need a license amendment to do strontium-90 decay correction, even though you're the AMP on a license or the license. And I think that's wrong.

MEMBER NAG: This is Dr. Nag. I think I understood your slide 13, which is why I made the

recommendation. I don't think I understand slide 14, because if you are an AMP that allows to do the 35.433, which is, you know, what has been described previously, then slide 14 should not even be there. You are not really understanding.

MEMBER WILLIAMSON: I mean, I agree. Then, the motion that over my opposition was accepted in the last slide it would seem to me would cover this, and we need to have a more specific proposal brought before us, and it's unnecessary to vote on at this time.

DR. HOWE: Just to clarify, I guess to address Mr. Lieto's point, we would never prohibit an authorized medical physicist from doing this, because that would still be part of the regulation. It just would make it easier on those people that are requesting exemptions to the regulation to demonstrate they had training and experience that would qualify them for an exemption.

MEMBER NAG: Yes, but that --

DR. HOWE: That was the intent.

MEMBER NAG: This is Dr. Nag. That would be covered under your Item 13, because under Item 13 you are giving them -- you are mentioning what are the specific requirements needed, and one of them would be

decay correction, and so on. So I think Item 13 will cover Item 14 if Item 13 is written correctly.

MEMBER LIETO: Well, no, Dr. Nag, I have to disagree there. This is Ralph Lieto again. Item 14 is totally unnecessary, because all this -- what the regulation states is that an AMP shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatment.

So if you're an AMP, you can do the decay corrections automatically. There is nothing that needs to be changed in 433. It doesn't need to be revised. Okay? Because that task is automatically authorized in the regulation.

So what Dr. Howe was intimating at was an issue that we addressed as a committee where an individual was not an AMP, did not have the credentials to meet an AMP, and he was requesting a variance from 433 to be allowed to do this. Okay? And that's an entirely different ball game altogether.

So I would think that we could just move on to slide 15 and not need to address the -- this suggested revision to Section 433.

MEMBER NAG: That's exactly what I meant. I think that slide -- Item 14 is really no problem

that needs to be resolved there, unless I'm missing something.

MEMBER WILLIAMSON: Well, the problem that -- I think the whole rationale for 13 and 14, I don't know why there are two here --

THE COURT REPORTER: This is the Court Reporter. Could you identify yourself, please?

MEMBER WILLIAMSON: Jeff Williamson. I think the same thing has been stated twice. What's driving this is not a reexamination of the role in manual brachytherapy. It is -- Dr. Howe wants to eliminate the role of the AMP in strontium-90 eye applications. So unless your qualified person can take care of this duty, they don't have as many variances to grant. I think that's what drives both these slides. Why there are two separate proposals, I haven't a clue.

CHAIRMAN MALMUD: This is Malmud. I'm not sure that it's fair to attribute a motive to Dr. Howe without asking Dr. Howe what her purpose was.

DR. HOWE: This is Dr. Howe. I was trying to address what the committee had indicated the last time we looked at an individual that had applied -- a licensee that had applied for an exemption for the eye applicator and had a person that was not qualified to

be an AMP.

And bringing it up in two aspects -- one would actually recognize a medical physicist that had training in those specific tasks to be qualified to do that, in addition to an authorized medical physicist. And the other was to more clearly explain what those tasks were.

So to some extent, the discussion is coming down to your earlier problems that had been discussed in looking at an exemption request.

MEMBER VETTER: This is Dick Vetter. Personally, I think it would read much more clearly if you deleted the words "related to the use of manual brachytherapy sources," because then it's focusing in on one of the tasks that are -- that will be delineated in Item 13.

So it would allow a medical physicist with training and experience in the specific task of decay correction, for example, to perform the task.

DR. HOWE: I think the assumption was whatever those tasks were that came up out of 13 would be what would be inserted in here.

MEMBER VETTER: Correct, but -- this is Dick Vetter again. Correct. But as soon as you throw in manual brachytherapy sources, it just throws the

whole thing wide open. I think we simply have to focus on strontium-90 tasks.

DR. HOWE: The specific tasks related to performing the strontium eye applicator.

MEMBER VETTER: Yes, correct. Whatever the tasks are related to the strontium eye applicator.

DR. HOWE: Okay.

MEMBER VETTER: Does that make sense to people?

MEMBER LIETO: This is Ralph Lieto. I agree.

CHAIRMAN MALMUD: Is everyone else in pretty much agreement?

MEMBER NAG: Yes. Dr. Nag agrees.

CHAIRMAN MALMUD: Thank you. Thank you for clarifying that, Dr. Vetter.

MEMBER VETTER: Well, in that case I would make a motion that we recommend revising paragraph 433 to permit a medical physicist with training and experience in specific tasks identified to perform the tasks of 35.433.

CHAIRMAN MALMUD: That's a motion from Dr. Vetter. Is there a second to the motion?

MEMBER NAG: Dr. Nag seconds.

CHAIRMAN MALMUD: All right. Any further

discussion of the motion?

(No response.)

All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

The motion carries unanimously. Thank you.

MEMBER WILLIAMSON: Oh, I'm sorry. Jeff Williamson. I didn't vote.

CHAIRMAN MALMUD: Dr. Williamson abstains. Let the record show Dr. Williamson abstained. Thank you, Jeff.

The next item, Dr. Howe?

DR. HOWE: Okay. The next three items are related to reportable medical events. In slide number 15, the issue is -- and if you read through all of the text you'll find that a medical event is if it -- if the dose differs from the prescribed dose. And for unsealed material, the prescribed dose can either be in a written directive or in the procedures in the Department. So we don't have a problem if there's no written directive for the unsealed material.

But when we get to sealed material, uses of gamma knives and HDRs, and other therapy type of

devices, if you don't have a written directive, and the dose is given incorrectly from what one would expect to give, or even if you gave a therapy dose to someone who wasn't supposed to get a therapy dose, it's not reportable under the reportable medical events.

And we're trying to fix that loophole that was identified by OGC by essentially saying an administration requiring a written directive -- and we would accept an oral directive meeting the requirements of 35.40(a)(1) -- does not exist at the time of the administration that would be reported as a medical event.

MEMBER WILLIAMSON: Doesn't 35.3045 require -- is not having a written directive grounds for a medical event?

DR. HOWE: No, it does not. Unfortunately, the only way you can get to a written directive is if the dose differs from the prescribed dose, and for sealed sources that prescribed dose is the -- by definition is the dose in the written directive. So if there is no written directive, there is no prescribed dose, and you can't differ.

MEMBER WILLIAMSON: But if they get the therapy administration, regardless of whether it's

correct or incorrect, that's still a violation of regulations, is it not?

DR. HOWE: It would be a violation of regulations, but it would not be reportable. So NRC would not be able to take whatever action it needed to take, whether it was putting out information -- it would not know the event occurred.

MEMBER WILLIAMSON: What would be the basis for doing the calculation of error? I mean, if there is no written directive, meaning no written prescription by the authorized user, what would be the basis for determining that error existed as opposed to just a license violation or a violation of regulation?

DR. HOWE: Yes. In this case, I think you have to separate it from violation. I think what we're really looking at is: is NRC receiving reports of errors in administration? And this is one type of error that we would not receive a report on, and we believe that it's an important error that we should receive a report on.

MEMBER WILLIAMSON: I understand. Forget the -- maybe I confused you with the way I asked the question. Let me try to do it in a more simple way. Granted, it's a problem that there could be two problems to occur at once. No written directive or

other -- or written directive like thing, such as a prescription, and an error being made in the treatment delivery -- I agree both things could happen.

If there isn't a written directive or written prescription, what would be the basis for determining that there was an error? That's my question to you. What would you use as a substitute for what was the intended dose?

DR. HOWE: I think we would probably depend upon our medical -- I think we would depend upon our medical consultant in that case to --

MEMBER VETTER: This is Dick Vetter. I'm confused about the exception you're making here for oral. I think the regulations allow an oral directive in an emergency, but that has to be followed up by a written directive.

DR. HOWE: Right.

MEMBER VETTER: And, in fact, that's consistent with Joint Commission. You can't allow an oral directive. So at some point in time very soon after delivery, even in an emergency, a written directive has to have been provided.

MEMBER WILLIAMSON: Correct.

DR. HOWE: And so what we're saying is that if you didn't have the written directive at the

time of administration, but you had an oral directive, we would consider that oral directive to be a legitimate written directive, you know, and you follow that up.

So we're not trying to say we got you if you didn't have a written directive because you had an oral one. We're just saying you didn't have a written directive, and you didn't have an oral directive at the time of administration. We would consider that to be reportable.

MEMBER WILLIAMSON: Well, I just don't know how -- I appreciate the conundrum. You had a situation where there wasn't a written directive, where there wasn't an oral directive, where there wasn't any piece of paper that clearly, you know, defined what the authorized user's clinical intent was, there's a problem in determining whether a given treatment is a medical event or not.

And because of this, the unscrupulous licensees could try to evade the reporting requirement perhaps by burning the written directive or something. Maybe this is the problem.

But, you know, having recognized the problem, I'm not sure how you could solve it in regulatory space. I mean, how would you change the

definition to substitute something else for the written or oral directive? That's what I see as the problem -- how you would do this in a regulatory space.

DR. HOWE: Well, if you read 35.3045, you have a medical event when a dose exceeds 5 rem effective dose equivalent to an organ or tissue or 50 rem shallow dose equivalent to the skin from any of the following, and this would be an administration requiring a written directive --

MEMBER WILLIAMSON: Correct.

DR. HOWE: -- when a written directive does not exist at the time of administration. So that your diagnostic nuclear medicine facilities that don't require a written directive are not in this category. It's only those therapeutic things that would require a written directive. There was no written directive, and the dose that was delivered exceeded these much smaller numbers, which are 5 rem and 50 rem through an organ or tissue.

So you've got your dose levels there, because they don't have to differ from something. They are dose levels.

MEMBER LIETO: This is Ralph Lieto. I'm still very confused by your basic assumption, because

3540, which is written directives, states, "A written directive must be dated and signed by an authorized user before the administration."

DR. HOWE: And, Ralph, what you're seeing is that, is there a violation to NRC requirements? And the answer is yes. Does the event have to be reported to NRC? And the answer is no. Does NRC want to hear about the event? We believe yes. So we're not concerned with whether there's a violation of NRC requirements.

What we're trying to do is hear about the event when a therapeutic dose is given and there isn't a written directive there for it. And it may be a person that gets a therapeutic dose that was never supposed to get any dose. That's not reportable to the NRC.

MEMBER WILLIAMSON: Can I ask, is the intention of your change to basically make any therapy administration that does not have the legally required written directive to be a medical event? Regardless of whether it, in fact, turns out to have been delivered in accord with the authorized user's clinical intention or not.

So a new provision of medical event would be any administration of byproduct material that meets

the criteria of requiring a written directive that does not, in fact, have a written directive. That becomes a medical event.

DR. HOWE: That is correct.

MEMBER WILLIAMSON: Okay. So it's basically re-adopting as part of the definition of medical event, the provision that used to be under I think the concept of reportable event, that had to be reported at least to the Radiation Safety Committee if the written directive were improperly filled out.

DR. HOWE: I don't have the -- I don't have those regulations in front of me.

MEMBER WILLIAMSON: It used to be. Okay. So at least now I understand.

MEMBER VETTER: This is Dick Vetter. I think an example that we addressed at our last meeting was part of Dr. Eggli's report where a technologist administered -- I don't know the exact amount, but perhaps it was one millicurie of iodine-131, when in fact they were supposed to administer 10 microcuries.

There was no written directive because 10 microcuries does not require a written directive, but the technologist went ahead and administered the 1 millicurie anyway. Now that's not reportable because a written directive was -- did not exist,

because the physician didn't write a written directive because one wasn't required. So the technologist made an error, and that's not reportable.

This change that Dr. Howe is proposing would require that to be reported. Am I correct, Dr. Howe?

DR. HOWE: Partially. We have the ability to get to the unsealed material, because there are -- because the -- if the dosage differs from the prescribed dosage, and the prescribed dosage for unsealed material is defined as either what's in a written directive or what's in -- let me look at -- to get the specific words.

"Prescribed dosage means the specific activity or range of activity of unsealed byproduct material as documented in either a written directive or in accordance with the directions of the authorized user for procedures performed pursuant to 100 and 200."

So we can get to those diagnostic I-131s that way. But if somebody was given a therapeutic I-131 that wasn't even intended to get anything, they came in for a bone scan and they got I-131, then we would not be able to get to them. That would not be reportable. And if you got a -- we have had people

get intervascular brachytherapy procedures that did not have written directive.

MEMBER LIETO: Do you mean they weren't supposed to get the intervascular brachytherapy and they got it? Is that what you're saying? This is Ralph Lieto.

DR. HOWE: We have had cases where the cardiologist and the authorized users have not discussed patients, and patients have been in line. And so when they went to do the IVB, since they were in line, they went ahead and gave the procedure. In some cases they come back -- in most cases they've come back afterwards and said, "Oh, yes, I would have given it."

MEMBER LIETO: Well, but that violates 30 -- that violates Section 40. This is prior to administration.

DR. HOWE: And we are not --

MEMBER LIETO: Reportable under that.

DR. HOWE: But we are not debating whether the problem is whether there's a violation of the regulations. What we're trying to fix here is that NRC is made aware of incidences in which therapeutic procedures are given without a written directive.

MEMBER WILLIAMSON: I think it's not

unreasonable. I think it will capture a very -- potentially a large set of events. It could, you know, capture -- in addition to these egregious events that you've talked about where the administration is given to the wrong patient or given grossly incorrectly relative to practice standards, it will capture probably a much larger number of events where there is some trivial omission of part of the information required by the written directive -- you know, like failing to sign it instead of just putting your initials or something. I remember under the old Part 35 that used to be a big deal. So I --

DR. HOWE: We weren't really trying to capture those. We were really trying to capture the ones in which there is no written directive.

MEMBER WILLIAMSON: I know. But -- and I'm sympathetic to the concern. The problem is you're going to capture a lot of innocuous ones as well. I mean, you'll capture events where maybe the physician filled out all of the blanks in the written directive but forgot to sign it, or the physician gave an oral emergency directive and neglected to sign it right away and signed it at 25 hours instead of 24 hours.

You get a bunch of what I used to call administrative misadministrations, not egregious cases

like you've mentioned, but essentially a sub-class of events which there isn't any gross error but there has been possibly, you know, a minor omission in filling in all of the required information for the written directive, so it wasn't quite proper, if you know what I mean.

And, you know, that can happen. But, for example, well -- so that's the issue. You capture the events you want, but possibly at the expense of capturing a much larger set than you intend.

And I think to answer Ralph, if you have a license -- a violation of regulations, you're not required to report it. Only certain types of violations have to be reported, so their concern is not that you would not be legally culpable for this mistake but that NRC wouldn't find out about, you know, erroneous treatments.

DR. HOWE: Until we did inspections, which could be anywhere from a year, three years to five years later.

MEMBER WILLIAMSON: That's right. And you might not find, you know, the violation. And, you know, the licensee is under no obligation I guess to admit it to you necessarily. So I see the problem.

I'm not sure, though, what you want to do

about all of the other cases that would be captured. You know, a good example would be in HDR intercavitary brachytherapy, I think you have to use prescribed dose. It's very clear. You have to use absorbed dose to fill in the written directive, whereas in manual brachytherapy/intercavitary brachytherapy, you could use milligram hours or total reference air kerma.

So if an authorized user filled out the written directive for high-dose rate intercavitary brachytherapy and total -- in terms of total reference air kerma, that's a technical violation. That is not a complete and legal written directive, although it's a clinically adequate one. So any treatment that was -- high-dose rate treatment that was given with a milligram hours or track prescription or written directive would automatically become a medical event under this change.

DR. HOWE: I don't think so. I think if there were enough information that you could determine whether what was given was what was intended, or what was given was what wasn't intended. You could come under another section of this.

This is not when a complete written directive doesn't exist. It's just plain when a written directive doesn't exist. But, I mean, the

technical words can be worked out if we -- if you would allow us to move forward with adding this to our rulemaking language.

MEMBER WILLIAMSON: Before I asked you, okay, I see you've got this class of events you want to identify, and I agree with your goal of identifying them. But without a written directive, how would you do the calculation to know that it's an error by more than 20 percent?

And then, I asked you, if it's your intent to have any administration of byproduct material, whether correct or incorrect, to be a medical event if there is no written directive, and you said yes. So I've been the last five minutes making my -- my discussion has assumed that's what you meant.

DR. HOWE: Yes. And you would -- we are intending to add this to A2. A2 does not have that it differs from what was prescribed. It says that you have a dose that exceeds 5 rem or a dose that is greater than 50 rem to an organ or tissue. This would be -- so you don't have to decide whether it's different from something in order to report it.

MEMBER WILLIAMSON: Correct. I understand that. You know, the Part A is simply to identify a threshold of dose delivery that's of medical or

clinical significance I guess. So you don't have a lot of very, you know, tiny microsieverts administrations being reported.

DR. HOWE: Right.

MEMBER WILLIAMSON: I understand that. But the example I -- I think under -- unless I'm really misunderstanding something, my impression is you can have a perfectly adequately and correctly delivered byproduct treatment, but have a technically incomplete or incorrect written directive and it would automatically be a medical event, because the written directive did not exist because it was not filled out completely or exactly correctly.

DR. HOWE: I don't think we're looking at it not -- well, I mean, that's something that we could discuss probably for hours.

MEMBER WILLIAMSON: I'm just asking how you would put it in the regulation. I don't want to dominate the conversation anymore. I think others -- if they don't think this is a problem, I'll just be quiet.

DR. HOWE: Because we have ways of getting to things if there is a written directive and it exists. And we can get to whether, you know, it's complete or not. But in this case nothing exists.

And, I mean, we could -- I mean, this obviously is something that would be debated for a while, and we could come up with final words that would satisfy everybody. But this was really meant -- our intention was to capture things in which there was no written directive, not that it was --

MEMBER WILLIAMSON: Well, I could make a motion, if the Chair would like.

CHAIRMAN MALMUD: Yes, thank you.

MEMBER WILLIAMSON: Yes. I move that the ACMUI recognize that the staff has identified a valid problem or shortcoming in the reporting criteria, and that they, you know, consider approaches that could be used to capture incorrect -- egregiously incorrect treatments in combination with no written directive in such a way as not to capture a large number of clinically innocuous events.

CHAIRMAN MALMUD: Well --

MEMBER WILLIAMSON: This is not endorsing their specific approach, but recognizing that they have a problem and it needs to be worked on and that we agree with working on it.

CHAIRMAN MALMUD: How about if we simply state it as follows, that we recognize that current regulation does not cover the accidental

administration of therapeutic doses to individuals when there is an absence of a written directive, and that we suggest that NRC develop a policy for this.

MEMBER WILLIAMSON: Well put. Much better than my statement.

CHAIRMAN MALMUD: Well, I'm not sure that it's better, but I hope it's just simpler.

MEMBER WILLIAMSON: Yes. I agree with it.

CHAIRMAN MALMUD: Then, I -- if I may, I'll -- we'll entertain that motion?

MEMBER NAG: This is Dr. Nag. I support that motion.

CHAIRMAN MALMUD: All right. We have -- it's been moved and seconded. Any further discussion of that motion?

(No response.)

If not, all in favor?

(Chorus of ayes.)

Thank you. Once again, Dr. Howe, the committee supports the spirit of your intention.

DR. HOWE: Thank you very much. Moving right along to 16, 16 should be a simple one. We found that people have had difficulty interpreting 35.3045(a)(3), because of the presence of "to an organ or tissue." That appears twice.

And we are just recommending that we use this phrase only once in this section, and that we take the second one out.

MEMBER LIETO: This is Ralph Lieto. I think it would change the entire meaning, because it would read, "A dose to the skin or organ or tissue, other than a treatment site, that exists 50 rem." That's not the intent, because you could have -- that means if your treatment exceeded 50 rem, then what you really mean is to an organ or site.

So I think it would actually end up being more confusing, and actually not capturing the situations that you wanted to capture.

CHAIRMAN MALMUD: Any other comments? I hear a voice.

MEMBER WILLIAMSON: Yes. It's Jeff Williamson. I agree with both of you. I think it is a little awkward, but it is clear now, to me at least, so I -- I agree as well. I agree it's awkward, but I agree it's clear now, and I am concerned with Dr. Howe's specific modification. It wouldn't be clear what the criteria -- the criterion of "exceed .5 sievert or 50 percent or more" would mean without it.

So perhaps if you use some pronoun or indefinite specifier that clearly related back to that

long phrase of skin or an organ or tissue.

MEMBER VETTER: This is Dick Vetter. I recommend you change the word "that" to a comma, "which." And then it refers back to dose, so it's a dose which exceeds 50 rem or 50 percent or more, etcetera, to the skin or organ or tissue other than the treatment site.

DR. HOWE: Okay. Let me see if I catch you. So you're saying that what's existing in the regulation now is where you would take -- versus that? That exceeds -- the first one -- a dose to the skin or an organ or tissue, other than the treatment site --

MEMBER VETTER: No, in your recommendation.

DR. HOWE: Oh, in my recommendation. Okay. In my recommendation, then I go that -- where it says "a treatment site that exceeds" you would put a comma.

MEMBER VETTER: Put comma, "which."

DR. HOWE: And "which."

MEMBER VETTER: And then, "which exceeds by .5 sievert," etcetera, refers back to dose.

MEMBER LIETO: I think that's a good grammatical device. Better than the original slide 16.

CHAIRMAN MALMUD: Does that achieve the purpose?

DR. HOWE: Right off hand, it looks like it does. But, of course, this is something you will see many times if it comes up for rulemaking.

CHAIRMAN MALMUD: Dr. Vetter, do you wish to reiterate it, or --

MEMBER VETTER: Sure. I -- do you want me to read the whole thing?

MEMBER VETTER: Yes, please.

MEMBER VETTER: I move that we recommend revising 10 CFR 35.3045(3) by deleting the second "to an organ or tissue" to read "a dose to the skin or an organ or tissue, other than the treatment site, which exceeds by .05 sievert (50 rem) and 50 percent or more of the dose expected from the administration defined in the written directive (excluding for permanent implant seeds that were implanted in the correct site but migrated outside the treatment site)."

CHAIRMAN MALMUD: Thank you. That's a motion.

MEMBER SCHWARZ: Second the motion.

CHAIRMAN MALMUD: Seconded. Any further discussion of the motion?

MR. ESSIG: Dr. Malmud, this is Tom Essig.

Just to clarify that that is 35.305(a)(3).

DR. HOWE: Sorry. I have a typo.

CHAIRMAN MALMUD: Thank you, Mr. Essig. Thank you, Dr. Howe. All in favor of the motion?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

The motion carries unanimously. Thank you.

Dr. Howe?

DR. HOWE: Okay. 17 is another problem where we have -- we have had people that have thought -- they haven't been able to interpret 35.3045(a)(3). They have actually thought that if the dose to the wrong -- dose to the wrong treatment site had to exceed by 50 percent the dose that was expected to be delivered to the right treatment site.

So if you are going for target A, and you were going to give 1,200 rads, and you made a mistake and gave 1,200 rads to the wrong treatment site, they would say that wasn't a medical event until you went to 2,400 rad. So we're trying to make this appear a little more -- a little clearer by revising that

section to read "exceeds 50 percent or more of the dose expected to that site from the administration, if it had been given in accordance with a written directive."

The whole part of 35.3045(a)(3) is "a dose to the skin or organ or tissue, other than treatment site, that exceeds by 50 rem or exceeds 50 rem or more to the dose expected to that site of the administration -- from the administration being given in accordance with a written directive."

MEMBER WILLIAMSON: Would that fit with Dr. Vetter's proposed change?

DR. HOWE: Well, Dr. Vetter's proposed -- if I were to follow his, then I would -- after "treatment site" I would put a comma and put "which."

MEMBER WILLIAMSON: May I ask a more general question?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Please do.

MEMBER WILLIAMSON: Yes. As I recall this -- a subcommittee of the ACMUI spent considerable effort recently trying to draft a new -- develop a new concept of medical event reporting.

THE COURT REPORTER: Excuse me. This is the Court Reporter. I need the ID of the current

speaker.

MEMBER WILLIAMSON: I'm sorry?

THE COURT REPORTER: The ID of the current speaker.

MEMBER WILLIAMSON: Williamson.

THE COURT REPORTER: Thought so. Thank you.

MEMBER WILLIAMSON: Okay. So to repeat, how do these proposed changes to the medical event reporting rule cohere or fit with this prior effort to more radically revise the regulation at least for the case of permanent seed implants?

DR. HOWE: This is Dr. Howe. What we're hoping will happen is that a commission -- well, a commission paper has already gone to the Commission where they have approved in concept that the requirements for reporting medical events has changed in accordance with what you had recommended previously.

And we're hoping that will reach a priority where we can start working on a proposed rule, and the staff is hoping that some of these changes will be addressed at the same time, so that everything can be handled as a complete package. That's our hope.

MEMBER LIETO: This is Ralph Lieto. So, Dr. Howe, then, what you're saying is that this change is consistent with the recommendations that the ACMUI had made in revising the medical event definition. Is that correct?

DR. HOWE: I guess what I'm saying is we're hoping to add these at the same time those changes are put forward as a proposed rule. And we will make sure that they conform with those changes. I don't know -- right now, I can't say these specifically conform. I do believe that they can fit in with those changes.

CHAIRMAN MALMUD: Does that answer your question?

MEMBER LIETO: This is Ralph Lieto. I take that was a definite maybe.

DR. HOWE: It's a definite maybe.

CHAIRMAN MALMUD: Thank you. Do we have a motion on the floor?

MEMBER WILLIAMSON: No, I don't think we do. I move that we accept Dr. Howe's proposal to add the words "to that site" to 35.3045(a)(3). And this is Jeff Williamson speaking again.

CHAIRMAN MALMUD: Thank you, Dr. Williamson. That is a motion. Is there a second to

Dr. Williamson's motion?

MEMBER VETTER: This is Dick Vetter. I will second that, assuming that he also meant to include comma "which."

MEMBER WILLIAMSON: I certainly -- I didn't because we've already approved that on a prior motion, but --

MEMBER VETTER: Oh, you're correct. That would include -- that would pick that up, yes. I second the motion.

MEMBER WILLIAMSON: It would pick that up, and I don't think -- I think we've already established that there's no contradiction between the two motions.

MEMBER VETTER: Gotcha.

CHAIRMAN MALMUD: The motion has been moved and seconded. Any further discussion?

(No response.)

All in favor, aye?

(Chorus of ayes.)

Any opposed?

(No response.)

The motion carries unanimously. Thank you. Dr. Howe, you're back on.

DR. HOWE: Okay. The final one I had is more of a question to the ACMUI to see if we should

proceed or not. And this was an issue that was brought to our attention, and we have an OGC interpretation.

When you look at the board certification criteria in 3551(a)(2)(i) you find that the supervisor -- that the work experience -- the work experience has to be provided under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission.

It is -- we believe that that certification board would be a board that would be recognized under 3551, but that's not what the rule says. The rule is written in such a way that it would also include a specialty board -- a medical physics specialty board that was recognized under -- and I have a typo here -- not 35.500 but 35.50. So that would include the diagnostic medical physics boards that are recognized for RSO use in 3550.

And the question is: is it acceptable for the medical physicists coming through the therapy authorization pathway to have received their medical physics training by someone -- by a medical physicist that is board certified in a therapy physics -- I mean, in a diagnostic physics certification that's recognized by us under 3550, or should it be a board

that's recognized under 3551?

CHAIRMAN MALMUD: So should it be either or -- either/or?

DR. HOWE: Either/or.

CHAIRMAN MALMUD: Why don't we address that question to members of the committee, first to our physicists.

MEMBER WILLIAMSON: Well, thinking here in a moment --

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Yes. Jeff Williamson. I believe it was not the intention when we drafted this proposal to recognize physicists certified in other areas of physics besides radiation oncology physics as appropriate personages in this role.

I would need to go back and look at the ABR eligibility requirements, which at least used to state that an authorized -- a physician boarded in therapeutic radiology or radiation oncology could also play that role. And that would be an acceptable marker of that kind of experience, that a physicist worked in a practice supervised by a board certified physician. So, you know, I would need to check that out before I could render a complete opinion on this.

DR. HOWE: To clarify Jeff's comment, 3551

does allow for the two years of full-time practical training and/or supervised experience in medical physics to be under the supervision -- I think there's -- in a clinical radiation facility. It doesn't say "physicians," does it?

MEMBER WILLIAMSON: I'm looking now. So this is actually --

DR. HOWE: Yes, it does not --

MEMBER WILLIAMSON: Can you tell me exactly the paragraph where this appears?

DR. HOWE: 3551(a)(2).

MEMBER WILLIAMSON: (a)(2).

DR. HOWE: There is no provision for a physician.

MEMBER WILLIAMSON: Yes.

DR. HOWE: Yes, there is.

MEMBER WILLIAMSON: Oh, there is. Okay.

DR. HOWE: For the physician who meets the requirements of an authorized user and --

MEMBER WILLIAMSON: Oh, there is in part double I.

DR. HOWE: Yes.

MEMBER WILLIAMSON: Okay.

DR. HOWE: 490 and 690.

MEMBER WILLIAMSON: Okay. Since that is

there, yes, I think that I'd like Ralph's opinion and Dick's maybe, too. But I think that changing single I in this way as you propose would be in accord with the intention we had.

MEMBER LIETO: This is Ralph Lieto. I would agree. I can't think of a situation where a diagnostic physicist of sound mind and body would feel comfortable in supervising brachytherapy type work. And so I would agree that it was totally the intention that the supervision be done by a physicist who had commensurate training and experience.

MEMBER VETTER: This is Dick Vetter. Yes, I agree with that.

CHAIRMAN MALMUD: So it sounds as if the three physicists on the committee are in agreement. Do we need a motion for that?

MEMBER WILLIAMSON: Can you help us out, Dr. Howe? Jeff Williamson.

DR. HOWE: Yes.

MEMBER WILLIAMSON: Since you don't have a slide, I don't know exactly what --

DR. HOWE: Yes, I didn't have a slide for that, because this is -- was just recently added. I think the change in concept would be to ensure that the supervision of the medical physicists who are

certified medical physics recognized by special -- a therapeutic medical physicist certified in therapeutic medical physics or something recognized in the section.

MEMBER WILLIAMSON: I think that's -- I would agree that's a reasonable statement of the motion.

CHAIRMAN MALMUD: Thank you. We'll accept the motion from Dr. Williamson. Is it seconded?

MEMBER NAG: I am not clear what the motion is. I'm sorry.

MEMBER LIETO: Could I make maybe a more specific suggestion to Dr. Howe?

CHAIRMAN MALMUD: Thank you, Mr. Lieto.

MEMBER LIETO: It would be that 3551 parens --

DR. HOWE: (a)(1)?

MEMBER LIETO: -- (a)(1) be revised to include that the supervision of the medical -- of a medical physicist be -- or have commensurate megavoltage and brachytherapy experience to the individual being supervised.

DR. HOWE: So you are thinking of picking up the terminology that we used in double I --

MEMBER LIETO: Yes.

DR. HOWE: -- and applying it to the physicist?

MEMBER LIETO: To the supervising physicist.

MEMBER WILLIAMSON: I think we could do it in a simpler way by basically stating that it be a -- that the supervising physicist be certified in medical -- by a specialty board recognized by the Commission, you know, as an acceptable credential for being an authorized medical physicist. That way we don't have to define what is meant by "an acceptable board" twice in the regulations.

MEMBER LIETO: You're still not -- it still doesn't get to the problem that Dr. Howe has identified of a diagnostic physicist versus the therapeutic radiation oncology therapist.

MEMBER WILLIAMSON: But a diagnostic -- a person only board certified in diagnostic or nuclear medicine physics could never become -- could never become an authorized medical physicist by virtue of board certification in that area. It's not recognized for -- under 3551 as an acceptable credential. It would be under 3550, but that's not the matter.

But I think, you know, it's just a matter of in double I here and --

MEMBER LIETO: Would it be better just to change the word "medical physicist" to "authorized medical physicist" -- in other words, just insert the word "authorized" in front of "medical physicist" in (ii)?

MEMBER WILLIAMSON: No, I --

DR. HOWE: That creates a problem for the -- this is Dr. Howe. That creates a problem, since we have issues with the agreement states, that they may not be listing people as authorized medical physicists.

MEMBER VETTER: This is Dick Vetter. The words that Dr. Howe put in her Word document I think actually meet the intent of what we're trying to accomplish here. Those words are "under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized for this section by the Commission or an agreement state."

MEMBER WILLIAMSON: I think that's an appropriate motion, yes. That gets to the point in a very straightforward way.

CHAIRMAN MALMUD: We will accept that motion. Is it seconded?

MEMBER LIETO: Second.

CHAIRMAN MALMUD: It has been seconded by

Mr. Lieto. Any further discussion?

(No response.)

All in favor of the motion?

(Chorus of ayes.)

Thank you. I think that completes your items. Am I correct, Dr. Howe?

DR. HOWE: You are correct. We came to the end, and we crossed the finish line.

CHAIRMAN MALMUD: In a timely fashion.

DR. HOWE: Yes. Thank you very much.

CHAIRMAN MALMUD: Thank you, Dr. Howe, for a yeoman's job. Let's see. Are there any other items to be discussed at this meeting?

MR. ESSIG: Mr. Chairman, this is Tom Essig. Only if you wish to recognize any comments from members of the public who may have been participating.

CHAIRMAN MALMUD: We always are willing to do so, since it's their interest we're concerned about. Are there any comments from the members of the public?

DR. CERQUEIRA: Yes. This is Manuel Cerqueira.

CHAIRMAN MALMUD: Could you spell your name, please?

DR. CERQUEIRA: C-E-R-Q-U-E-I-R-A. And I guess the one item that really wasn't on the agenda, which I thought was going to be on there, related to the issue of an RSO and who can basically sign off for an authorized user for the RSO experience. I mean, I saw that on the agenda for an earlier meeting, and I guess either it was already discussed or it hasn't been discussed at all.

CHAIRMAN MALMUD: It wasn't on the agenda for this meeting, and I must say that --

DR. CERQUEIRA: This would be for 290 users. And it was obviously the discussion about the 390 and who could sign off, but --

CHAIRMAN MALMUD: Well, may we hear your opinion regarding the issue?

DR. CERQUEIRA: Well, again, I remember several years ago when we had discussions about radiation safety officers for 300 and higher uses that, you know, we felt it was appropriate for people to have specific training in the type of therapy that was being used, and that not all, you know, medical physicists would receive the whole spectrum of use, and, therefore, we required that there be sort of specific training in that area.

And somehow I -- in some of the earlier

agenda items there was a discussion as to whether -- and if you were going to be an RSO, could an authorized medical user sign off on you -- in terms of the training and the experience. And there was some interpretation that this would only be done by another RSO, which certainly for the cardiologists and some of the other users is going to present a problem.

So I guess I would really like to I guess get some idea of when this would come up on the agenda next, if at all. And I would -- is Dr. Zelac still on, or -- because I believe he was the one associated with the item.

CHAIRMAN MALMUD: Ron Zelac, are you still with us?

(No response.)

No.

MEMBER NAG: This is Dr. Nag. I think since this is not on the agenda, and it is bringing up a new issue, it should be discussed in a separate meeting.

CHAIRMAN MALMUD: Yes.

MEMBER NAG: But it certainly -- you know, it's certainly separate from what we have been called for.

MEMBER VETTER: This is Dick Vetter.

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: This was actually discussed at the last ACMUI meeting, and this is the result of that slippery slope we began. Dr. Cerqueira, you may remember how the ACMUI -- the position the ACMUI took on these matters, and then the issue of attestation came up. And more recently, as I recall the discussion, the NRC added the requirement that the attestation for an authorized user to be the RSO must be provided by an RSO.

DR. CERQUEIRA: Yes, sir. I guess it would -- it was discussed at the last face-to-face meeting.

MEMBER VETTER: Yes. Right. And that is problematic. It's even problematic for the RSO, because in a large training program the RSO doesn't have the opportunity to interact very much with the physicians who are in training, but yet must attest that they could be the RSO. So that is problematic.

DR. CERQUEIRA: Well, again, I really defer to the committee's judgment and Dr. Nag that it not be in a suitable form, but I think it really does need to have some discussion, perhaps at subsequent meetings.

CHAIRMAN MALMUD: May we bring this up as

an agenda item at the upcoming meeting, Mr. Essig?

MR. ESSIG: Yes, you may.

CHAIRMAN MALMUD: Would you please put it on the agenda for us?

MR. ESSIG: Certainly.

CHAIRMAN MALMUD: Thank you. Dr. Cerqueira, thank you for bringing it to our attention.

DR. CERQUEIRA: My pleasure.

MEMBER NAG: Dr. Nag. Since we are about to end, can we confirm that our NRC meeting is still scheduled for October 24 and 25? We were supposed to find out if the meeting room, etcetera, were available.

CHAIRMAN MALMUD: I think Mr. Saba would have the answer to that.

MEMBER NAG: Can you confirm whether we have availability for the room and whether the meeting is still for October 24 and 25?

MR. SABA: Yes. Yes, it is still the same date. I will confirm that with an e-mail soon.

CHAIRMAN MALMUD: And location, Mr. Saba?

MR. SABA: It's usually the same. It's usually in this building in the same conference room that we had before.

CHAIRMAN MALMUD: Back at the NRC?

MR. SABA: Rockville. And something else I wanted to tell you that -- remind you. Please send your timesheet. It's due by Friday.

CHAIRMAN MALMUD: Thank you very much for that reminder.

Are there any other items from the members of the public besides Dr. Cerqueira?

(No response.)

We do have with us Chris Gallagher from the ASMC, Emily Wilson from Astro, and Mike Peters from SNM. Any comments from any of you?

(No response.)

If not --

MR. GALLAGHER: I would say -- Chris Gallagher with ASMC. I would echo I think Dr. Cerqueira's comments about the radiation safety officer issue. And ASMC is pleased that the ACMUI will discuss it at their next meeting.

CHAIRMAN MALMUD: Thank you.

MEMBER LIETO: Dr. Malmud?

CHAIRMAN MALMUD: Yes, sir.

MEMBER LIETO: Could we ask Dr. Cerqueira and Mr. Gallagher if they would be willing to maybe provide some type of statement of the problem specifically from their perspective as authorized

users? Because sometimes I think we medical physicists kind of look at it from maybe a little bit different side of the fence than the clinical side. And if they could maybe give us some specifics, that would be very helpful.

MR. CERQUEIRA: Happy to do that.

CHAIRMAN MALMUD: Thank you. And Dr. Cerqueira knows how to address -- to whom to address that I'm certain.

MR. CERQUEIRA: Yes.

CHAIRMAN MALMUD: For those of you who are not familiar, Dr. Cerqueira preceded me as the Chairman of this committee.

MR. CERQUEIRA: Five wonderful years.

(Laughter.)

CHAIRMAN MALMUD: Is there a motion for adjournment?

PARTICIPANT: So moved.

PARTICIPANT: Second.

CHAIRMAN MALMUD: Thank you all, and thank you for your participation. I thank staff for its work and the members of the public for having been present. Thank you very much.

(Whereupon, at 5:30 p.m., the proceedings in the foregoing matter were adjourned.)