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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

(ACMUI)

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MEETING

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TUESDAY,

MARCH 2, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met at 8:00 a.m. in the Auditorium of the Nuclear Regulatory Commission, 11545 Rockville Pike, Dr. Manual Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D.	Nuclear Cardiologist, Chairman
LEON S. MALMUD, M.D.	Health Care Administrator, Vice Chair
DOUGLAS F. EGGLI, M.D.	Nuclear Medicine Physician

COMMITTEE MEMBERS: (cont.)	
NEKITA HOBSON	Patient Advocate
RALPH P. LIETO	Medical Physicist, Nuclear Medicine
RUTH McBURNEY	State Robinson
SUBIR NAG, M.D.	Radiation Oncologist
SALLY WAGNER SCHWARZ, R.Ph.	Nuclear Pharmacist
ORHAN H. SULEIMAN, Ph.D.	Food and Drug Administration Representative
RICHARD J. VETTER, Ph.D.	Radiation Safety Officer
JEFFREY F. WILLIAMSON, Ph.D.	Therapy Physicist
NRC STAFF PRESENT:	
THOMAS ESSIG	Designated Federal Officer NMSS/IMNS/MSIB
PATRICIA K. HOLAHAN, Ph.D.	NMSS/IMNS
DONNA-BETH HOWE, Ph.D.	NMSS/IMNS
CHARLES L. MILLER, Ph.D.	NMSS/IMNS
ROBERTO J. TORRES	NMSS/IMNS
ANGELA R. WILLIAMSON	NMSS/IMNS/MSIB

A-G-E-N-D-A

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

(8:05 a.m.)

CHAIRMAN CERQUEIRA: Good morning. My name is Manuel Cerqueira, and I'm the Chairman of the ACMUI, and this is a preparation -- now is this an open or closed meeting?

MR. ESSIG: This is open.

CHAIRMAN CERQUEIRA: It's open. Okay. So one of the agenda items this morning between now and when we meet with the Commissioners is really to go over the Commission briefing. So maybe, Tom, since the NRC Staff is going to be doing the initial portion of it, maybe you want to review that first? Part 35 Licensing and Inspection under the New Part 35 Pamela Henderson. Are you going to go over any of that with us or preview it with the Committee, or is this --

MR. ESSIG: It would be my suggestion that we could best utilize the time here to provide Ralph any insights that might be needed in his presentation. I mean, it's kind of our hour to do with what we please.

CHAIRMAN CERQUEIRA: Sure. Okay.

MR. ESSIG: Certainly, you're welcome to copies of the slides of the other presentations, but I don't know if at this point -- we can't change the

slides. They've already gone to the Commission, so they would be for information only. We can certainly do that.

CHAIRMAN CERQUEIRA: I guess the one thing that may be of some help is the sense, we're going to be talking about the review of method of NRC Reconstruction. It might be worthwhile to see Dr. Sherbini's presentation so we at least have some --

MR. ESSIG: Well, it's actually going to be mine.

CHAIRMAN CERQUEIRA: Oh, it's going to be your's. Okay. So what does the Committee feel? Would it be of some help to have Tom go over his presentation so we could --

DR. NAG: I think we went over that yesterday.

DR. VETTER: Yes. I personally would like us to discuss Part 35 issues.

CHAIRMAN CERQUEIRA: Okay.

DR. VETTER: Unless we're all comfortable with whatever information he has, and he could review that for us, and then go from there.

DR. WILLIAMSON: Yes. I would like to hear that sort of data, at least a summary of the content.

CHAIRMAN CERQUEIRA: Ralph.

MR. LIETO: I'm here to serve the Committee.

CHAIRMAN CERQUEIRA: Excellent. So how do you want to do it? Do you have your slides?

MR. LIETO: I think they're in the handout right here. Starting with the second slide, just a summary of the proposed rulemaking dates, when things started, involvement of the ACMUI with Staff and the discussion sessions, and just identify that there's these three major issues -- topics that I wanted to present. One was about board certification, probably a lengthier part of it has to do with the Preceptor Statement, and then some transitional issues that have been brought up by the Committee, make a comment that the --

CHAIRMAN CERQUEIRA: Now, Dick, is this what you want, or do you want Ralph to maybe just kind of go through this?

DR. VETTER: This is fine.

CHAIRMAN CERQUEIRA: This is fine. Okay. Good.

MR. LIETO: And then transitional issues. I mean, if you want I could go through the whole thing, I mean, just go through the presentation as

sort of a warm-up, and then just kind of -- we could do that too.

MR. ESSIG: Are there copies of the --

DR. VETTER: Yes.

CHAIRMAN CERQUEIRA: We have the slides.

MR. ESSIG: It's interesting the Committee has them and we don't. We got them this morning. Oh.

DR. VETTER: Are they right in front of you there?

DR. NAG: That's the one Angela gave this morning.

MR. LIETO: Just to introduce myself and thank the Committee or the Commission for the opportunity to comment on proposed rules. Then to indicate that the NRC published the proposed rule on December 9th seeking comments on the revision of the training and experience requirements, and that these training and experience requirements affect authorized users, authorized medical physicists, authorized nuclear pharmacist and radiation safety officer, and that the authorized medical physicist is a new designation.

The NRC proposed amendments to training and experience which affect the approval of these authorized individuals via both the current mechanisms

which are recognition of board certification and the alternate pathway.

The proposed rules involve significant work by the ACMUI with the NRC Staff, and from discussion sessions with representatives from the affected board and the professional societies.

On behalf of the ACMUI we wanted to bring to the Commissioners' attention some issues relating to the proposed rule. There are three particular aspects that we feel should be commented on. These have been raised in ACMUI meetings since the Advisory Committee last met with the Commission, and also were raised during the drafting of the proposed rule. These three aspects of the proposed rule involve board certification, a preceptor statement, and transitional issues in going from current regulation to the proposed.

One of the questions raised during the comment period in the proposed rule asked should the word "attestation" be used in place of the word certification and preceptor statements? The ACMUI would like to strongly re-affirm its recommendation to use the term "attest or attestation" in Part 35.

It should be noted that the comment period ended last week on February 23rd. Also, I'll state

that there may be individuals from the ACMUI that may have some additional comments on issues affecting the proposed rules and its future implementation.

The criteria for board certification to be recognized and listed in Part 35 is the crux of the proposed rulemaking. The importance of board certification cannot be emphasized enough. However, it needs to be understood that board certification provides a mean to assess and document the comprehension of a body of knowledge and/or basic skills. It does not determine the training program content or adequacy, nor does it determine competency to supervise safety programs.

If the NRC expects that medical events can be related to board certification, this is a misunderstanding of the board process. Inadequate radiation safety training is a reflection of an individual's training program, not their board certification.

DR. WILLIAMSON: Can we comment?

CHAIRMAN CERQUEIRA: Yes, please.

DR. WILLIAMSON: Are you sure you want to say that? You know, they're making certain assumptions about board certification which maybe we should just --

MR. LIETO: I took that largely from the Minutes.

CHAIRMAN CERQUEIRA: Maybe we could move that since it's not being --

DR. WILLIAMSON: I mean, I know it's perhaps in the initiative, but there's a certain sense in which that's true, but there's also -- I'm sorry that it's in the Minutes. I'm sure that's what the boards themselves say, so at a certain level I think it's true, but at a certain level it's also misleading. I think that as a tool for calling out experienced and reasonably well-trained professionals, board certification has served us well for many decades now. And I think to sort of attack that connection serves no useful purpose.

CHAIRMAN CERQUEIRA: Dick.

DR. VETTER: I think the whole misunderstanding here revolves around the word "competence". Boards certainly do demonstrate that you have the knowledge and skill to perform your professional duties. The issue is are you competent, and competence is demonstrated on a day-to-day basis. And that goes back to this whole issue of requiring preceptors to sign a preceptor statement for people who are board certified.

MR. LIETO: Do you want me to strike the whole sentence or do you want me to replace "inadequate radiation safety training with competence?

DR. VETTER: Competence. Personally, I think that's the issue, it's competence.

CHAIRMAN CERQUEIRA: Yes. Why don't you read the original and then the revised statement?

MR. LIETO: I think it was the last sentence, which was "inadequate radiation safety training is a reflection of an individual's training program, not their board certification." And their suggestion was replace "competency" is a reflection, or radiation safety competence is a reflection of the training program, not certification.

DR. VETTER: What were the first few words?

MR. LIETO: "Inadequate radiation safety training."

DR. VETTER: Why are you assuming that anyone is getting inadequate radiation safety training?

MR. LIETO: Well, that was the -- I think relating to board certification and tying board certification to medical events.

DR. VETTER: But there is no - - there has

been no tie.

MR. LIETO: No. But that's been one of the issues that's been raised at least in the last meeting with the Commission --

DR. VETTER: Where the Commission has that opinion.

MR. LIETO: Right.

DR. VETTER: I don't know where they get it.

MR. LIETO: What I guess I'm trying to reflect is that our agreement is that it doesn't. And that was the reason for the --

DR. WILLIAMSON: I'm not sure I'd agree with that. You know, honestly I think that's sort of a level of train -- it's very speculative whether it does or doesn't. But my hunch is, is that somebody that -- a group of persons who have passed the boards probably overall would do better at radiation safety practices than an equivalent group that has not.

MR. LIETO: Then I'll just end it with that.

DR. WILLIAMSON: So I see no point, and I think we're just asking -- you know, we don't want the rule as its broadly formed now to be overturned, and so I don't think that it's --

MR. LIETO: So I'll just end it with --

DR. WILLIAMSON: Yes, it's very speculative one way or the other. I would just drop it.

DR. EGGLI: I would like to take a slightly contrarian approach. Not all training programs across all groups of authorized users emphasize radiation training to the same degree. And there are training programs where -- and there are generic categories of training programs where radiation safety is significantly de-emphasized at the training program.

DR. WILLIAMSON: That could be, but what useful purpose is served by drawing their attention to that fact?

DR. EGGLI: Public safety.

CHAIRMAN CERQUEIRA: But do you have any data to support that?

DR. EGGLI: There is an organization called SCANS, which is Society of Chiefs of Academic Nuclear Medicine Departments who collected data on this kind of training, and over several years tried to influence the training in nuclear medicine. And it was the strong opinion of this group that there were categories of trainees where radiation safety was in

fact de-emphasized.

CHAIRMAN CERQUEIRA: But again, that's certainly not information that I was familiar with, and I'm just not certain what purpose that --

MR. LIETO: It's obviously quite controversial, and so I'll just strike that sentence.

DR. WILLIAMSON: What is your sort of underlying purpose? What are you trying to achieve with these comments? I mean, what were you --

MR. LIETO: Well, basically, this is a reflection of what the Committee has discussed since we last met with the Commissioners on the proposed rulemaking, and what went into the proposed rule. I mean, that's what I thought the purpose of this was, to give them sort of a status report on things that have happened since.

DR. MALMUD: The SCANS report I'm familiar with. I think it would be wisest to simply address the issue of board certification as indicating that when one is board certified, what the director of the training program indicates is that we have received the requisite fund of knowledge and are familiar with it in order to practice whatever our specialty is. I don't think we should touch the word "competence". That's something that is achieved and improved upon

with experience, but simply state that the board certification is an indication that the individual has the requisite fund of knowledge necessary to practice his or her specialty. That's what it is. Don't you agree?

DR. WILLIAMSON: I do. I think it tests basically a breadth and to some extent depth of knowledge. It has in addition to that certain prerequisites that limit or mandate a certain type of training. I agree it may not be followed ideally as it should in all cases, but I think we've argued in the past that board certification is an important mechanism and has served the community well in general, and so I don't see any mileage in trying to undermine that view.

DR. MALMUD: And in fact, just for the record, and in fact, most boards require more training hours than does the NRC recommend. The issue of the differences among the boards, which is I believe what you're addressing, is an issue which I don't think it would serve us well to bring before that Committee at this time, because that would open up another issue for discussion which is not the issue on the table at the moment, even though there is evidence that the number of training hours differs among the programs.

That's just my personal opinion.

CHAIRMAN CERQUEIRA: So how do we want to word this now?

MR. LIETO: I think it's best just to strike it out. It's obvious -- because it will, I think, give them maybe a misunderstanding of what the Committee's intention is. And I've already got a statement about that board certification is a means to assess and document comprehension of a basic body of knowledge and skills.

CHAIRMAN CERQUEIRA: So comprehension, certainly nothing about competency.

MR. LIETO: Right.

CHAIRMAN CERQUEIRA: Something softer would be "exposure", which is really a non- committal sort of term.

DR. WILLIAMSON: And it does also carry with it some limitations or expectations for a kind of a training, because it does have an important role shaping, I would say, minimum requirements for training, and the nature of the experience you have to have.

CHAIRMAN CERQUEIRA: Right. And we've had quite a discussion when the boards actually came here, you know, and Dr. Hendee from the ACR. And again,

there were issues about program directors versus authorized users. I don't think this is the forum to necessarily get into those kind of issues. So is everyone comfortable with the statement that Ralph is going to make?

MR. LIETO: Forget I said it.

CHAIRMAN CERQUEIRA: Okay.

MR. LIETO: The next point has to do with Section 35.50 which addresses training and experience for radiation safety officers. Repeatedly during the rule revision process, the ACMUI stated that the training and experience revisions must not exclude existing recognized boards. In paragraph specifically 50(d)2(i), there's a new paragraph added to allow medical physicists to serve as RSOs if they are certified by a specialty board and the certification process has been recognized by the Commission or an agreement statement.

It appears to be intended to authorize as an RSO board certified medical physicists who are not AMPs. However, as stated, the proposed rule disqualifies certain certification categories in the American Board of Radiology and the American Board of Science and Nuclear Medicine from which many currently certified medical physicists serve as RSOs.

Well, this may be unintentional by the NRC. It must be rectified before the final rulemaking process is published, or the final rulemaking you should say is published. Process for a board to be recognized and listed in the NRC website is an entirely new concept and requirement. This will require formal application process by the boards, regardless of the length of time that they have existed. ACMUI suggests that the notice also go to major societies whose members comprise the various board diplomats. And I'll just list the boards.

DR. WILLIAMSON: I'll make a suggestion. The RSO issue you raised I think is a really important one, so I think to add a line indicating what the consequences will be if these individuals, for example, board certified nuclear medicine physicists are excluded from the process be appropriate.

DR. VETTER: Relative to that issue, Ralph, do you know specifically what's excluding them?

MR. LIETO: It's the requirement in Section A that has to do with the documented years of applied health physics. I think it's three or five, depending on how, I guess, it's read exactly. But in those categories since they're all master's candidates, I think it's the three year piece that

does it. I've heard conflicting comments that the American Board of Science and Nuclear Medicine has two years -- and someone else says no, it does have the three years -- but I do know that they did sign, I think in a letter in the comments that went to the Commission, that they supported that aspect. So I'm assuming that they feel that that affects the --

DR. WILLIAMSON: Yes. I think so. Now just to clarify further, I think there are two kind of classes of RSO that are implicitly defined by that rule, 35.50. One is the kind of unrestricted RSO where the content of services offered by the licensee is not limited by the personal work experience of the RSO. And the second category is RSO whose sort of scope of RSO duties is limited to those modalities which the individual has some work experience. And I think the category that we're disputing now is the second category, so what is not at issue are the basic requirements for being an unrestricted RSO, but being the RSO of a smaller operation where, in fact, the board certified radiological or nuclear medicine physicist may be by far the most appropriate skilled and knowledgeable person to serve as RSO for a small licensee.

CHAIRMAN CERQUEIRA: Dick, go ahead.

DR. VETTER: I think we need to identify what the fix is, and maybe later when we come back we have to make a motion or something, but just to throw out the fact that there's a problem, I'm not sure that's adequate. I mean, perhaps here that's all we need to do, unless we know it's a very, very easy fix and we specifically identify it. But at some point in time today, this Committee is going to have to identify the fix in order to give the NRC some guidance.

DR. WILLIAMSON: It's not a very straightforward fix.

MR. LIETO: Yes. I agree with you, Dick. There was in the slide originally what I thought was a fix, and staff looked at it, and they did not feel it was the fix. So I guess it was a little bit more convoluted than I thought.

DR. WILLIAMSON: So can we put that as a discussion item for this afternoon?

CHAIRMAN CERQUEIRA: Right. We an do that.

DR. WILLIAMSON: Talk about fixes, what the staff's attitude is towards this matter.

MR. LIETO: The next was just simply in terms of the process for listing, that the NRC plans

to notify the boards by a letter and/or notice, but that in addition, when the process is established, a work shop with the stakeholders should be held for the purpose of addressing the specifics to finalize the process for broad listing by providing a two-way dialogue with the NRC and the affected groups or boards.

The next slide, the discussion about the preceptor statement. This is one aspect of the revision that has envisioned training and experience rulemaking that has been the NRC maintaining this requirement for preceptor based on input from the ACMUI. The requirement for a preceptor statement was decoupled from the board certification pathway to meet the NRC directive. This is a new regulatory requirement for both board certified and alternate pathways for obtaining NRC authorization, so now each applicant bears the burden for obtaining a preceptor statement.

The ACMUI believes that the definition of the preceptor will greatly impact the implementation of this requirement. The current definition is, and then I'm just going to read it right off the slide -- emphasizing the articles, an individual and directs the training.

A comment that the preceptor statement must be a flexible, practical, and document that minimizes implementation burden, and allow the preceptor who is not necessarily the one providing the training and experience.

An example here would be a program director who may not be an authorized user or authorized medical physicist, but oversees the overall training of the individual and can document the performance and comprehension of that individual during the training program.

It should also possibly provide for the input of multiple preceptor statements. Now a suggestion from the ACMUI for NRC consideration might be that to modify the definition to "an individual who provides or directs training and experience, or more directly an individual who provides, directs, or can verify the training and experience." But again, these are just suggestions for consideration to address the implementation.

DR. WILLIAMSON: So one issue you're taking on is the connection between preceptor and having to be AMP or AU on agreement state or NRC license. One might argue that's sort of a lost cause to argue that. I've lost that battle.

MR. LIETO: Well, I think it was something that we really discussed last time, and it was quite, I think, strongly felt by the Committee as a whole that they may be the best person to comment on their comprehension, and skill, and knowledge base.

DR. WILLIAMSON: The -- sorry.

DR. VETTER: Can we come up with a very concrete example of where that would be a problem? For example, if you get HDR, is there a physician that comes in and trains the physicians on the use of HDR, and then certifies that those new physicians will be competent? Because that's what the language says.

MR. LIETO: I could see where it might happen, Dick, would be say in a radiation oncology program where they get their training with unsealed radiopharmaceuticals in their medicine department. And so there would be a nuclear medicine director and/or maybe authorized user that would be able to document that training and experience; yet, their work with other sealed sources would be an entirely different --

DR. WILLIAMSON: That's addressing the multiple person. I think that's uncontroversial and something they will do. But coupling this from the preceptor being an AU or AMP I think is a more

controversial and difficult issue.

CHAIRMAN CERQUEIRA: It's more controversial, and the way we ended up going in this direction was I think when the ACR came in, Dr. Hendee didn't feel that the person signing the statement would necessarily be an authorized user for an AU. And if we go back four or five years when we first started t his process, I mean, it was felt that we really needed somebody to assume responsibility. And it was felt that for radiation safety that the authorized user should be that individual or an appropriate AMP-type.

DR. VETTER: But the problem is when a physician, when a licensee gets a new type of use, there is no one at the institution who is an authorized user.

CHAIRMAN CERQUEIRA: Yes. No, I understand in that situation, but we're talking more for the general individual, radiologist and nuclear medicine physician or cardiologist who's had training, who can sign off.

DR. WILLIAMSON: So I think --

DR. VETTER: But the regulation is all-encompassing. It must cover all circumstances. And I think it's going to be problematic.

DR. WILLIAMSON: So my suggestion would be, is I think we're going to lose the battle. You know, we've already talked them into decoupling preceptorship from the board eligibility requirements just for this exact reason, because they insisted on retaining the connection between preceptor and being a named person on a license. So I think a more effective, winnable strategy is to negotiate about the details of the definition of what the preceptor does. So my suggestion would be that --

MR. LIETO: Well, I think that's the point here.

DR. WILLIAMSON: Yes. Well, no. You're attacking the connection between preceptor and being a named person on a license. I don't think we're going to win that. My suggestion would be we try to fix the definition of preceptor so it's broader. And one suggestion I would have is, has knowledge of the competence and skills of the applicant. Okay? So this would then allow colleagues who haven't been directly involved in the primary training, but who have been in a position to observe or supervise the individual, to attest to that individual's competence, so that's the kind of fix I think that could be sold. I don't know what the staff's opinion is.

CHAIRMAN CERQUEIRA: Not attest to competence. I mean, I don't think anybody has ever gone in that direction. Doug had a --

DR. EGGLI: Again, I think there are situations where a general training director is not the person with any knowledge of the level of training the individual has received. And there are some situations where it is beneficial to have an authorized user, an authorized medical physicist, and RSO, in fact, be the preceptor for those individuals. And I do think in some situations there's a public safety issue. And I think that public safety issue overrides the inconvenience of this being broadly applied.

DR. NAG: If I remember the discussion we've had when the board people were here, one of the major problems would be that a change in the preceptor, that preceptor who actually taught the authorized user, trained this person is no longer there, so the training director serves de facto as the one who is going to sign off. And the training director -- all the paperwork that is there in an institution is in the name of the training director. And even if that training director leaves, the paperwork will still be there, so the new training

director can sign off on their behalf.

DR. EGGLI: I disagree with that. Anybody who finishes a training program should walk out of that training program with their preceptor statement. There should not be an issue of having to come back five years later and ask for a preceptor statement. We keep copies of every preceptor statement that we write in the institution. If somebody loses their preceptor statement, we can file a copy for them. But if you get your preceptor statement before you walk out the door, this is a non-issue.

DR. WILLIAMSON: That's not realistic for radiation oncology, your approach.

CHAIRMAN CERQUEIRA: This may not be applicable across the board. But, Leon, you've been patiently waiting.

DR. MALMUD: I thought that Jeff's description would be applicable and encompassing; and that is, that the training program director or his designee has the knowledge, and rather than using the term "competence", has knowledge of the training and skill of the preceptee. Is that acceptable? Has knowledge of the training and skill of the preceptee.

MR. LIETO: Well, I think the controversy here is they have to be a person that has been

approved on the license or approved in the broad scope.

DR. MALMUD: That's why I said or his designee. In other words, I may be the chairman of the department, but I may not be the director of residency training. In fact, in our department, which is not meant to be a universal example, the chairman is not the training program director. There is always a designated training program director. And in many departments that is the case, so that if it is the director or his designate having knowledge of the training and skill of the preceptee, I think it covers most situations. Any further comment?

CHAIRMAN CERQUEIRA: Dick.

DR. VETTER: I think the regulations will allow the NRC in guidance space to accommodate your view of who the preceptor is. But the regulation also says, this is very explicit, that the preceptor must attest to the competency of that individual.

DR. WILLIAMSON: That's not what it says. I'll read what it says for radiation safety, for example.

DR. VETTER: Radiation safety is a little different.

DR. WILLIAMSON: Okay. Let's go to the

other one.

CHAIRMAN CERQUEIRA: Go to the authorized user, or the physician.

DR. WILLIAMSON: "Has obtained written certification signed by a preceptor authorized nuclear pharmacist that an individual has satisfactorily completed the requirements in Paragraph B(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist." Let's see if the physician one is the same.

CHAIRMAN CERQUEIRA: I mean, this is the issue. I think the Commissioners consistently have wanted the word "competency", because it basically puts some liability on the training programs and the person signing the statement, and no matter how many times we've gone to them with this, they have basically balked and been very steadfast. The problem, the boards when they made their presentations, they did not want to attest to competency, and so I don't think we've really resolved this. Ruth.

MS. McBURNEY: That's probably why it was decoupled, that the boards do not do that. It still has to be another preceptor doing it.

DR. MALMUD: One way of dealing with this may be to recognize that competency is not a constant throughout life. And, therefore, that the individual could attest to the competency of the trainee at the completion of the program. That does not mean that the trainee is competent one year later, which would deal with the legal liability; namely, when I trained you, you were competent. Well, what happened to you in a year, I can't speak to that.

CHAIRMAN CERQUEIRA: Jeff, and then Subir.

DR. WILLIAMSON: I wanted to correct something I just said. I was reading out of the Part 35 as currently published. I'm now going to read what it says.

CHAIRMAN CERQUEIRA: This is the revision from our subcommittee?

DR. WILLIAMSON: Let me try to make it clear. I'm doing my best here. The original Part 35 that -- I read out of the Part 35 that took effect in October. The current rule which discussion just closed states as follows -- this is for the 35.690. It says, "As obtained, written certification that the individual has satisfactorily completed the requirements in Paragraphs A or B of this section, and has achieved a level of competency sufficient to

function independently as an authorized user for each type of therapeutic medical unit for which the authorized user -- individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in 35.690 . . . .".

MS. McBURNEY: It still says certification.

DR. WILLIAMSON: It does say competence in here. It says, "Has achieved a level of competency sufficient to function independently as an authorized user." So I suggest that maybe we want to say level of skill and knowledge.

MR. LIETO: I don't want to get into that, because that -- what you're talking about there is changing requirements of the individual for authorized user status or whatever, and that's not what I'm presenting right here. This is the precept, dealing with who can be a preceptor, so to speak, by definition.

DR. WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: Dick.

MR. LIETO: So I guess the question is, the controversy I still don't have any resolution on is we want to state that it may not be an authorized

user or authorized --

DR. WILLIAMSON: I think that's the most controversial thing of all.

MR. LIETO: If there's not consensus, I won't state --

CHAIRMAN CERQUEIRA: And the committee has not come to a consensus, and I think for this afternoon's agenda, that --

DR. WILLIAMSON: That's not quite true either. We had a very clear consensus that that person, this preceptor need not be an AU. So right now I'm arguing a tactical point that we've lost that battle, and what percentage is there in renewing the war.

CHAIRMAN CERQUEIRA: Dick.

DR. VETTER: I think Jeff is exactly right. I think this is going to become problematic when it comes to implementation. For example, when a licensee gets an HDR, some new type of use, the individual comes in and trains them is not an authorized user on that license. They can't be, unless you want to hire them to come in, so there are some practical issues that will become problematic that we'll have to sort out. But we're not going to win this battle if we bring it up again.

CHAIRMAN CERQUEIRA: I agree with you, and this is probably not th forum to try to argue it. I mean, if the Commissioners have questions, they can ask it. But what --

MR. LIETO: Do you want me just to stay away from that specific prepositional phrase, if you will, and just -- and if it comes up and they bring it up, bring up these examples that there's going to be some problematic implementation of this if it has to be authorized user or authorized RSO?

CHAIRMAN CERQUEIRA: I think that's the most legitimate way to do it.

DR. NAG: I think although we seem to have lost a couple of times before, I think it's still very important that the ACMUI puts forward the view that yes, we put this before you, you didn't agree, but it builds some of the problems that will exist if we allow -- I mean, if the preceptor has to be the authorized user, you know, these problems do exist. We have to again -- you know, sometimes they may not accept the first time, second time, but you keep on haggling three, four times, at some point they may have to give up.

CHAIRMAN CERQUEIRA: All right. Dick.

DR. VETTER: I guess my suggestion would

be that we identify it as a continuing problem, that it may be problematic during implementation, that ACMUI is here willing to work with the staff to resolve those issues.

CHAIRMAN CERQUEIRA: I think that's the best way to put it, because as we've observed from this discussion, we have not resolved it within our own ranks, so I think the verbiage that you used was appropriate, the language. So, Ralph, did you --

MR. LIETO: Yes. I'll just say an example would be a program director who has the knowledge of the applicant's skill and training experience.

CHAIRMAN CERQUEIRA: That's implementation.

MR. LIETO: There are some other issues that we need to bring up.

DR. WILLIAMSON: I think another example that's really worth mentioning, it is important, is a practitioner who acquires a new modality where there isn't -- that wasn't reflected in the original residency training of the individual, and for which there is no authorized user for that modality that can sign a preceptor statement. Now how is that to be handled?

CHAIRMAN CERQUEIRA: Yes, but this isn't

the forum to get into these specific examples. I think --

DR. WILLIAMSON: Yes, I think it is. I think he has to define the problem that we need to work on.

CHAIRMAN CERQUEIRA: All right. But he --

MR. LIETO: If you let me go on, I'm going to get into the specifics about preceptor issues.

CHAIRMAN CERQUEIRA: Okay.

MR. LIETO: And the questions that have been raised. It's on the next couple of slides.

DR. WILLIAMSON: I think the solution is messy, but the problem is clear.

CHAIRMAN CERQUEIRA: Go ahead, Ralph.

MR. LIETO: Obviously, several questions and concerns have been raised, have arisen in ACMUI discussion on implementing this preceptor statement requirement. The ACMUI does not expect to obtain answers at this meeting with the Commission, but wishes to express these issues for resolution during the final rulemaking process. For example, who can be a preceptor? What documentation is required for an individual to be recognized by the NRC as a preceptor? What information does that preceptor need or require to make an attestation for training and experience?

What are his or her recordkeeping requirements to document this decision? And grandfathering with respect to Section 35.50, for example, when changing from one license to another licensee, does another preceptor statement need to be submitted for this individual? Must it be updated every seven years to satisfy recentness of training rule if that experience - - the licensee changes licenses. How is it handled if a preceptor is unwilling to provide a statement because of personal reasons, or perceived liability concerns? What liability concerns does that preceptor bear, especially if NRC is looking at a relationship between medical events and training experience. How would it be handled if the preceptor is unavailable due to death, training program termination, or some other cause in which the length of time between the training and experience and the applicant makes their request for authorization.

Ideally, a generic statement form would be the most acceptable and practical; however, can this be done such that the statement language is appropriate for an authorized user and RSO, a medical physicist, a nuclear pharmacist, and/or for applicants who have not yet completed board certification.

There may arise situations where an

individual may receive multi-modality training at different institutions or facilities, or most training was received at one facility or one licensee, and then completed under a second licensee. Will multiple preceptors be acceptable, or does one preceptor have to address the full training and experience?

The ACMUI feels if it's the latter case, this would be very problematic for an individual to get a preceptor statement and would support the acceptance of multiple preceptor statements.

Another issue lies, and this I'm not really strong on a comment, but another issue is licensee's whose radiation safety committees are authorized to approve authorized users or medical physicists. They currently enjoy an expedited process, approval process mechanism, but with the preceptor statement implementation may incur delays in that approval process.

DR. NAG: Can you go over that, what you mean by that?

MR. LIETO: I'm thinking like broad-scope programs and some specific programs where the radiation safety committee can authorize the user or medical physicist, and so they may incur delays in their process to approve that user on to their license

or whatever because of delays in getting the preceptor statement information.

CHAIRMAN CERQUEIRA: I would probably try to keep it simple again, because we're probably going into too much detail that we're not going to really be able to resolve.

MR. LIETO: Obviously, we raised many questions and concerns that the preceptor statement could create a bureaucracy of its own. Based on past experience with Part 35 licensing, many problems arose with regulatory guidance become de facto regulations. The preference is that if it is required, it should be in Part 35. However, we suggest that implementation of preceptor statement occur in guidance space and with the use of the frequently asked questions on the NRC website to allow flexibility in addressing these many issues.

And then in the next slide we talk about some of the transitional issues that have been brought up in going to the revised Part 35. There are a few issues of concern that licensees and other members of the regulated community have raised. One has to do with individuals currently in training programs. They have not had the opportunity to document their training experience because it was not a requirement;

yet these individuals in training need to have the opportunity to document their training and experience.

A possible recommendation for consideration is maybe the training and experience requirement should be applied to individuals who are entering training programs now, or after some specific date in the year 2004.

The authorized medical physicist is a new definition which did not exist previously. It's come to our attention that some agreement states do not explicitly list physicists on the license. In order to assure that the current shortage of authorized medical physicists is not made worse, a mechanism is needed to ensure that not only an initial pool of authorized medical physicists is not compromised, but also to provide as a source of preceptors for new authorized medical physicists.

Another transition issue involves nuclear medicine authorized users. Before Part 35 was revised, I-131 authorization was based on therapy versus diagnostic applications, rather than the activity thresholds, which current regulations follow.

In other words, an authorized user -- users were authorized under Part 200 to use I-131 for diagnostic imaging and localization studies which

exceeded 30 microcuries. These were essentially studies for assessing thyroid cancer in patients that were going to be treated, but did not exceed a few millicuries. Now it requires that that physician need the training and experience for therapy applications requiring a written directive, which is Section 392, so some method needs to be found so that authorized users currently providing this study to patients are permitted to continue.

Because the comment period has just closed, additional issues may be raised before the final rulemaking process. The ACMUI can provide valuable assistance in this regard, and will make itself available during the review and implementation of these changes. Again, on behalf of the committee, we take the opportunity to provide comment on this critical change. That's it.

CHAIRMAN CERQUEIRA: Good. Jeff. Dick. Sally, okay?

MR. LIETO: The latter half is more non-controversial.

CHAIRMAN CERQUEIRA: Roger, do you want to make a comment since you --

DR. BROSEUS: Excuse me, because this is really your part of the meeting, but I would observe

that in my view, that many of the points that Dr. Lieto went over fall into -- they're not new problems, and many of them are not related specifically to the changes for T&E for recognition of boards. Many of them are implementation problems, and I think they're being dealt with now. For example, multiple preceptor statements. I spoke with Pam when I saw your comment about that, and that's handled now. There are exceptional cases where you need more than one person to attest, I'll use that word today, to the competency, so that's just an observation I have about the content of many of your -- the character of many of your comments from my point of view.

DR. EGGLI: And I can attest to the multiple preceptors. Right now for when I train a cardiology fellow, I do their clinical experience. They get their basic didactic experience elsewhere, and they submit to NRC two preceptor statements, and none of them have had trouble getting licensed.

CHAIRMAN CERQUEIRA: That's true. Dick.

DR. WILLIAMSON: Roger, if I may ask, how do you handle the situation where a practice acquires a gamma knife, and none of the physicians at this facility are authorized users for gamma knife. Who signs their preceptor statement?

DR. HOWE: We had gamma knife physicians in the past, and so there are gamma knife authorized users available.

DR. WILLIAMSON: Yes, but none of them have been involved in the training of the individual, so if Hospital X, which has three radiation oncologists, none of whom are authorized for gamma knife, gets a gamma knife -- if they go through the one-week vendor-supported training course, you know, these other authorized users across the country don't know these people from Adam. Who signs their preceptor statement?

DR. HOWE: I think we look at it as a case-by-case, and you're getting to some of the issues that we do with the emerging technology where you're in the beginning, so we have to give some leeway on the very first people.

CHAIRMAN CERQUEIRA: Ruth, do you want to comment?

MS. McBURNEY: The way we did in Texas and probably some of the other agreement states is for certain modalities to have that person go to another facility and observe about three cases, two to three cases involving the use of that modality, if it's like HDR something like that. For some of the other

emerging modalities, if they've been authorized for something similar in that modality, we will authorize them.

DR. WILLIAMSON: Well, I think you know Ralph's point can be reduced to the concern that we want the rule language to be consistent with the level of flexibility that would allow the medical director of say this one-week training program who presumably is an AU for gamma knife, to be able to sign those preceptor statements.

MS. McBURNEY: Yes, and that's what we allow.

CHAIRMAN CERQUEIRA: I would try to avoid specifics, because if it's authorized user or medical physicist, there's going to be unique things. And I'm not sure it's necessarily productive for the meeting with the Commissioners to get into those specific implementations.

DR. WILLIAMSON: I think enough examples have to be given to indicate what the nature of the problem is. Otherwise, it's too abstract. I don't think we need to argue each individual case, but just to give some examples of what the problems might be I think is a very useful strategy, since we're not advocating a general solution at this time.

DR. NAG: Yes. I think we do have to point out some of the problems that implementation of a straightforward statement that the authorized user be the one who is certifying that these are the problems that you are going to create. And unless we -- we have already been blamed that we put forward a rule not knowing the problems it's going to create. Here we know that these are the problems we are going to create and that may allow the Commissioners to give you the flexibility, that let's not create these problems.

CHAIRMAN CERQUEIRA: Ralph, go ahead.

MR. LIETO: I was just going to add that I thought in reviewing the Minutes, or I should say the transcripts from the last couple of meetings, that obviously it was recognized, we're not going to change this preceptor requirement. But I think that as we look at its implementation, a lot of issues have been raised by both this committee and others, the newness and the details of this is really going to affect licensees, the states and regions that have to approve users and medical physicists and RSOs. And we need to be prepared for that type of issue.

CHAIRMAN CERQUEIRA: Lynne, you have a comment?

MS. FAIROBENT: Yes. Dr. Cerqueira, I just want to clarify for the record, you accredited Bill Hendee with the American College of Radiology. Dr. Hendee was actually speaking on behalf of the American Board of Radiology, ABR. And I just wanted to be sure that that was adequately reflected in the transcript.

CHAIRMAN CERQUEIRA: You're correct. Okay. All right. Tom.

MR. ESSIG: May I suggest we move on to the other --

CHAIRMAN CERQUEIRA: I was just going to do that.

MR. ESSIG: If it helps, I could quickly run through the slides that I have, because I'll be going on before you. It's just a single sheet of paper. I'll pass it out. There are only six slides, and I think there are some left over for the audience, as well. And, of course, it's captioned "The NRC Method of Dose Reconstruction" but it's specifically, we're going to be talking about the exposure that occurred at St. Joseph Mercy Hospital. And I'm just noting that we conducted a special inspection in October of 2002, a female patient in July of that year had been administered 285 millicuries of I-131 for

treatment of thyroid cancer. And that her patient, during her stay in the hospital, her patient's adult daughter was observed to be frequently at her mother's beside. The first day no one was allowed in the room, and then after that the visitation restrictions were relaxed and days two through four, or 50 percent of the time days five and six, the daughter was in the room essentially all but four hours based on interviews with her. Then the patient died on July 7th, after being admitted on July 1st.

The inspection report documented the daughter may have received a total effective dose equivalent of 15 rem. The licensee did not collect a bioassay sample from the daughter; thus, the total effective dose equivalent explicitly assumes no internal exposure. Approximately 20 other members of the public were exposed. Of these, 10 received doses between 100 and 500 millirem, and the remaining 10 received less than 100 millirem.

On May 7th, the second bullet on the action slide here, the letter from Regional III Regional Administrator imposed a civil penalty to the licensee of $6,000. The civil penalty consisted of two parts; first, for licensee activities which caused members of the public to receive doses in excess of

public dose limit of 100 millirem per year. And second, for the failure of the licensee to investigate and implement corrective action when it became known that a relative of the patient was not following the licensee's radiation safety practices.

And as far as other actions to date on slide 3, the NRC in December 2003 received a letter from the President of the Society of Nuclear Medicine and the President of the American College of Nuclear Physicians which forwarded a critique of the dose evaluation which was in the Region's inspection report.

The critique which was authored by Doctors Carol Marcus and Jeffrey Siegel offered that the NRC's dose evaluation was as much a factor of 17 higher than it should be. We have conducted a preliminary evaluation of that critique and have addressed the five principal issues raised in it. And we will finalize our evaluation once we receive the ACMUI's views.

On slide 4, on January 12th, a letter from Chairman Diaz to the presidents of SNM and ACNP noted that the ACMUI has been tasked to provide an independent analysis and recommendations, if appropriate, regarding the alternate dose

reconstruction offered by the SNM and ACNP.

The subcommittee was established within the ACMUI on January 29th, 2004 to review the dose evaluation contained in the inspection report and the critique of it prepared by Doctors Marcus and Siegel. The subcommittee was specifically requested to review each aspect of dose evaluation, and offer a critique -- and the critique offering alternative methodology, and to determine whether or not it agrees with the approaches and why.

And slide 5, we are expecting ACMUI's report later this month, but are sensitive to the committee's need for additional discussions and the time to assess the additional information. And we plan to use the Region III assessment, our own evaluations, the ACMUI report and form our conclusions regarding the merits of the SNM critique, and will use the results of this evaluation to inform future evaluations of this type.

And lastly, a report will be prepared detailing staff's findings and conclusions for the chairman's signature which will be appended to the final response letter to the Society of Nuclear Medicine and the American College of Nuclear Physicians. That's my presentation. I ran through it

rather quickly.

DR. MILLER: Tom, based upon our discussions yesterday, the comments about we're expecting the report later this month, I thought we agreed yesterday that it would take about four more weeks.

MR. ESSIG: That's still later this month.

DR. MILLER: Well, we're into March. That will get us into April.

MR. ESSIG: Okay.

DR. MILLER: Maybe if you could just modify this comment slightly to say in about a month?

MR. ESSIG: Okay. We can do that. Sure.

DR. MILLER: Give flexibility to it.

MR. ESSIG: Sure.

DR. MILLER: If that's okay with the committee.

MR. ESSIG: No problem. I was just going on Jeff committed to have it within four weeks.

(Simultaneous speech.)

DR. WILLIAMSON: That depends on the staff producing some data in a timely fashion. If we get the data the day before the report is due, that will be problematic.

MR. ESSIG: I understand.

DR. WILLIAMSON: I'm saying, I was told it may not be simple to obtain said data.

CHAIRMAN CERQUEIRA: I hate to play musical chairs, but would it be more appropriate to have your presentation dovetailed into Leon's? Because you're going to do your --

MR. ESSIG: Yes.

CHAIRMAN CERQUEIRA: We'll be at the table at different times.

MR. ESSIG: Yes.

CHAIRMAN CERQUEIRA: The staff will give its presentation the way the Commission does it, and you will leave the Commission table and then ACMUI will go to the Commission table and make your presentation.

MR. ESSIG: The Commission has been informed that this is the order that we're going to go.

CHAIRMAN CERQUEIRA: And that can't be modified? I mean, just in terms of -- I mean, you're going to do your presentation --

MR. LIETO: Leon and I switch order?

CHAIRMAN CERQUEIRA: Pardon me?

MR. LIETO: Could Leon and I switch order? In other words, Leon go before me.

DR. MILLER: To keep the continuity.

CHAIRMAN CERQUEIRA: Yes. Otherwise, it's going to be disjointed.

DR. MILLER: I think you can propose that when you get to the table to keep the continuity. I'm sure the Commission will accommodate.

MR. ESSIG: Yes. I think as part of your opening remarks you can say --

DR. MILLER: Well, actually you're going to -- I'm going to make some initial opening remarks, and I'm going to talk about the fact that there will be two speakers from the staff today and I'll introduce Pam to speak, and then Tom will speak. At that point in time, Dr. Paperiello will say the staff has completed its presentation. The Commission will ask questions of the staff. When that's done, then the staff will leave the table, and ACMUI will go to the table. Maybe, Dr. Cerqueira, in your opening remarks you might say to keep continuity we'd like to address those deconstruction issues first, and then we'd go into Ralph's presentation.

CHAIRMAN CERQUEIRA: Now in terms of whoever is controlling the slides, we should get some idea ahead of time whether we can do that.

DR. MILLER: Yes. They're usually

controlled from the back room.

MR. ESSIG: Yes, we control them. SECY does not offer that service, so Angela will be in the slide --

CHAIRMAN CERQUEIRA: There you go, as long as Angela can do that.

MR. ESSIG: I have to inform Angela that that's what we'll be doing though.

DR. VETTER: I have a philosophical question for Tom.

MR. ESSIG: Yes.

DR. VETTER: In your fifth slide you ended by saying "form conclusions regarding the merits of the SNM critique." Why don't you concluding regarding the current methodology for dose reconstruction that the NRC uses?

MR. ESSIG: We can certainly --

DR. VETTER: You see the difference.

MR. ESSIG: Yes, I see --

DR. MILLER: I think there's an outgrowth to that. I think that's where we want to ultimately get to. But what Tom's addressing is the tasking that was specifically given by the Commission.

MR. ESSIG: And that's why it was focused on --

DR. VETTER: All right. I understand then.

DR. MILLER: I think a natural outgrowth of that is to do exactly what you said.

MR. ESSIG: Yes. And the issue would have never arisen, most likely, had we not received this report, so that's why it has such a major focus.

CHAIRMAN CERQUEIRA: All right. Dr. Malmud, do you want to go over your's?

DR. MALMUD: My presentation is rather brief. I'll just introduce myself. I'm Leon Malmud, a board certified nuclear physician and Dean Emeritus of Temple University School of Medicine, serving as a representative of health care administration on the ACMUI. The chairman of the ACMUI, Dr. Cerqueira, appointed a subcommittee consisting of a patient advocate, a medical physicist, radiopharmacist, a therapy physicist and myself as chair to review material relating to radiation dose estimates in the St. Joseph Mercy Hospital incident.

Briefly, a patient with metastatic thyroid cancer who was also in renal failure was treated on an in-patient basis with 285 millicuries of I-131. The renal failure is relevant because in patients with impaired renal failure, the administered dose of I-131

is retained longer in the patient's body than would otherwise be the case.

The patient succumbed to her illness six days following the I-131 treatment. During that six day period the patient's daughter, whom we are told was given radiation protection guidelines in order to minimize the radiation dose that she would receive from exposure to her mother, chose to ignore the guidelines so that she could be physically close to her terminally ill mother. As a result of the daughter's non- compliance, she received a higher than allowed radiation burden to herself.

The NRC's methodology for calculating the radiation burden to the daughter is being called into question, not the fact that in this instance that the radiation burden to the daughter, even in the best case scenario, exceeded the 100 millirem limit for a member of the public per the guidelines.

We're still in the process of collecting data and questioning the assumptions presented. For example, did the daughter sit by the patient's bed for 12 hours a day for three days with her arms on the bed, and then do so for 20 hours a day on days five and six? What was the real half-life of the I-131 in the patient? How was it measured? These are just a

few questions.

In the absence of adequate contemporaneous records, what assumptions should be made before calculating the radiation burden to the daughter? How should a similar situation be addressed in the future? What guidelines would be helpful to RSOs and licensees in addressing non-compliance by public visitors? Would more timely notification of the Regional Office have been appropriate?

We hope to have a final report available within four weeks for both the ACMUI and the NRC. Thank you.

CHAIRMAN CERQUEIRA: Brief and sweet. Any comments?

MR. ESSIG: I just had one. Dr. Malmud you said impaired renal failure?

DR. MALMUD: Impaired renal function. I think I said function.

MR. ESSIG: I thought I heard failure.

DR. MALMUD: I read it incorrectly, but I wrote function.

DR. WILLIAMSON: You did say impaired renal failure.

DR. MALMUD: Did I? All right. Thank you.

MR. ESSIG: I was listening.

DR. MALMUD: And I wasn't reading my own writing.

CHAIRMAN CERQUEIRA: Sally.

MS. SCHWARZ: I just wanted to ask one question that really doesn't have to do with your presentation at the moment, but for the subcommittee -- the article that was written by Marcus and Siegel. I don't believe that we ever received the full actual calculations that they performed. We just received the first several sheets as part of the committee, kind of a summary of the work. Is there a way that as part of what was faxed to the committee members, subcommittee members, we could get the actual calculations so we could review those too?

MR. ESSIG: We will certainly give you what we have, which is about a 12, 16-page -- I'm sorry. It's 17 pages.

MS. SCHWARZ: That would be good, because we didn't receive that.

MR. ESSIG: Oh, you didn't receive that. Something happened in the --

DR. MALMUD: What happened -- you're correct. I didn't realize that you hadn't received it either. I had received an abbreviated copy, and then

I did receive the full copy. So you didn't receive the full copy, perhaps -- I have a full copy here.

MR. ESSIG: We can take care of that.

DR. MALMUD: We can take care of that right now.

MR. ESSIG: I didn't realize that.

DR. WILLIAMSON: I think I have a full copy but there weren't detailed calculations in there particularly.

DR. MILLER: We don't have those either.

DR. WILLIAMSON: No. I mean, I don't think there are any detailed calculations by anybody.

MR. ESSIG: Not from Marcus and Siegel.

DR. WILLIAMSON: There is the inspection report, and it's addenda that the Region prepared, nd then there is the manuscript as submitted and reviewed by Dick, the journal part of Dr. Marcus' --

MS. SCHWARZ: And the manuscript does have the detailed calculation.

DR. WILLIAMSON: No, it doesn't -- it as a critique and statements that it's off by this or that. Some of which, you know, are not exactly true.

MS. SCHWARZ: The assumptions that they made were part of the --

DR. NAG: The assumptions made were in

there.

DR. WILLIAMSON: The fact is nobody has the basis for a critique because we haven't seen any data, nor have they.

DR. MALMUD: Did the other members of the committee also not receive the full article which is 17 pages?

DR. EGGLI: I did not.

CHAIRMAN CERQUEIRA: I think it's really important for the subcommittee to define the material that they need to make a full evaluation, and we should make certain that all of the, certainly the subcommittee members. Did the rest of the ACMUI wish to receive copies, as well? I don't think there's any -- I certainly don't. I think the subcommittee -- Tom, I think it's important to get it out, complete records of everything that you have that they need.

MR. ESSIG: What I would suggest is shortly after everyone returns to their office, we'll schedule a conference call with the subcommittee, and you can voice whatever needs you have, and we'll --

CHAIRMAN CERQUEIRA: I think it would be best to define the material that they need and get it out to them as soon as possible. And then set up the conference calls. But, you know, the fact that some

of the committee got part of the material and others didn't, the subcommittee, I think is a problem. Jeff.

DR. WILLIAMSON: I think there's an issue with claiming we're going to be done in four weeks, because obviously, we're going to be meeting you know, without -- we're going to be having unnoticed meetings, and the subcommittee will formulate its recommendations. But my understanding of the Sunshine Law requirements are, is that this report has to be deliberated in public by the full committee before this report can be submitted to the staff.

CHAIRMAN CERQUEIRA: That's right.

DR. WILLIAMSON: So I think that it's optimistic to say that's going to be done in four weeks.

MR. ESSIG: That will be done by a noticed phone call, conference call. I mean, we're not proposing getting the full committee together to deliberate on the report.

CHAIRMAN CERQUEIRA: If you're to get it to the commissioners in four weeks, then we should set that up now. Otherwise, it's not going to happen.

DR. WILLIAMSON: I think it's kind of optimistic to think we're going to have all these -- that's my worry, because we do have to have a noticed

meeting.

MR. LIETO: Can I have a clarification? I'm trying to understand which topic we're talking about with this four-week period. I thought there were two tasks, two short-term tasks of the subcommittee. The one was going to be the calculation reassessment and critique which is going to be done in four weeks. The second one that Dr. Malmud is referring to in his presentation, that was going to be passed too, and I didn't - - are we saying that we're going to have both of them done in a month? I mean, that's what it sounds like to me, and I'm thinking that maybe the one that Dr. Malmud is referring to might take a little bit longer.

DR. MALMUD: Excuse me. By the second task, do you mean how we should deal with this issue in the future?

MR. LIETO: Right.

DR. MALMUD: That really I don't think is a major task, in that these are recommendations which would just be helpful to RSOs in general. I think that the current guidelines probably give us adequate means of dealing with this. But it would still be very helpful to the RSOs and to the licensees to know specifically what do we do in situations such as this,

when a member of the public in a tragic situation such as this, refuses to cooperate. This is not a stranger. This is a --

DR. WILLIAMSON: Well, that's not the only issue. I think the issue is how to manage patients whose family members request exemption from the 100 or 500 mR limit for compassionate rationale.

DR. MALMUD: You're correct.

DR. WILLIAMSON: Not just those who disobey the instructions of the -- so I think you're making --

CHAIRMAN CERQUEIRA: We're going to need to go upstairs to be on time for the Commission briefing. But before we leave, we need to make sure that the charge to the subcommittee is clearly written and distributed to all the committee members. And that should be done by the end of this week.

You know, Charles, we have to give some idea of when we're going to have this to them. And, obviously, that's of concern to you -- what are we going to way, four weeks?

DR. MILLER: I think for the purposes of the Commission meeting it's safest to say that the subcommittee will try to complete its activities in four weeks, an we will convene a conference call of

the full committee as soon as possible thereafter.

CHAIRMAN CERQUEIRA: Yes. I think that's the right language, because when we reconvene again we need to set these timelines.

DR. WILLIAMSON: And then, you know, we'll set these timelines at the meeting this afternoon to go forward. I don't want to box you into four weeks, because if we give the Commission a finite timeline, Commissioner McGaffigan will push to get it done especially in that timeline.

DR. MALMUD: So I'll change my last sentence to say that we hope to have a final report of the subcommittee available in four weeks for review by the ACMUI.

CHAIRMAN CERQUEIRA: Yes.

(Whereupon, the proceedings in the above-entitled matter went off the record at 9:18 a.m. and went back on the record at 12:49 p.m.)

CHAIRMAN CERQUEIRA: The transcription service is now available, so if people would like to get started we can.

And a couple of people have asked me to maybe add a couple of things sort of immediately when we're getting started and one is the -- I guess we really need Tom and Trish here. The whole issue of

the inventory and the process and what's been going on and what the ACMUI can do to help. Maybe we'll wait for Tom to come back.

The other thing that Ralph asked that perhaps we do is to just sort of review the charges, if any, that were put to the Committee by the Commissioners.

DR. MILLER: Mr. Chairman, if I can, I want to caution all of us. We heard what the Commissioners said at the table today. Now what they'll go back and do from the meeting is they will deliberate on what they call a Staff Requirements Memorandum. That's the official guidance that we'll get. So to jump from anything that they said verbally, I think you can anticipate some of the things that may be coming, but the jump from anything that they said verbally we have to be cautious on.

They'll deliberate how they want to direct the guidance to be done and sometimes that takes two or three iterations of discussions amongst the Commission offices to make that happen. We did hear from some of the Commissioners verbally on their views.

We have to do the bidding of the whole Commission once they make up their mind. So what

we'll do is as soon as we get the SRM, that will give us the guidance of what we have to charge ACMUI with doing.

CHAIRMAN CERQUEIRA: Ralph, is that --

MR. LIETO: I don't have any objection with that. I just thought that there were a couple of things that, like for example, regarding the sealed source information that Commissioner McGaffigan very politely, but sternly, encouraged us to get those inventories in, so to speak.

CHAIRMAN CERQUEIRA: Yes.

MR. LIETO: And I was thinking that maybe we might want to go back to various organizations that might be affected by this, so that their membership, if they're contacted, you know, this is what you need to do and maybe just to get the word out there so that people start something along that line.

CHAIRMAN CERQUEIRA: Sure.

MR. LIETO: The other thing was about the implementation of Part 35 this morning. I have some I guess this going to be a surprise, I have some strong opinions about certain things, that I think -- just want to kind of put out on the table. I don't know if we're going to go anywhere with it, but I think it would have been helpful if we had some input

on -- not input, but some advance notice on what was being presented. Because I think there's reasons why some of that stuff is currently out there.

And I think some of the guidance that NRC is giving us, I personally have some reservations. Those are the kind of things that I thought maybe might be good to kick around and discuss a little bit.

CHAIRMAN CERQUEIRA: So do you want to initiate that?

DR. MILLER: I think that's reasonable to have a discussion. I am just cautioning everyone with regard to the official capacity of what the Committee would do at the Commission's direction.

MR. LIETO: I guess just to start off on the first issue having to do with the sealed source in the IAEA charge, if you will, to the NRC, is that there's this -- I won't say necessarily a reluctance, but maybe lack of due diligence in responding to the NRC inquiry for their inventories that I agree the point that Dick made earlier that getting an e-mail from somebody is not -- that doesn't have some kind of official imprimatur kind of bothers us all.

In fact, this is the second time it's happened to me. And so I myself will also admit that I didn't respond either. And it's not a very simple

inventory to respond to either, request.

But be that as it may, I think that we can have sort of the -- maybe if Trish or Tom can help us with sort of -- if you have questions who to go to type of a thing. There are various listservers that we could put this out on that businesses interact with as well as -- I think mainly it's going to affect the therapy end of the community because that's where the high activity sources lie and maybe going to representatives of those organizations to say if you've been contacted and you have not responded, you need to do this. It's important that you follow up on this. And have the societies also, the professional societies encourage the individual licensees that they need to complete this inquiry.

CHAIRMAN CERQUEIRA: Can I ask you a couple of questions, maybe both you and Dick? Did you receive the official letter from NRC?

DR. VETTER: No.

CHAIRMAN CERQUEIRA: No.

DR. VETTER: I don't remember receiving a letter. Just a cold e-mail.

DR. MILLER: That's the first step of the problem, if that was an oversight or if it ended up some place else in the organization and never got to

you.

MR. LIETO: I don't recollect one. I'll be honest.

DR. MILLER: The second issue is then how to follow up on that with regard to the collection of the information. There are -- we do have staff contacts that can help you in that regard, probably I'm thinking Merri Horn would probably be -- I don't know if you know Merri Horn, but we can certainly get you the contact. She works in my Rulemaking Branch.

DR. VETTER: Through an exchange of e-mails I did hear from her.

MR. LIETO: Lots of times people get -- you get asked for the information and so forth and I think there's some real underlying importance attached, obviously.

DR. MILLER: Absolutely.

MR. LIETO: And if -- not to say whenever you get asked by -- asked something from the NRC it's not important, but informational items may not be a high priority in relationship to other daily activities.

DR. MILLER: Tom, you're trying to secure copies of the letter, so at least all of the Committee members have the letter.

MR. ESSIG: There were a number of attachments and copies are --

MR. LIETO: And we could maybe use -- sending something to the various -- professional newsletters and ask them to print something to the effect of this and if you got questions where to go, just to kind of maybe get some of those blanks filled in.

CHAIRMAN CERQUEIRA: I guess for the staff we identified as a fact that even though you may have put together a procedure in place, the end users have not gotten in a very systematic way --

DR. MILLER: Well, I don't know if that's true or not.

MR. ESSIG: Well, at least data points.

DR. MILLER: Yes, two data points that said you two personally didn't see it and what I'd have to go back and check is who was the addressee of the letter to each of your licensees or was there an oversight and you didn't get it.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: I would not suggest it was not systematic. I'm assuming that a lot of people got this e-mail. But I don't know. Maybe there was a letter of some sort as well. I don't know about that.

I'm not suggesting it's not systematic. What I object to was, what I objected to was the fact that I was being asked to share my inventory with a contractor who was working on behalf of the NRC.

That was all explained to me very, very clearly and politely. But when I read down, okay, I asked where was this going and they said it's strictly voluntary and it's going to be shared with the following and obviously the contractor, but when you read down further, there are numerous federal agencies who will have access to the data.

I am a little worried about the potential openness of this. Here I am supposed to be taking action to prevent someone from coming in and stealing our radioactive inventory --

DR. MILLER: And now you're e-mailing it out to everybody.

DR. VETTER: I'm e-mailing it out.

DR. MILLER: I was not aware that that was going on. I had just assumed that the way the data was being collected was people were --

DR. VETTER: And I'm certainly exaggerating. I'm not saying it's e-mailed to everybody. I'm just worried about the number of agencies who will have access to it and the number of

people within those agencies that have access to it.

I haven't been reassured about the safeguarding of this data.

DR. MILLER: That's a fair comment.

CHAIRMAN CERQUEIRA: What's the wishes of the Committee now? We've identified that there may be some issues and I apologize for my broad statement.

MR. LIETO: I guess I'll just make a recommendation and maybe we can go from there, would be that ask NRC Staff to give us information on who licensees can contact as a verifying source if they have concerns about completing these inventories. And secondly, to urge licensees to respond to this inquiry if they have not already done so.

DR. MILLER: Merri Horn is the NRC project manager for this effort.

MR. LIETO: I'm looking, like I said, just sort of an informational broadcast versus some of the listservers and physics listservers and Society listservers and newsletters type of thing. Get the word out.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: Personally, Ralph, I'll disagree with that. I would rather not go public, but rather that I get another e-mail of some sort directed

to me and to you and all those who are requested to do the e-mail, reassuring us of some things, rather than tell the whole world that we're supposed to do this. Now the whole world knows we're doing it.

CHAIRMAN CERQUEIRA: Ruth?

MS. McBURNEY: In Texas, we have -- there's been another follow-up from NRC with a list of our licensees that have not responded and we took the initiative to contact all of them and have reassured them that this is information that is being collected for this database and that's what the agreement states are doing is sending out another contact to all those licensees. Now whether NRC is going to do that, I don't know.

CHAIRMAN CERQUEIRA: Does the Committee want any further action on this or just sort of an information item for staff?

DR. VETTER: I guess I think the Staff just need to be aware of what our concerns are and to perhaps act accordingly.

MR. LIETO: I have no problem with that.

CHAIRMAN CERQUEIRA: That's been registered. All right. I think we should go back to the agenda.

Several members have identified the fact

that they have early flights and have to be out of here by 3 o'clock so in order to -- and Dr. Nag, unfortunately had to leave early already, so I think it will be important to try to get through some of these issues in a timely fashion.

The first item is proposed changes to abnormal occurrence criteria and Angela Williamson will be doing the presentation.

Angela, are you going to need the full hour, do you think?

MS. WILLIAMSON: No. I shouldn't. It depends on how many questions you have.

CHAIRMAN CERQUEIRA: Okay.

MS. WILLIAMSON: Okay, I'll make this very quick --

CHAIRMAN CERQUEIRA: No, you don't have to make it quick, but we should get to the points and provide the information you need.

MS. WILLIAMSON: I want to start out by saying that I probably should have named this, instead of proposed changes to abnormal occurrence criteria which sort of suggests that this is a definite thing that we're looking to do, I should have probably made it more clear that this is not -- changes to the AO criteria is not within the realm or the authority of

my particular office, Nuclear Materials Safety and Safeguards. It's actually within the realm of the Office of Research.

So what I'm about to discuss with you today I should probably call it preliminary proposed changes because actually the Office of Research, they own the AO criteria and it's possible that there will be no changes. So I just want to make that very clear to everyone that we want your input, but for reasons that may not be clear to me or anyone in NMSS, it just may not go forward.

DR. MILLER: I guess if I could just augment what Angela is saying. I think what would be valuable to us and NMSS is these are some views that developed at NMSS, so it would be helpful if we could get the Committee through dialogue to either support it, recommend modification to it, including don't go forward with it or whatever, so that we can continue to dialogue with the Office of Research with regard to what the appropriate recommendation would be, if any, for a change.

MS. WILLIAMSON: Okay, I want to very quickly define abnormal occurrence. An abnormal occurrence, as you can see on the screen is an unscheduled incident or event which the NRC determines

to be significant from the standpoint of public health and safety.

And there are several different types of AOs. The less common types, what I mean by that term is that the types that we don't see occurring as often amongst licensees are those involving releases to the environment, involving theft or diversion, or involving the design or construction of license facilities. And as you might guess, the more common types of AOs involve over-exposures and medical events.

Now if this transpires, this proposed change goes forward, what I have here in the red text shows you what we plan to add to the medical event AO criteria. What we're saying here is that we want the consideration that a dose to those organs, those organs, the lens of the eyes, the gonads, so on and so forth, but we want to add or to tissue which results in permanent functional damage. The reason why we're considering adding that language to the medical event AO criteria is that it would be a way for us to definitively capture events involving intravascular brachytherapy.

However, we don't want to catch every event involving intravascular brachytherapy so by

adding the language or to tissue which results in permanent functional damage, that would exclude those IVB events in which the tissue just got a little -- just got over-exposed, but there was no permanent damage done to the tissue.

DR. WILLIAMSON: Can you go back to that slide? Two comments. One, I think it would be helpful if you outlined for the group what the purpose of AO is an dhow it is used in your congressional reporting. I'm not sure that everybody here has been involved in the discussion of the AO provision before.

Secondly, go ahead, I'm sorry.

MS. WILLIAMSON: Okay.

DR. WILLIAMSON: Then I'll ask my other question.

MS. WILLIAMSON: Okay, we are required to report certain events to Congress and these events are defined as abnormal occurrence events and so what we have to do is we have to -- every year we have to capture those events that meet the abnormal occurrence criteria definition and we assemble a report for Congress and we forward it to them. The report I believe is called NUREG-1100 if memory serves me correctly. And as far as I know, it's for their information. I don't know that they do anything more

with it than just be informed by it.

Dr. Miller, you might want to correct me if I have an incorrect understanding of that, but they do want to know about these things.

I suppose it's always possible for them to come back to us and ask us questions about those things, but I cannot speak to what is routinely done with this information.

DR. MILLER: Just so that we're all clear, the abnormal occurrence report to Congress covers all of NRC's regulated activities for reactors to materials. So over the course of many years if we go back to Three Mile Island and Chernobyl and things like that, the Congress is always interested in the state of affairs in what I'll call the nuclear arena. So that abnormal occurrence report is something that Congress has asked for over time.

Depending upon what happens in any given year and what the nature of Congress is, sometimes we get feedback, sometimes we don't.

DR. WILLIAMSON: Okay, now my technical question. It is not clear from this what you want to include and exclude. I think I hear you saying that you want to exclude events which may give 10 gray to some tissue in intravascular brachytherapy due to an

equipment malfunction or something, as we discussed in the last meeting, but not unless it results in permanent functional damage to the tissue. Is that correct? You want to not report 10 gray events unless they have a functional damage to the tissue?

MS. WILLIAMSON: No. There's an "or" there.

DR. WILLIAMSON: Yes, I see.

MS. WILLIAMSON: It's "or". So what we're saying is the rest of it still applies, but in addition, would be inclusion of any event in which there's permanent functional damage to tissue because you see there can be 10 gray to a person's finger, but that's not going to result in permanent functional damage, obviously.

But if there's 10 gray to tissue which causes permanent functional damage, there really narrows down that type of event, what kind of event would that happen in which that might occur, an IVB.

DR. WILLIAMSON: I'm still confused. The way it's written just in the black which I assume is the current rule is that any event which gives a 10 gray to any tissue or organ is automatically going to be reported as an AO, isn't it?

MS. WILLIAMSON: No.

DR. WILLIAMSON: No? It says there "is equal to or greater than 1 gray to a major portion of the bone marrow, dah, dah, dah, or equal to or greater than 10 gray to any other organ.

MS. WILLIAMSON: Organ.

DR. WILLIAMSON: Okay, so the distinction rests in your mind on what is a tissue versus an organ.

MS. WILLIAMSON: Exactly.

DR. WILLIAMSON: So you don't consider the epithelium of a blood vessel to be an organ?

MS. WILLIAMSON: Exactly.

CHAIRMAN CERQUEIRA: Doug?

DR. EGGLI: So Angela, you're saying if permanent injury results at a dose of less than the 1000 rad dose then that's reported in addition to any dose over and above?

MS. WILLIAMSON: No, that's not what I'm saying.

MS. McBURNEY: The 10 gray still goes --

MS. WILLIAMSON: Exactly. The 10 gray, the criteria above what you see in red has nothing to do with permanent functional damage. That's just strictly the reporting of that dose to that type of organ.

DR. EGGLI: But if any dose causes permanent functional damage it's reportable?

MS. McBURNEY: No. Above 10 gray.

DR. WILLIAMSON: It's got to be above 10 gray.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: I think the fix to this would put in there after your first red or put a parentheses 3 and then just say equal to or greater than 10 gray to tissue which results in blah, blah, blah which sounds like what you want.

DR. WILLIAMSON: What's your definition of organ?

MS. WILLIAMSON: Organ is not defined in Part 20.

DR. EGGLI: I have another question on the A part. Do you really mean there "unintended dose to the bone marrow"? What about an intended or planned dose to the bone marrow?

MS. WILLIAMSON: Well, if it's planned, if it's therapeutic, that's different. We're talking about doses that people receive that they shouldn't have received. When those doses are at those limits are greater, then they would meet the AO criteria.

DR. WILLIAMSON: See, it has to be a

medical event or misadministration already, so that means there has to be some component of rogue delivery.

MS. WILLIAMSON: Exactly. Appendix A, criterion 4 for medical licensees states that a medical misadministration or a medical event that -- so this is merely beyond being just a medical event or a misadministration. If you're in an agreement state, it's a little bit more than that. It's a dose threshold that includes a medical event or misadministration.

DR. WILLIAMSON: So a treatment with a leaking source that gave a correct dose of 10 gray to the tumor would be an AO, even though the dose is correctly --

MS. WILLIAMSON: No, no, no. If you prescribe a dose, that's different.

DR. WILLIAMSON: Well, I'm just reading your definition. See, a correct treatment given with a leaking source as I understand a medical event because it was given with a leaking source, it's a medical event independent of whether there was any dose delivery error or not. So as I would read this a correctly given treatment, given with an incidently leaking source would both be a medical event and also

an abnormal occurrence just because both paragraph A -- so, I think Dr. Eggli's point has some merit still.

There are classes of misadministration or medical event that you might not want to report here that seem to satisfy this definition. I guess I consider that an incidental comment.

CHAIRMAN CERQUEIRA: Leon?

DR. MALMUD: Jeff, are you recommending some changes in the words as they are on this graph, on this --

DR. WILLIAMSON: Well, that sort of depends on the way this is interpreted and handled at the level of guidance and implementation.

I'm just pointing out that the way AO is now defined it actually could include a large class of events that weren't intended. Like if you treated a prostate brachytherapy patient with 75 seeds, one of them happened to crack open in the procedure and leak, that would be a medical event if you detected that because you treat the patient at the leaking source and because you gave 140 gray correctly or incorrectly it doesn't matter to the prostate which is some organ. This would satisfy that definition. That's all I'm saying, an observation I'm making.

CHAIRMAN CERQUEIRA: Dick, help us out

here.

DR. VETTER: Just to clarify, first of all, the only thing new is what's in red. Is that correct?

MS. WILLIAMSON: That's correct.

DR. VETTER: And is the intention for the 10 gray to apply to that tissue?

MS. WILLIAMSON: Yes.

DR. VETTER: Then how about if you remove the comma and the word "to", "to any other organ or tissue which results in permanent functional damage", is that your intention?

MS. McBURNEY: Then the permanent functional damage would also apply to organ, as well, if you did that.

CHAIRMAN CERQUEIRA: So Ruth, how would you change it to make it --

DR. VETTER: Then the first suggestion where we --

MS. McBURNEY: I like the suggestion of as a 3, to make it clearer, equal to or greater than 10 gray to tissue which results in permanent functional damage.

CHAIRMAN CERQUEIRA: Ralph, would that fix it?

MR. LIETO: It was my suggestion, of course.

(Laughter.)

MS. SCHWARZ: I have a question. Is that unintended dose?

CHAIRMAN CERQUEIRA: That's unintended.

DR. WILLIAMSON: Not necessarily, if it's a leaking source, it could be the intended dose. That's my point.

DR. SULEIMAN: I'd like to clarify something.

CHAIRMAN CERQUEIRA: Sure.

DR. SULEIMAN: The term "organ" and "tissue", I was waiting for it to reappear, but the terms are used synonymously. I mean you have dose models and I think the way it's worded here it sounds like it's an either or and I think maybe to any other organ or tissue would probably be -- if you just put organ or organ and tissue would probably be more meaningful.

DR. WILLIAMSON: I think it would be good if our medical experts here could define for us what tissue and organ means because it does seem an inconsistency. I would think that all organs are tissues, but perhaps not all tissues are organs.

DR. MALMUD: The largest organ in the body is the skin. And the expression of the term "tissue" seems to be applying to a region of that organ, rather than the organ in toto. And it is quite possible to give quite a significant dose to a portion of that organ which is quite damaging, yet the majority of the organ is not affected.

So tissue from my understanding of it and we can pull out a copy of Dorland's if we wish to confirm it, but can be any collection of cells from any organ. But an organ has a definite definition and the largest organ in the body is the skin.

So I think that it is the skin, in particular, which is generating this issue for us because clearly it seems that the intent was to deal with a portion of that organ rather than the organ in toto. Am I correct?

MS. WILLIAMSON: Yes, exactly. We have the dose limits for organs which is in black. So what we're trying to do is narrow down the tissue issue.

DR. WILLIAMSON: Would it be more helpful if you said "part of an organ receiving at least 10 gray which results in permanent functional damage"?

MS. WILLIAMSON: What we're trying to do is capture IBV events in which there's permanent

functional damage.

DR. WILLIAMSON: And you don't think they're captured now because when a 10 gray medical event occurs it only occurs to a fraction of the epithelial lining of the blood vessels so therefore you view it as not an AO?

MS. WILLIAMSON: It can be argued either way. If in an IVB event 10 gray or a 1000 rads occurs or greater occurs outside of the intended treatment site, it can be argued that that's an AO.

What we're trying to do is not forward 12 AOs to Congress in a year.

DR. WILLIAMSON: I understand.

MS. WILLIAMSON: But what we want to do is narrow that definition so that just certain IVB events are captured and what makes the most sense to us at this point is just to only forward those in which there's permanent damage inadvertently done to the patient.

DR. WILLIAMSON: What is confusing me, I guess, is in your minds, the minds of the staff, what is the difference between tissue and organ and I've heard two possible things. I mean one might consider organs as discrete anatomic structures that are covered with epithelial linings or something and

tissue is like connective tissue that's not itself an organ. That's one possible interpretation. The other interpretation has been raised by maybe our Vice Chair and he suggested maybe your concern is partial versus whole organ irradiation.

So I'm uncomfortable because the terminology and intent isn't very clear.

MS. WILLIAMSON: The short answer to that is that they can, to some extent, can be a bit interchangeable because organ is not formally defined in Part 20.

DR. WILLIAMSON: But organ, I'm sure your OJC would say then that the definition of the word would revert to ordinary anatomic or medical uses. So just because it's not defined in Part 20 doesn't mean you have license to use the words anyway you want.

MS. WILLIAMSON: Well, we do have the option to consider IVB events in which an unintended portion of the vessel was irradiated at 1000 rads or greater. We have the option right now to consider those AOs.

So what we're trying to do is find a way to not consider those AOs in the short term. Now we can always go back -- I can't say we can always go back. We can consider formally defining organ in Part

20 which --

DR. WILLIAMSON: That's a lot of work.

MS. WILLIAMSON: But in the meantime, just for the purpose of taking care of this AO criteria, we can --

DR. WILLIAMSON: I know. I'm not trying to be -- attack your intention. I'm just saying what I hear isn't making sense and holding up to critical inspection and it seems to me it leaves a big ambiguity what phrases conditions 2 and 3 mean unless it's spelled out a little more. And so that's why I'm asking you what exactly do you mean by organ versus tissue and do you -- if you mean partial irradiation of an organ, then you should say partial irradiation of an organ or portion of an organ that results in permanent functional damage, if that's the issue.

CHAIRMAN CERQUEIRA: Sally?

MS. SCHWARZ: That's what I was going to say, why not say or to a portion of an organ or part of an organ which results in permanent functional damage to the tissue, just change that.

CHAIRMAN CERQUEIRA: Dr. Malmud likes that.

DR. MALMUD: I like that because it still uses the word organ, appropriately and refers to the

portion of the organ as tissue which is also correct. Does that capture the spirit of what was intended though, Angela?

MS. WILLIAMSON: It's a slightly different answer than I expected, but --

(Laughter.)

If you have a formal recommendation, then I would --

DR. WILLIAMSON: Can I ask a question to Dr. Malmud first?

CHAIRMAN CERQUEIRA: Go ahead.

DR. WILLIAMSON: Does every collection of cells in the body belongs to an organ or are there collections of cells in the body that do not belong to organs?

DR. MALMUD: Well, the circulating blood cells are generally not referred to as an organ, meaning the contents of our blood vessels. So I guess in that instance the answer is no. Every collection of cells is not necessarily --

DR. WILLIAMSON: But all other ones besides the circulating blood cells --

MR. LIETO: Let me clarify. I actually published some stuff that refers to tissue and/or organs and I'm going to quote from the ICRP

Publication 8. I just happen to have it with me, okay?

(Laughter.)

I'm just going to quote one sentence. I don't think we need to get into it. I think organ doses are defined historically for nuclear medicine dosimetry calculation and I think hear we're talking about dose to a certain part of normal tissue. I didn't want to use the word tissue but it may transcend several organs. I mean it's not limited. But to avoid confusion the expression "other organs and tissues has been used in the Tables of Biokinetic Data." Because the term is used inconsistently, tissue, doses. I think it may have entered the literature when we were talking about mammography doses where the breast consists of adipose and glandular tissues and it's the glandular tissue that's at risk. So the real academic said it's really critical tissue within that organ.

But I think for this discussion, I think -- you don't want to average the dose to part of the blood vessel when it in fact, if you were to define the blood vessels as an organ or tissue, you'd have to average all of the tissue in the entire body. So I think you're really talking about a high dose to a

very small geometric area of the body.

MS. WILLIAMSON: That's correct. That's correct.

CHAIRMAN CERQUEIRA: Lynne, do you have a comment in the back?

MS. FAIROBENT: Lynne Fairobent with ACR. I actually had two questions. One may be for Jeff Williamson since Dr. Nag had to leave.

Jeff, in adding this sort of additional language will we be capturing AOs perhaps unintendedly from permanent seed implants where seeds may migrant to the lung that we may not have captured before or to other tissue?

And then secondly, the way this is structured, in order for A to be valid, there's an "and" that follows the end of A and we have not seen what follows this. So I don't know what the other conditions are for meeting this in order to be an AO.

I don't know Angela, if you have that additional text with you or not.

MS. WILLIAMSON: I don't.

MS. FAIROBENT: Obviously, A is tied to something else in order to be a valid criterion and without seeing that I'm actually at a loss for what is the "and" criteria that needs to also be met in this.

DR. WILLIAMSON: I think to try to answer the first part of the question which was directed to me, I think migration of a seed into the lung would not be because Angela's trying to tie this to a permanent functional injury. So I guess if seed drifted into the lung and caused some terrible medical complication, then yes, but obviously the vast majority, if not all of these seeds that migrate may cause a large focal dose in the lung, but they don't cause a permanent functional injury. So they would not be reported.

I don't know. You know, please don't misunderstand the reason for my concern, but you've now put in this rule language two different concepts, tissue and organ and people can have a lot of arguments about what that means, so if there would be some way of saying what you need to say without having to wrestle with this. Maybe you could say and modify number two so it says "glandular organ" and then number 3 could be "or any other tissue" and that would make it clear. Perhaps that would be one way. I just don't know.

MS. WILLIAMSON: Well, maybe adding glandular organ would make it a little more clear.

DR. SULEIMAN: No. Glandular implies a

secretory or excretory function that not all organs may have.

MS. WILLIAMSON: Okay.

DR. MALMUD: I think if I may try to quote that which Sally said earlier and if we go back to that Appendix A, we read through sub A as it is. Then it says "or the gonads" on line 4 "comma, or equal to greater than 10 Gy to any other organ, or insert number 3 equal to or greater than 10 to any portion of an organ which results".

I'll say that again. It's as you have it up there with 2 saying "equal to or greater than 10 to any other organ, or (3) equal to or greater than 10 Gy to any portion of an organ which results in permanent functional damage."

MS. WILLIAMSON: Is that the recommendation of the Committee then?

DR. MALMUD: I present it as a question. Is that wording acceptable to the Committee?

CHAIRMAN CERQUEIRA: Dr. Vetter says yes. Sally agrees?

MS. SCHWARZ: Yes.

CHAIRMAN CERQUEIRA: Agreement on this side? What about over here, Ralph, you object?

MR. LIETO: So the vessel would be

considered part of an organ.

DR. MALMUD: The blood vessel would be part of the organ in which it's located.

MR. LIETO: So for the heart I could see that. What happens when we start looking at larger veins and arteries for these types of intervascular brachytherapy? This treatment is coming down the pike or like we're doing now in research in terms of dialysis patients. Then a definition -- I wouldn't think it would fit.

CHAIRMAN CERQUEIRA: I feel a little uncomfortable not having any of the radiation oncologists here, Dr. Nag and Dr. Diamond. But it seems like everybody else is pretty much in agreement.

We have Dr. White in the back who is a radiation oncologist.

MR. WHITE: Actually, I'm a medical physicians, Gerry White from AAPM.

I hesitate to engage in a technical disagreement with the Committee, but just back to the prostate seed embolized in the lung. It's not immediately -- and Jeff has a lot more dosimetry calculation experience than almost anybody in the world, but it's not immediately clear to me that an iodine seed embolized in a vessel in the lung,

necessarily gives a lower total dose than a thousand, than an intravascular event that you want to capture.

The red language does not talk about permanent functional damage to an organ. You don't have to have failure of the lung function in order to be captured.

DR. WILLIAMSON: But there's one thing you're forgetting. There are really three conditions that have to be met for the red text. First, it's got to be a misadministration. In the case of a seed embolizing in a natural way to the lunch is specifically exempt. Seed migration is specifically exempted as grounds for a medical event. It wouldn't even come that far.

So it has to have first be a medical event on some grounds or another. Secondly, it has to give this dose, more than 10 gray, to the structure, whatever it is, that's what we're debating and then for the red text, not only does it have to meet those first two conditions, but there has to be a third condition of permanent functional damage. And this is the difficulty we're wrestling with.

The only disadvantage I can think of Dr. Malmud's suggestion is that possibly it now makes 2 sound like it has to be a whole organ dose. So whole

organ doses don't have to have permanent functional damages, but partial organ irradiations do to be counted in this and I'm not sure -- somebody interpreting number two number is being so limited so that if half the kidney is irradiated, but there's no permanent functional damage, that's not going to be an AO any more, whereas you had the discretion to consider it an AO the way this was written. So it's kind of a complicated issue.

MS. WILLIAMSON: Okay. I want to make it clear. Maybe I didn't hear you right. I want to make it clear that in the other cases, when you see number one equal to or greater than 1 gray or 100 rads to a major portion of the bone marrow, to the lens of the eyes or the gonads, or equal to or greater than 10 gray or a 1000 rads to any other organ, permanent functional damage does not apply to 1 or 2.

DR. WILLIAMSON: I realize that.

MS. WILLIAMSON: Okay, okay.

DR. WILLIAMSON: What I'm saying is you're adding a condition number 3.

MS. WILLIAMSON: Right.

DR. WILLIAMSON: Which is very similar to 2, except now the criteria are partial organ irradiation and functional damage. So it makes it

seem by implication that number 2 is limited to whole organ irradiation and I'm not sure that's the consequence you intend. Because now someone can come and argue, you know, okay, I made a big boo boo with cobalt-60 teletherapy, put the field in the wrong place and I zapped half the kidney to a dose of more than 10 gray. Well, the patient's kidney function is still okay, no permanent function, no damage and I've only irradiated half the organ, therefore it shouldn't be an AO because your condition number 3 implies that condition number 2 applies only to whole organ irradiation.

MS. WILLIAMSON: We don't want the definition of irradiation to an organ to change in any way. All we really want to do is capture.

DR. WILLIAMSON: I know you don't want to --

MS. WILLIAMSON: Is capture the IVB events in which permanent functional damage occurs. That's all we want to do. We just want to limit it to that, so we capture just those and not regular IVB -- this was, we thought, our way of addressing certain IVB events. What we're looking for language that will help us to capture just those IVB events and not affect the organ limits that are up there on the

screen.

DR. MALMUD: May I suggest once again that we use the wording that was suggested by Dr. Schwarz and beginning with line 4, (2) equal to or greater than 10 gray to any other organ, or (3) equal to or greater than 10 gray to any portion of an organ which results in permanent functional damage.

Now may I suggest that we tentatively agree on that, but get the opinion of the two radiation oncologists who are members of this Committee, but are absent from the Committee at the moment and then give a conditional approval if they agree. If they disagree, then we'll have to deal with it once again.

Is that reasonable?

MS. WILLIAMSON: It sounds like you want us to bring this back before the Committee?

DR. MALMUD: No, I don't want to bring it back if the two radiation oncologists agree, then it's done. Can we do that?

MS. WILLIAMSON: If you're recommending something, we need a motion.

DR. MALMUD: I'll make that a motion that we adopt the wording introduced by Dr. Schwarz, the wording I just read and that we approve -- I make a

motion that we approve the wording I just read, conditional upon the agreement of the two radiation oncologists, members of this Committee who are absent right now. And that would complete it, if they agree.

CHAIRMAN CERQUEIRA: Is there a second on that?

DR. VETTER: Second.

CHAIRMAN CERQUEIRA: Any further discussion? Dr. Miller?

DR. MILLER: This has been a great intellectual discussion. It's probably over my engineer's head, but what I just heard Dr. Malmud propose causes me to be concerned about the issue that Jeff brought up with regard to No. 2. What is the intent of No. 2? Is it intended that you would get 10 gray or more to the whole organ or if you got it to a portion of the organ, could that still be considered an AO? If the intent is that it could still be a portion of the organ, and be an AO, is No. 3 undoing part of the intent of No. 2, if anybody follows what I said.

DR. WILLIAMSON: I do. And it's up --

DR. MILLER: It's caused me to have to go back and think okay, what do we really mean by No. 2.

MS. McBURNEY: That was my concern too as

to how that might impact then what No. 2 means.

DR. WILLIAMSON: But I actually like the new interpretation of No. 2 so I will vote for it as it stands.

DR. MILLER: What it would mean in my understanding of it would mean that No. 2 would then become attached to a meaning of a dose to a whole organ and No. 3 would only become an AO if a portion of that organ was actually damaged.

DR. WILLIAMSON: Actually damaged.

DR. MILLER: Which I think is a reasonable definition.

DR. WILLIAMSON: Except that -- I do think it's reasonable, but it's different than what you have now. That's all I've been trying to point out to you.

CHAIRMAN CERQUEIRA: Dr. Malmud and then Dr. Eggli.

DR. MALMUD: It's that which I intended for the outcome to be, but I remain concerned that the two radiation oncologists who have not had a chance to review this agree.

One of them may say wait a minute, this is not sufficient. We really need to be concerned about 10 gray to a part of an organ which doesn't appear to give permanent damage, but which we know may cause

permanent damage.

If they say that, then we're back to relooking at this, but I would value their opinion very much.

CHAIRMAN CERQUEIRA: Doug and then Sally?

DR. EGGLI: First of all, I don't think you've put a time limit on the development of the permanent damage which may be made having expressed that here, but I think that the concept of it being an event if there's a consequence fits the whole concept of risk-informed policy which is to say even if the partial organ got a 1000 gray, if there are no functional impairments that result from that, should it philosophically be an unusual occurrence that needs to be reported?

And again, to go back to the new philosophy that that we're not just reporting for the sake of reporting, but we're reporting because it means something. This new definition, I think fits the concept of a meaningful abnormal occurrence.

CHAIRMAN CERQUEIRA: So risk-informed, performance-based.

Sally?

MS. SCHWARZ: And what I was just going to suggest is that if the decision of the whole Committee

is required, can the medical oncologists, radiation oncologists be e-mailed for an answer as far as their vote?

CHAIRMAN CERQUEIRA: Well, I don't know so much a vote -- I guess if both of them approve it, then basically we would have the approval of the Committee. If they don't, then it would really need to come back for further discussion between the radiation oncologists who are more intimately involved in doing this and may have other awarenesses than what we're having.

DR. WILLIAMSON: I think for Dr. Diamond and Dr. Nag to give an informed judgment, I think to vote on this fresh without any background or any explanation or hearing any of the -- at least a summary of this debate, it's probably not realistic. Unless there's a real urgency associated with this, I would suggest we bring it up at our mid-meeting conference call and get their opinion after explaining the debate.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: When will the transcript of this be available because I would say just say hey guys, go read these pages on the transcript. This is what everybody said back and forth and we need a

decision on the motion and give them maybe a couple of weeks after the transcript is available to them and go from there.

CHAIRMAN CERQUEIRA: I see general nods of approval.

Leon?

DR. MALMUD: I would like to ask Angela Williamson if there is a sense of urgency about this?

MS. WILLIAMSON: No, there's not. Like I said before, this product is really owned by the Office of Research and for other reasons that we're not clear on, they may decide that this is not even a smart thing to do at this time.

So we were just trying to get some very preliminary opinions about what you think of this.

CHAIRMAN CERQUEIRA: We have a call on the question.

All in favor?

(Ayes.)

Opposed?

So the motion was carried and basically if -- Angela, when you get the transcripts, if you could identify this particular discussion item and make sure that Dr. Nag and Dr. Diamond receive it and ask them specifically to comment on the motion and any

additional information that they feel is relevant which may change the wording that was suggested. If they approve, then I think you have your answer. If they don't approve and you need more information, it really does need to come back to the Committee.

Jeff?

DR. WILLIAMSON: I'm sorry --

CHAIRMAN CERQUEIRA: We already voted on it.

DR. WILLIAMSON: I know, but could we have at least a brief answer to the question that was raised by Lynne Fairobent? What follows -- I'm sorry, could we have a brief answer to Lynne Fairobent's question? What is the other condition.

CHAIRMAN CERQUEIRA: Could you repeat the question, Jeff? None of us can recall.

DR. WILLIAMSON: The question is what is the qualification following the "and", the final "and" in that paragraph?

MS. WILLIAMSON: Unfortunately, I don't have that with me.

CHAIRMAN CERQUEIRA: So we can't answer that question.

MS. WILLIAMSON: No, we can't answer that.

DR. MILLER: Angela, is that something

that as we move on to the next topic that you could go up and get?

MS. WILLIAMSON: Yes.

DR. MILLER: At least the Committee would have that available before we adjourn today.

CHAIRMAN CERQUEIRA: It would put closure on this particular item.

DR. MILLER: Because it's right in the AO report.

MS. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: Great. All right, thank you very much, Angela.

The next item on the agenda then is the transition issues in Part 35 implementation. And our own Ralph is going to --

MR. LIETO: Well, you have -- I think it was distributed yesterday or this morning, basically it's the printout of the slide from the presentation this morning on transition issues.

There were really three specific issues that were addressed. One has to do with individuals currently in training programs. And the implementation of the training and experience rule which I know that it's supposed to become effective next fall, actually this fall.

CHAIRMAN CERQUEIRA: October 24, 2005, it will be three years since the rule was enacted and then it does become the official standard.

MR. LIETO: So that individuals, physicians, medical physicists, whoever, who are -- pharmacists who are in training now, that if they need to document their training and experience to meet the preceptor requirement, that the implementation of this would occur for those -- the requirement for the preceptor would apply to those who are entering programs this year.

One suggestion was June of 2004, but whatever. I'm not married to a specific date of the year, but I think it shouldn't apply retrospectively to individuals who are completing their training in the next year or so.

CHAIRMAN CERQUEIRA: Or who started their training.

MR. LIETO: That's right.

CHAIRMAN CERQUEIRA: Doug?

DR. EGGLI: I need to agree with that. As a person who writes a dozen preceptor statements a year and I've never had to for the people with deemed status, it would be very hard for us to go back and reconstruct the experience of our senior residents in

order to write a legitimate preceptor statement for them.

So I agree with Ralph that some kind of a transition time is necessary for us to start to collect the data that we need to write a valid, verifiable and documentable preceptor statement.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: What is the Staff's expectation for the amount of data that must be collected and recorded to verify for a preceptor statement?

CHAIRMAN CERQUEIRA: Do you have any expectations on this?

You're willing to just take the letter.

MR. ESSIG: I'd have to defer to one of the --

CHAIRMAN CERQUEIRA: Roger is making his way to the microphone.

DR. BROSEUS: We shared with the Advisory Committee a direct revision of Form 3313A. And it's based on the current form. There's discussion in our guidance in Volume 9 of NUREG-1556 and so we're just going one step beyond that and the only changes there are where there are changes in the rule that would result in a need for change. For example, the

decoupling of the preceptor statement from the requirement for board certification, results in a need for an individual or licensee actually, to submit a preceptor statement up to this point, if a board was recognized by the NRC. That was sufficient.

There are a couple of other changes, for example, based on the recommendations of the Committee, they asked to have recommended and we incorporate it into the proposed rule requirement for T&E training and experience that is specific to the types of use a person is applying for as an RSO, AMP, ANP, etcetera. Okay?

The third significant change comes in for collecting data to enable a medical physicist to be an RSO since we're accommodating a new class. Not withstanding the comments that we've heard from Dr. Leito today, we have accommodate in our draft form changes to accommodate that new class.

And so I personally don't see big changes in this and I don't personally see a big issue here.

CHAIRMAN CERQUEIRA: Doug?

DR. EGGLI: Right now, for our residents who are diplomats of the American Board of Radiology, most of them don't require a preceptor statement to get a license. Board certification is adequate proof.

For the alternate pathway people which has been all of our cardiology fellows who come through, I document their experience on every procedure, the number of procedures they perform, what they've done in the hot lab, what kind of regulatory activity they've engaged in, how many times they've milked a generator, how many times they've compounded a radiopharmaceutical, how many times they've injected a patient, how many times they've done a contamination survey, how many times they dealt with the equipment in setting up the examinations.

All of these are required of the nuclear cardiology certifying exam and nuclear cardiology certifying exam requires these items, in fact, as part of the preceptor statement for a preparation for the preceptor statement for licensure. I cannot go back and reconstruct that information for other 200 series radiology residents and we have not kept track of that information as we know.

CHAIRMAN CERQUEIRA: So you're saying that basically what you're doing in a sense that right now, even the radiologists and the nuclear medicine physicians would require that sort of receptor letter.

DR. EGGLI: They require that kind of documentation on a preceptor statement on which we

have had for American Board of Radiology and for American Board of Nuclear Medicine. We have not collected that because they had beam status. We've collected it for the cardiology fellows because previously they were alternate pathway and we wanted a thorough and complete preceptor statement for the individual.

DR. WILLIAMSON: So I'm going to ask Roger again, if I may, Mr. Chair?

CHAIRMAN CERQUEIRA: Yes, please. Ask Roger.

DR. WILLIAMSON: Does the preceptor statement for the 3500 AUs require the level of detail that Dr. Eggli has mentioned?

DR. EGGLI: If you look at the preceptor statement it does.

CHAIRMAN CERQUEIRA: You'll need a microphone.

DR. BROSEUS: I'll put on a mic so you can be sure to hear me.

CHAIRMAN CERQUEIRA: Plan to stay awhile perhaps.

DR. BROSEUS: As I understand the question, what's the level of detail required for an authorized user to have this documentational preceptor

statement for use under the 200 --

DR. EGGLI: Right, the preceptor statement --

DR. BROSEUS: Under the current rule, under the current rule it is sufficient to be board certified.

DR. EGGLI: Right.

DR. BROSEUS: Okay?

DR. EGGLI: So they don't have --

DR. BROSEUS: Under the coming rule, if a board certified, if you're board certified by a board recognized by the NRC, plus a preceptor statement and the preceptor statement there's some discussion right now about how that should be structured, not structured, but what a test versus certifying. So the wording -- basically, it's document board certification and have a preceptor statement.

Now if somebody is coming in on the alternate pathway, there shouldn't be really big changes. There were some what I would call tweaks to the requirements.

DR. EGGLI: The preceptor statement for the board certification candidate looked like the alternate pathway --

CHAIRMAN CERQUEIRA: I don't know how it

could in the sense that if it can be -- we haven't really decided whether you need to be an authorized user or you know an authorized medical physicist to sign it. Maybe if the program chair is going to sign it, they're not going to have that kind of knowledge.

DR. EGGLI: Currently, there's only one preceptor statement included for all comers that have a preceptor statement and that has links on it for delineating the experience with multiple categories of 200 use.

DR. BROSEUS: For the alternate pathway.

DR. EGGLI: Yes, that's because the board certification pathway doesn't require a preceptor statement at all currently.

DR. BROSEUS: Correct. And one would still have to -- an individual who was an authorized user, applying for authorized user status for example, you still need to document what the training and experience was to meet the alternate pathway and there's quite a detailed --

DR. EGGLI: The question is does one have to in the future for the board certification candidates have to document experience in a similar fashion to the alternate pathway as it currently exists?

DR. BROSEUS: Under our draft, the only change was (1) document board certification; (2) have a preceptor statement and (3) document that T&E that is specific to the type of use. That's a new requirement that you all recommended.

DR. EGGLI: That's the --

CHAIRMAN CERQUEIRA: Donna-Beth, do you have a comment? Can you clarify it?

DR. HOWE: Yes. I think what we do is we have a preceptor statement that meets the rule and Roger is going a little bit beyond where you're looking for the answer. The answer you're looking for is what does the preceptor have to say when the individual is board certified?

DR. EGGLI: Exactly.

DR. HOWE: And what the preceptor has to say is they recognize the person is board certified and then they have to make the statement that they believe, according to the current rule, current and proposed rule, that the individual is competent to function independently as an authorized user, an authorized medical physicist, an authorized nuclear pharmacist.

So instead of documenting all of the hours and things for the alternative pathway, they're just

saying we recognize he's board certified and that he can function independently.

It's a simpler, there's less information on the form.

DR. WILLIAMSON: So I think the answer is no, but it's not being given -- it's being given in a very hedged way.

CHAIRMAN CERQUEIRA: I don't fully -- are you happy?

DR. EGGLI: No.

CHAIRMAN CERQUEIRA: Do you understand it?

DR. HOWE: You do not have to quantify their training and experience other than the fact they have the board certification. But then you have to be comfortable if you're the authorized user to state that you think they can function independently.

DR. BROSEUS: Donna-Beth, correct me if --

DR. EGGLI: Which may be a function of those items that I'm not quantitating?

CHAIRMAN CERQUEIRA: Exactly.

DR. BROSEUS: Let me take it one step further and correct me if I'm wrong.

DR. HOWE: Then there's the other modalities.

DR. BROSEUS: Our draft also includes a

space to fill in by the authorized user those sections that they're attesting to the ability of the person to meet the requirements. And that's about it for the information.

In other words, if it's 35.200, fill in 35.200, make a statement. It's not a lot of stuff and I would suggest that you may find it useful to go back and look at the draft that we sent out and I would expect we could share that data with you.

DR. WILLIAMSON: I am looking at the proposed form 313 and that's what it says here. It says preceptor certification. There's a blank. Yes, I certify that the individual in Item 1 has satisfactorily completed the requirements in Part 35, sections and paragraphs. Yes, I certify that the individual has achieved a level of competency to function independently as an authorized blank for blank uses. And it's just this little tiny section. So that's what's there.

DR. EGGLI: As a preceptor who does a lot of these, how will I be taken to task for that statement? I will have no supporting documentation for that first attestation on the preceptor statement.

DR. WILLIAMSON: Well, I think this is -- I'm going to speculate now and say what I think is in

the staff's minds. I could be wrong, but I think what they have in mind is a process that's very similar when you write a letter of recommendation for somebody who is up for tenure or promotion and you give kind of a general overview of their abilities or merit, given their career for this position. And I think what they have in mind is a similar kind of subjective, if you want to put it that way, judgment.

CHAIRMAN CERQUEIRA: Roger and Donna-Beth, is that your interpretation?

DR. HOWE: That's my interpretation because when we did the OMB clearance for the current 313A, the documentation and record keeping was just to fill the form out. There was no requirement in the rule or anywhere else for NRC to collect any other data or to have any other records. So it is the Board's certification. It is the certification statement.

CHAIRMAN CERQUEIRA: Now is it your intent also for people who are applying via training and experience or the alternative pathway that that same form would be used?

DR. HOWE: Yes. If you look at the form it takes you, Element 1 identifies the person that wants to be an authorized user, ANPA. Item 2, I

think, or Item 3 is the Board certification. It tells you to go to certain parts of the form. And then the rest of the people keep right on going down the form and they have to provide the documentation to show their -- for nuclear medicine, their hours added up to 700 for the didactic and the work experience.

CHAIRMAN CERQUEIRA: So basically, there's documentation of 700 hours and now what -- so if Dr. Eggli who is an authorized user signs the form, you're going to be happy with it. There's still a lot of discussion as to who can sign that form certainly for the people that are applying via board certification. It may not be an authorized user, an authorized medical physicist, an RSO.

DR. HOWE: All I can comment to is the proposed rule right now and the proposed rule would be if the individual wanted to be an authorized user for 200, then the person signing the preceptor statement that they thought they could function independently, they have board certification --

CHAIRMAN CERQUEIRA: Right.

DR. HOWE: That they could function independently as an authorized user for 200 uses, would be an authorized user for 200 uses.

CHAIRMAN CERQUEIRA: That's still our

understanding, but we've heard a lot of objections from the boards themselves that they would not be able to complete that.

Jeff?

DR. WILLIAMSON: I really think that we have to look at this on the terms it's being handed to us. This is, I think, viewed by the staff. I'm summarizing what I think their intent is now. They can correct me if I'm wrong. We have a certain process we do now. In the Radiation Safety Committee in the broad-scope licensing when we approve authorized users, if they're fourth year residents who have not yet passed the boards, we go through this very long detailed chronology of how many cases they've done, category by category, name them as authorized users on the license if they meet the alternative pathway requirements and we have to have a lot of documentation for that.

If they have board certification, you know, we make the presumption that they've met the eligibility requirements for those boards. They have the 700 hours or its equivalent. They have the appropriate case experience required by the residency and accreditation committees and so forth and we don't have to do that.

In the Radiation Safety Committee we look to see that they really have that certificate. We examine the years of experience they've had at other institutions and we vote, yes, you may be an authorized user and there's no presumption that in the Radiation Safety Committee we have to collect this huge ream of data on them like we do the uncertified candidates. And I think that's the spirit of which that's intended here, for all the categories is that in addition they want some individual who is an AU or ANP or whatever who has some knowledge of the candidate's training and is in a position to attest to the competence of the person to do this job. They want a signature and that's basically all that's being asked.

DR. EGGLI: And I guess the question comes down to what's the liability on that signature because in the board certification previously, I wasn't required to make any kind of attestation for someone who is board certified. Now I am being required to and it is one issue again to provide a chronological list of experiences. That's very objective and there is no risk if you're signing that kind of attestation.

The more general attestation not backed up by any kind of documentation is for the preceptor, a

higher risk process, particularly if there are consequences that fall back on that preceptor at some point in the future if that individual doesn't perform up to snuff.

CHAIRMAN CERQUEIRA: Yes, but I think the argument has been that some of that is no different than anything else that we do in medicine, that that's kind of there are other safeguards in place and that the NRC should only be involved in the issues of radiation safety --

DR. WILLIAMSON: We all participate in credentialling activities. We write letters of recommendations. Hospital credentialling committees make judgments based on looking at the person's CV without examining this huge volume of data to really show the person did these things, so I think we're maybe making a little too much out of this?

DR. EGGLI: Actually, that may not be quite true because to be credentialed for a finite number of procedures in any hospital these days you have to produce the documentation that you've had the experience.

Credentialling, these days, is a function of documentation of experience, but you cannot be credentialed in many areas without documentation.

DR. WILLIAMSON: Well, I think the NRC is saying that's up to you then what standards of evidence you require.

CHAIRMAN CERQUEIRA: That's been basically, you know, and I think the SNM really argued that they shouldn't be involved in this at all, that basically it should be left up as a practice of medicine issue beyond a certain hour of training and experience.

Leon?

DR. MALMUD: Doug, you're correct. The credentialling process is though independent of that which we are being asked to do with regard to the NRC.

DR. EGGLI: I understand. And we're credentialling them?

DR. MALMUD: Correct. So that I think a university certifies an individual has completed his or her requirements for a degree and it's signed by the President of the University, the Chairman of the Board, neither of whom has ever even met the candidate. They have relied upon the processes within the university to certify that these students have finished the requisite number of credits and courses, and hence they sign it. I think that we're in a similar situation on a lower scale with regard to

certifying that the resident has had adequate training. We need not personally have been involved in that training, although we understand from the NRC that they want the person who assumes the responsibility for it to be an AO himself or herself.

Is that a fair summary, Dr. Howe?

CHAIRMAN CERQUEIRA: Okay. Lynne, you've been waiting patiently.

MS. FAIROBENT: Lynne Fairobent, ACR. A couple of points. One, Dr. Eggli, I think that you've hit the nail on the head. We have or share some of your similar concerns from our members now with the decoupling of the preceptor statement from the board process.

It is unclear or not clarified yet and I'm hopeful as Ralph has urged this morning that there be a meeting with the boards and stakeholders to discuss the implementation as we go forward on recognition of the board process.

I think it's equally important that there be discussions on what is an appropriate preceptor statement. I think that with the decoupling of the preceptor from those individuals who would have now come in by virtue of board certification, these issues are raised and I do think Dr. Eggli that at this point

you are probably going to have to provide those detailed documentations on your radiologists coming through nuclear medicine departments because they may or may not have completed their board certification process at the time they're coming through under your training program. They may not have sat for their final orals or if they had, the results of the oral exam may not yet be known to you as the preceptor authorized user who needs to sign to give them that documentation to then move on to be listed on their first license.

I think there are a whole host of implementation issues with the decoupling of the preceptor statement from the board processes that had not been recognized prior to when they were linked together. I think that this is something in the implementation phase that we all are going to have to sit down and collectively look at appropriate guidance and two-way discussion because it's now my members that are going to have to be signing the preceptor statements.

I think you very well articulated it, the difference between what you do now for an individual under the alternative pathway, versus someone who is coming to you via board certification. I think has

been minimized and no longer that distinction is there.

DR. EGGLI: And finally, my only reason for raising this issue was to make sure that there isn't a group who gets caught in this transition.

MS. FAIROBENT: Yes, and I would agree with Ralph's comment earlier. I think it's very important that we look at the timeliness of when these new regulations apply to those in-training programs and I think it's also critical that the new regulations and the timeliness of them are given adequate transition time to be reflected by the residency review committees who set the training curriculums as well as the boards to reflect whatever changes may necessarily be on their examination process.

CHAIRMAN CERQUEIRA: But, Lynne, we've gone over that before, and it doesn't -- none of the changes that the NRC is going to require now are any more than what they have required in the past. So the Residency Review Committee should not have to implement any changes in the hourly training requirements for people who are applying.

MS. FAIROBENT: It may not be in the number of hours. It may be in subject content area to

ensure that --

CHAIRMAN CERQUEIRA: For diagnostics, certainly no, and even for the radiation oncology. The only areas where that may become an issue is in specific devices, and we've come up with ways to deal with that.

MS. FAIROBENT: We've talked in the radiation -- with our radiation oncologist at ACR, and there is a potential, and the potential is for ROs under 390, in order to be able to do unsealed material use, and whether or not they -- in their residency programs that material is being sufficiently covered. We believe it is, but they are going back and looking at it.

CHAIRMAN CERQUEIRA: But if it isn't, then all they have to do is document specific training in that instrumentation, which is, I think, the point that has been made a few times.

Ralph, and then Jeff.

MR. LIETO: Two things. I disagree with the statement that was made before that whatever training and experience criteria you want to establish, or make an attestation, is up to you. I think that sets a tremendous disquality across the system.

I think there should be minimum standards established, and I think that goes into the -- you know, what we were talking about or presented this morning to the committee about what -- what is the -- what is the preceptor attesting to? And what documentation do they need?

I think that we've already identified some of the issues for people who are not board certified. But, then again, I think there may be those people who are seeking board certification and are in transition that may need the specific documentation.

My second point is I'd like to get back to the original transition issue, which is about those individuals who are in training and when these training and experience requirements should go into effect for them. In other words, the suggestion was, and I'll just make it as a recommendation, that training and experience should not have to -- or should apply to individuals entering training programs after June of 2004.

CHAIRMAN CERQUEIRA: Well, actually, the new -- the revised rules are in effect. I guess that three-year period is really for the agreement states to become compliant, right? So people who started who are already in training can apply either under the new

rule, which became law in October 24, 2002, or under the existing rules, which we extended, because the old rule, you know, became -- you know, was no longer applicable, other than the fact that we did a two-year extension.

So I agree with you, we need to set the rules for grandfathering, but I think technically people who -- you know, it applies to people who are currently in training, and even people -- you know, because the new rules did go into effect in 2002. And I think the 2005 requirement is for compliance by the agreement states. Am I correct on that? Yes, okay.

Now, Jeff, you had a comment, and then we'll go to --

DR. WILLIAMSON: Yes, I have three comments. One is a response to what Lynne said, and I think the case she presents is of a radiology resident who has completed the training program but not yet completed board certification either for fact that the results are not known or maybe has failed or conditioned the exam.

Well, that's no different than it is now. And so I don't see how that supports -- has anything to do with the issue of what level of documentation you have to keep for board certified candidates.

The second point is is it has taken us 30 minutes to get out of the NRC staff the answer about what is the level of documentation required on the part of a preceptor for an individual that is board certified. And I had to actually read their mind, so to speak, or interpolate.

So, clearly, you know, I think NRC has to come up with a -- I appreciate why they're being so cautious and wanting to cite just what the rule language is. But to state clearly, unambiguously, in ordinary language what is expected or not expected, and where the burden of -- and indicating to what extent the burden of deciding the level of documentation depends on the individual preceptors or the community as a whole.

You know, you really need to communicate this clearly, and we shouldn't have to be guessing what you all mean, like I did.

And then, finally, they said yes or no, after I had repeated it, you know, in a couple of different ways in simple, ordinary language. Now, you know, the other half of the committee doesn't like it, but I think maybe that's the way it is. That's really -- okay, I'll stop there.

CHAIRMAN CERQUEIRA: Ron?

DR. ZELAC: Ron Zelac, NRC. I think it might be somewhat instructive on the question that Jeffrey was just mentioning to keep in mind the current rule, the rule that we're operating under now, the requirements that exist now.

The proposed rule changes to training and experience are not becoming more prescriptive by any means. If anything, they're moving in the other direction. So where we are now can be looked at as a baseline for where we are going.

And the current requirements, as most of you know, are -- and particularly I'll choose an example of 200 usage -- we are talking about a total -- and the alternative pathway. We're talking -- and the preceptor requirements, in terms of what the preceptor has to attest to or certify.

The current rule simply states a total number of hours of training and experience. Yes, indeed, there are particular topics that are covered that are supposed to be included in the training and experience. But the attestation at the bottom by the preceptor is simply referring to the totality of that -- the 700 hours, and what has been covered in that 700 hours, and the ability of the individual to serve independently.

In fact, it says the individual -- this is the -- what the preceptor is attesting to. "The individual has satisfactorily completed the requirements in paragraph C(1), which is the alternative pathway" -- and this is common for the other as well -- "of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under," and so forth.

That's all that's being asked for, and no detailed records are required, as Donna-Beth had mentioned, on the part of the preceptor in order to make this attestation and provide the required certification.

DR. WILLIAMSON: Thank you for that clarity.

CHAIRMAN CERQUEIRA: Yes. And, Doug, getting back to some of your points, I mean, initially when this was being drafted, we had put in specific hours in terms of didactic-type material. And it was actually the SNM that did not want any of that in there, and it was really at their request that that was taken out for the 200 users, and it was just left to 700 hours total, without any documentation, you know, of specific areas covered.

DR. EGGLI: Now, the only thing that's unresolved is essentially, since the NRC wants an AU to sign off, there's a reason for that. The question is: what is the liability effectively of the preceptor in this process? The only -- and I understand the Society's goal in eliminating lists.

But yet for the person who actually functions as the preceptor, the list serves as a backup reference if the credentials of the individual, from the radiation safety point of view -- not from the point of view of medical practice but from the radiation safety point of view, are ever questioned.

It would strike me that the -- that NRC wants an AU's signature because they want somebody that they can hold responsible.

CHAIRMAN CERQUEIRA: Well, I think it's a simplification that, you know, getting back to Leon's point, that the president of the university signs off without having -- you know, and he certainly is not attesting that this person has mastered all of the material.

DR. EGGLI: But the president of the university doesn't have the NRC breathing down his neck.

CHAIRMAN CERQUEIRA: No, that's true. And

I -- there may be some implications that have to be addressed. But certainly, at this point, I think as that individual is signing -- and we still have a lot of debate, but they have, you know, covered the material, and they can do it competently.

DR. EGGLI: And the RRCs historically have not looked at the -- the RRCs have historically not looked at the content vis-a-vis the NRC requirements in great detail, as they -- as they evaluate the program.

CHAIRMAN CERQUEIRA: I think that's valid, yes.

Ron?

DR. ZELAC: The purpose, as I understand it -- and if there's someone else that has a different point of view, please correct me -- the purpose, as I understand it, of having an authorized individual sign the preceptor statement is primarily because the authorized individual knows what the duties are, knows what the concerns are, knows what it should -- what information and knowledge is required in order for this individual for whom he or she is signing to function independently as the authorized whatever.

That's the purpose, not to have some way to go back to then chastise a preceptor whose

signatory didn't perform as expected. That's the contrast with the alternative, which has been put forth several times, to have something akin to a program director for a training program sign.

The program director may or may not be an authorized individual. The program director who is an authorized individual will clearly, and should clearly, know what the requirements are for a person to function independently. Whereas the program director might be well removed from the specific needs if he is not, or she is not, actually a user.

CHAIRMAN CERQUEIRA: That certainly was the intent all along, but I think what you're seeing now is the reality of people getting cold feet and having to sign that statement. That's --

DR. WILLIAMSON: Well --

CHAIRMAN CERQUEIRA: That's the bottom line.

Yes.

DR. WILLIAMSON: Well, I think that, you know, this is sort of a new performance-based, risk-based -- no, risk-informed, performance-based environment. We asked for flexibility; we got it. So, you know, I actually think the burden --

(Laughter.)

-- the burden is on us and our societies to kind of come up with reasonable criteria how we're going to do this. And I think we should do it ourselves rather than ask them to do it, if you want my opinion on the matter.

I don't think this is an issue that we should ask for laws and more regulations that -- prescriptive regulations that we have to write. I think we should, you know, take the challenge of keeping our own house in order and solve the problems ourselves.

I think a second point I want to make is -- respond to Dr. Cerqueira's suggestion that we have an opportunity to change this from an authorized person preceptor to some program director or something else. I think that was recommended and has been long the position of this -- of the ACMUI.

I think we can talk about it as much as we want. The staff has in their hands an SRM from the Commissioners which said, "No, you're not doing it that way. The preceptor is going to be the way it is, and it's going to be an authorized person." So, you know, I think there's not much they can do except advise us how we might approach the Commission again if we wish to try to at this, you know, late moment

try to get that overturned.

I just want to point that out as an element of process. The staff, at this point, has no ability to reverse that decision.

CHAIRMAN CERQUEIRA: Yes. So, you know, it must be the role of the Chairman's last meeting, because I can remember when Barry Siegel had his last meeting going into a tirade that sometimes you get what you ask for.

(Laughter.)

And we've been asking the NRC to get off our backs for the longest time. Well, now they've done it, and we're going to have to assume, you know, some -- we're going to have to be very careful of the people we sign off on. That's part of the responsibility that we're assuming.

But I think all of us on the committee five years ago, and on the committee now, would rather have policing from within than having the NRC necessarily, you know, impose some of these rules and regulations.

All right. Ralph, what's the next item?

(Laughter.)

That's point one of slide 1.

MR. LIETO: Do I really need to go on?

(Laughter.)

Well, you know, I'll be honest with you. I'm still -- what is the resolution regarding individuals and training? Basically, SOL? I mean, they're stuff out of luck?

CHAIRMAN CERQUEIRA: No, I don't think there's a problem.

MR. LIETO: Sadly out of luck?

CHAIRMAN CERQUEIRA: No. I think, you know, basically, they can still apply under the old rules pre-October 24, 2002, which was, you know, the alternate pathway, or by board certification without any other documentation. So that is in effect until October 24, 2005.

Part of the reason we're trying to do this revision is to have something else in place when that temporary extension goes away to fix some of the other problems that we identified with the revision which was implemented on October 24, 2002.

So, technically, people who started their training up until that point can apply either under the old or the new rules. And so I guess if you started your --

MR. LIETO: Well, I'm trying to think, okay, let's say someone comes out of a program in

December 2005. All right? They have to have a preceptor statement. Okay? And --

MS. McBURNEY: Have they passed their boards?

MR. LIETO: -- and/or have passed the boards.

DR. WILLIAMSON: No, they have to pass --

MR. LIETO: Not and/or, but or have passed the boards.

DR. WILLIAMSON: No.

CHAIRMAN CERQUEIRA: Well, since they started their -- well, I mean, if they started their training at a point where the old rule was still in effect, which will be until October 2005, all they've got to do is present their board certification without anything else, and that should automatically qualify them.

MR. LIETO: No, because the new rules will be in effect after that point.

CHAIRMAN CERQUEIRA: Right.

MR. LIETO: The old ones go away.

CHAIRMAN CERQUEIRA: Right.

MR. LIETO: So even though their training would occur under -- when you had the two method -- the two -- should I say criteria -- now you only have

the one.

CHAIRMAN CERQUEIRA: Yes. But they started their training when the old one was in effect, so they apply under either one.

DR. WILLIAMSON: Can I comment on this? I think that you're wrong. I think once the rule changes, the rule changes.

CHAIRMAN CERQUEIRA: But what do you --

DR. WILLIAMSON: And it doesn't matter when your training starts, you have to follow the new rule. There is no discussion.

CHAIRMAN CERQUEIRA: Well, I would disagree with that, because you can't --

DR. WILLIAMSON: Well, that's the way it is.

MR. LIETO: That's my point.

DR. WILLIAMSON: Can I try to answer Ralph's question? I think --

CHAIRMAN CERQUEIRA: Well, no, no, wait a minute, because I -- I'm not sure I'm totally wrong. Leon, I mean, what's your feeling as an educator who -- when people come into a training program, are they held to the rules that are --

VICE CHAIRMAN MALMUD: If you want my candid opinion as an educator, I don't know what all

the excitement is about, because it's the simplest thing in the world. I don't know what all of the concern is about, because it's the simplest thing in the world for the training program director, or his authorized user designate, to fill out this form with the resident.

It can be done today. There is no deficiency that I'm aware of in any training program. In fact, the training program's requirements for education far exceed the minimum requirements of the NRC. So I think we are worried about something that's not an issue, and I would have no difficulty at all in dealing with the issue today.

We have a tradition of filling out these forms. I don't see where the enormous workload is.

DR. WILLIAMSON: I guess I'm saying -- I would agree completely with Dr. Malmud. I don't think there's a problem. I think that, you know, now we have a board certification pathway without a preceptor statement required for a little while longer, and we have an alternative pathway.

When the new rule takes effect, we'll have an alternative pathway that's essentially just a minor modification of the one we have today. It's very, very similar. It's not going to require very

different reporting or documentation requirements. We will now have a board certification pathway that is the same except for one more requirement, and that is the preceptor statement.

But we've just heard there are no new reporting or documentation requirements for either pathway. So I don't understand what is the concern about retrofitting, you know, existing -- students who are just about to go in the training pipeline. To me this seems like there's not a problem.

MR. LIETO: You know, I -- then, why, on God's green earth, did you guys have me sit before the Commission and present this? We went through it in the morning, and no one -- no one challenged that that was not needed to be presented.

DR. WILLIAMSON: Well --

MR. LIETO: There's no way -- hold on.

DR. WILLIAMSON: All right.

MR. LIETO: If this was not -- I mean, you know, I'm really upset about the fact that I sit before this Commission and present this as a transitional issue when really it's not an issue. If it's not an issue, it should have never even been put on their plate.

Secondly, if none of these transition

issues are going to be addressed -- in other words, these are things that we're going to just say, "The rule comes into effect. You have to deal with it. That's the way life is." I mean, that makes it very simple. It makes it simple for everybody.

Some people are going to be disenfranchised; others aren't. But I think, you know, if that's the attitude that we're going to take --

DR. WILLIAMSON: No, no.

MR. LIETO: -- I -- well --

DR. WILLIAMSON: Let me defend myself.

MR. LIETO: Well, let me finish.

DR. WILLIAMSON: Okay.

MR. LIETO: Then I think that -- that one of the things that needs to be understood is what this committee is going to ask the staff for and what they're not. If these are not transitional issues, then let's not discuss them. Okay? We've got other things on the agenda to address.

DR. WILLIAMSON: I think that in terms of my answer to you it is not clear to me until this moment -- until we had this long discussion and got the appropriate feedback from the staff that it wasn't a valid issue.

You know, it is only through this conversation it has sort of -- and detailed review of this Form 313A, which I should have admittedly maybe reviewed before, that it has sort of become clear how this particular transition issue does not seem to be a problem for NRC. It may be a problem for our community how to absorb it.

But the other point is the other transition issues I think are very important. I think, you know, just because, you know, it -- it turns out upon detailed review and debate that maybe there wasn't so much of a problem with the training program retrofitting does not mean that the other issues are not perfectly valid.

I happen to think the grandfathering, the issue of AUs not being mentioned on agreement state licenses, the problem of multiple AUs, the problem of what do you do when you get a new unit and there isn't an AU in your institution who can sign the precept, all of these are I think really important problems.

VICE CHAIRMAN MALMUD: Ralph, it is a transition issue, and it's correctly brought before the committee.

My point was that what's being asked of us is not an enormous burden. It's an additional form,

which we already have a staff to deal with. So we could actually just say, "Beginning July 1st, for everyone who hasn't completed training by July 1, 2004, this form is a requirement." And that would be -- that would serve everybody well.

I have a question about your point, Ralph. Who are you concerned would be disenfranchised? That's what I didn't quite grasp. Who is going to be disenfranchised? Who are you concerned about?

MR. LIETO: Well, regarding these transition issues, I think there are issues regarding medical physicists, and there is also the issues regarding authorized users who provide diagnostic studies with the I-131 imaging and localization procedures. These are issues that came up not only here, they've come up I think -- I'm pretty sure they're on the comment page -- regarding the proposed rule, and they are issues that have been brought up to me personally by individuals.

VICE CHAIRMAN MALMUD: But that is the issue that we were just discussing with regard to the authorized user certification.

MR. LIETO: No. My point was about all of the transition issues.

VICE CHAIRMAN MALMUD: Oh.

MR. LIETO: I mean, if we're going to -- I mean, basically, the -- you know, the sense that I'm getting is that the rules, when they come into effect, okay, that -- that's the way we're going to have to deal with them. It just gives me the sense that, why -- why are we discussing transitional issues? Okay?

If the tact is going to be that we're going to just say, "You've got to comply with the rules. When they come into effect, the new rules come into effect, you have to accommodate them." We've gotten what we want.

DR. WILLIAMSON: I --

CHAIRMAN CERQUEIRA: Go ahead.

DR. WILLIAMSON: Okay. I think it's not sort of zero or one, black and white. I think that one transition issue seems to have turned out maybe to not be as serious an issue as we thought. So that doesn't mean the others aren't.

I really think that our charge here is to look at the transition issues, and within the confines of the SRM that kind of is right now I think a realistic political barrier that we can't transgress, we need to figure out and help the staff figure out how we can tinker with the rule language to make sure that we have, you know, enough flexibility in the rule

language to accommodate the transition issues.

So it's -- okay. So it's half and 9.5. So one issue -- one transition may not be a real transition issue, or at least one that concerns the NRC anymore. It concerns us as a community.

But the other 9.5 I think are really valid issues, and I think what we need to do is one by one assess the staff's views on them, look at the rule language, and see if we can tinker with it to make it have the requisite level of flexibility to accommodate these in a satisfactory way. That's an important duty in the next 30 days that we have to do.

CHAIRMAN CERQUEIRA: Yes. I agree with that. And then, again, you know, we've got this revision which your committee has worked on, which has gone to the -- to the main NRC that still is going to need changes to try to give us a fix that's going to occur when the old rule goes away.

DR. WILLIAMSON: Yes. I think they can accommodate words like "attest" and --

CHAIRMAN CERQUEIRA: Right.

DR. WILLIAMSON: -- instead of "certify." And I think we can probably, you know, modify the language. Where I think we will get in trouble is if we try to, you know, run broadside against what the

SRM said and decouple AU or authorized personage from being a preceptor. I think that, you know, that will require another ruling by the Commission to an alternative SRM.

And we didn't really make the case I think clearly enough to them that we wanted another decision. If we really thought we needed to do that, we should have done that in a more clear form. But that would have required a great deal -- you know, several hours of analysis and debate to figure out that problem.

I think we've got a lot of work ahead of ourselves to go through each one of these transition issues in detail.

CHAIRMAN CERQUEIRA: Yes, I think we do, and we're also going to -- two of our committee members are going to be leaving in about half an hour So I think we probably should move on with some of these issues.

DR. MILLER: Dr. Cerqueira?

CHAIRMAN CERQUEIRA: Yes?

DR. MILLER: I just wanted to make a point of clarification on something that was said earlier. The expiration date for the old rule is not 2005, it's 2004.

CHAIRMAN CERQUEIRA: Okay. You're right. Okay. So that's sooner.

DR. MILLER: So that's part of the reason for the urgency of trying to get the revised rule promulgated prior to that happening.

CHAIRMAN CERQUEIRA: Yes. Okay, you're right. I misspoke, you're right.

All right. So, Ralph, do you want to go on with some of the other issues? What are we getting here?

MR. LIETO: The one maybe that might be the most straightforward would have to do with the authorized users of I-131 for diagnostic purposes meeting the training and experience for written directive use. There are those individuals out there that have -- that do not do therapeutic applications, just do the imaging and localization procedures.

With the transition of the Part 35 revision that is based on activity, the imaging and localization procedures for I-131 move into a written directive category. And so you now have to have -- well, there is a concern that those individuals are now going to have to apply as authorized users under a category that they do not have the training and experience --

CHAIRMAN CERQUEIRA: We're talking about the endocrinologists, is that -- no?

MR. LIETO: Not just endocrinologists, but it could also be radiologists who are doing just imaging and localization procedures under the old Part 200 --

CHAIRMAN CERQUEIRA: Right.

MR. LIETO: -- which the I-131 was. It's not that they aren't familiar with the documentation aspects for above the 30 microcuries, but now they have to meet the therapy application criteria, which they -- therapeutic application criteria, which they did not have to do and have not done before, and may not have the training and experience for documenting it.

VICE CHAIRMAN MALMUD: Ralph, these are people who are currently doing it, currently using I-131 for --

MR. LIETO: That's correct.

VICE CHAIRMAN MALMUD: -- diagnostic purposes, let's say in doses up to three millicuries for whole body scanning, for post-operative evaluation of thyroid metastases.

MR. LIETO: Correct.

VICE CHAIRMAN MALMUD: Okay. And is that

privilege going to be taken away from them? Won't they be grandfathered? Question. Actually, Dr. Gray, do you want to address it? Excuse me.

DR. HOWE: Can I address the issue?

VICE CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: Yes. We're currently dealing with that issue right now on licensing as we're bringing old licenses into the new Part 35. And what we've recognized -- it's even a little more complex than we thought -- is that we do have nuclear medicine physicians that are used to using diagnostic I-131 for whole body scans.

And we're making sure that those individuals are granted the authorization under 300 to continue to do those procedures. So they are grandfathered into what they could do before. We are bringing it up. They are going to be identified as a limited use under 300 for the less than 30 millicurie criteria.

Another element that we're finding that you haven't addressed is that we have a number of I-131 300 users that in the past we have authorized for hyperthyroidism, thinking that they were under 30 millicuries, and, in fact, they are over. And so we're having to recognize them as -- as also meeting

the criterion over 30, and giving them the authorization on the license that they can use that material.

Your other issue is that current nuclear medicine people in training will have to meet additional criteria, and they will have to meet the -- I think it's 80 hours of therapy training and experience that's for the 30 -- for the 392 or the 393, depending on how much activity they'll be using later. They will need to meet that criteria, but they won't have to meet the full 300 -- the 390 criteria.

MR. LIETO: Well, is there a concern that you're going to have on their -- on the license they will be listed as being qualified or authorized for under 33 millicuries for therapy application when really they don't have the training and experience for it? Or is it going to be specific -- more specific than that?

DR. HOWE: They are not going to be authorized for full 300 use, because their training and experience is under the 392/394. So they will be authorized to use under whatever the activity -- maximum activity is for 392, or the maximum activity for -- the minimum activity for 394.

So that authorization will be in the

license, so that those physicians can continue to do what they had historically been doing.

DR. WILLIAMSON: What about new physicians? What about -- you know, it seems to me that the nuclear medicine imaging people are the most qualified people to read these I-131 uptake exams. So how could -- I think the question before us is: how can we modify the rule in a perspective way to make sure that this group of people in the future doesn't get disenfranchised?

VICE CHAIRMAN MALMUD: If I may, I believe that Dr. Howe has just explained to us that the current users will be grandfathered for I-131 for diagnostic purposes and I-131 for therapeutic purposes in excess of the assumption of 30 millicuries, which had been the limit, but which will be raised to some higher number. Did I understand you correctly?

DR. HOWE: We don't distinguish between diagnostic and therapy anymore. It's --

VICE CHAIRMAN MALMUD: All right.

DR. HOWE: -- a written directive or not a written directive. So they will be authorized for -- so if you were a diagnostic nuclear medicine physician that was doing three to five millicurie whole body scans, then you'll be authorized for 200

use, and you'll be authorized for 300 for use for which a written directive is required for materials under so many millicuries, which is the 392 criteria.

VICE CHAIRMAN MALMUD: How many millicuries is that in the 392 criteria? The reason I'm asking the question is it's relevant clinically, you know, that if the patient is being treated for Grave's Disease, in general the dose would be less than 30 millicuries, but not always. But if they're being treated for Plummer's Disease, the dose might be higher, up to 50 millicuries, roughly speaking.

DR. HOWE: Yes. The numbers in here are 33 millicuries. And what we found out is what we thought was an even split earlier at 33 millicuries to the hyperthyroid versus the cancer patients isn't there.

There are some -- some procedures that are over 33 that are not for cancer treatment, and so we're having to -- to make sure that those physicians are still authorized to do -- use that amount of activity that they need to use.

VICE CHAIRMAN MALMUD: You are, of course, correct. And those patients who are not cancer patients, but who require a higher dose of I-131, are generally patients who have Plummer's Disease, which

is nodular toxic hyperthyroidism -- nodular toxic goiter.

So, once again, I think what you're communicating to us is that those who are currently providing those services will not be disenfranchised.

DR. HOWE: That's correct.

VICE CHAIRMAN MALMUD: Okay.

DR. HOWE: And --

VICE CHAIRMAN MALMUD: That gives to Dr. Lieto the assurance that I believe he was seeking in making this an item on the agenda.

Is that correct, Ralph?

MR. LIETO: Yes.

DR. HOWE: But one of his issues was that now an up and coming 200 physician will have to meet the criteria, not just of 200 but also some of the criteria in 300, and that is true also.

VICE CHAIRMAN MALMUD: Yes, that's for an up and coming nuclear physician.

DR. HOWE: That's correct.

VICE CHAIRMAN MALMUD: Yes. I think --

DR. EGGLI: Or diagnostically valid as --

VICE CHAIRMAN MALMUD: I beg your pardon?

DR. EGGLI: Or for a diagnostically valid --

VICE CHAIRMAN MALMUD: Well, I think there the question is a little -- is not being addressed directly, because Dr. Howe indicates this was for an up and coming nuclear physician, but not necessarily for a radiologist who does nuclear medicine. Is that correct, Dr. Howe?

DR. HOWE: It would be anyone that would be coming in for 200 uses. I was just using nuclear physician to kind of distinguish between our --

VICE CHAIRMAN MALMUD: Okay.

DR. HOWE: -- 400, 500, 600 category.

VICE CHAIRMAN MALMUD: Now, if I may, it would then -- what would then happen is that the credentialing process for the radiologist who wants to do I-131 therapy for thyroid cancer --

DR. WILLIAMSON: Yes. Just imaging.

VICE CHAIRMAN MALMUD: You -- no, I don't believe -- were you discussing imaging with more than 30 millicuries?

DR. EGGLI: No. Imaging with more than 30 microcuries.

DR. WILLIAMSON: Yes, that's what we're discussing.

DR. HOWE: Yes. And if you're over 30 microcuries, which means you need a written directive,

then you'll come under 35.392, which is less than or equal to 33 millicuries.

DR. EGGLI: At a diagnostic level that will not be --

VICE CHAIRMAN MALMUD: No, you didn't -- would you please repeat what you just said, Dr. Howe?

DR. HOWE: Okay. If you are a diagnostic physician --

VICE CHAIRMAN MALMUD: Radiologist.

DR. HOWE: -- using nuclear medicine procedures, and you're using over 33 microcuries -- 33 microcuries is the point -- 30 microcuries is the point at which you need a written directive. Okay?

So you will then have to meet not only criterion 200, but the criteria in 392, for those uses that you have. If you are currently doing those things, we will give you the authorization in your license to continue to receive that material.

VICE CHAIRMAN MALMUD: Thank you. Now, what about the issue that I believe Dr. Eggli is addressing, and I think Dr. Williamson indirectly addressed, and that is a radiology resident who will, I believe under the new ABR rules, only require four months of nuclear medicine training in his or her residency, who finishes the residency, has had a four-

month rotation in nuclear medicine, and is at a remote hospital and wants to use I-131 in a therapeutic modality for either Grave's Disease, Plummer's Disease, or thyroid cancer, in doses of 10, 20, 50, 100 millicuries -- millicuries.

There it would require not an NRC recognition, but would that require just the credentialing of the hospital? Or would the NRC have an interest in that as well?

DR. HOWE: We have an interest in authorization if you go over 30 microcuries, because you go from 200 to 300. We don't distinguish whether you're diagnostic or you're therapeutic in 300. We just distinguish that you now need a written directive.

But if your practice is limited to I-131, then you have these alternative requirements in 300 for 392 or 394, which are dependent upon your having training and experience using the amount of material that's in 392 or 394. Those are not the full requirements for 390. So you will need to meet the requirements in 290 and 392 or 394.

VICE CHAIRMAN MALMUD: So that if the training supervisor or the authorized user for that resident, when he or she completed this training

program, indicated that that individual had had experience in the use of I-131 for the treatment of hyperthyroidism and thyroid cancer, and attested to that, that individual would qualify for use of I-131 for -- in doses in excess of 33 microcuries?

DR. HOWE: That individual would essentially I think be attesting that they've successfully completed 80 hours of classroom laboratory training applicable to the medical use of sodium iodide 131. For procedures requiring a written directive, the training must include those items. They could be done concurrently with the 200, but it would be that 80 hours, and the authorized user could certify that.

VICE CHAIRMAN MALMUD: So the director of the Residency Training Program, or the authorized user, would have to have certified that the radiology resident, in completing his or her four years of radiology residency, had included within that training 80 hours with respect to the use of unsealed radioisotopes for therapy.

DR. HOWE: Well, it doesn't have to be for therapy, just requiring a written directive.

VICE CHAIRMAN MALMUD: Okay. Thank you.

DR. EGGLI: The issue here is, though, the

diagnostic imaging, not the therapeutic. This person will have to have 300-level qualifications to administer 500 microcuries of iodine MIBG for a standard diagnostic study.

DR. HOWE: And that's correct, but it will be -- ah, that would be 390, because it's not --

DR. EGGLI: That would be 390.

DR. HOWE: -- sodium iodide 131.

DR. EGGLI: That would be 390. So to do diagnostic nuclear medicine, the complete spectrum, the candidate will now have to qualify under 290 and under 390.

CHAIRMAN CERQUEIRA: Right.

DR. HOWE: That's correct.

DR. EGGLI: And that's a dramatic increase in the requirement for diagnostic, not therapeutic, nuclear medicine.

CHAIRMAN CERQUEIRA: Right. Neki, you wanted to make a comment?

MS. HOBSON: Well, I'm, you know, listening to all of this discussion, and it seems to me the discussion is coming from the point of how these regs are going to affect the physicians, the health care deliverers.

And I'm just wondering, how is it going to

affect patients? Are there going to be enough people out there qualified and licensed or empowered to perform the kind of procedures that are needed? Or will patients either have to go without those procedures or travel four hours away to find a practitioner who is qualified?

So, you know, from a patient's perspective, how is this going to --

CHAIRMAN CERQUEIRA: I think the rules are less restrictive, so in a sense it should make it -- there should be more people out there available to do it. What we're doing now is identifying certain little unanticipated results, which may prevent some physicians from not performing some of these procedures.

But that really wasn't the intent, and we're trying to find ways of revising the rule which will allow that, so that, you know, nuclear medicine physicians or radiologists who can, you know, do diagnostic and therapeutic treatment with I-131, how can we make it available to them without adding any more restrictions? So I --

MS. HOBSON: Wouldn't, you know, a person who is now qualified and authorized to do X procedure --

CHAIRMAN CERQUEIRA: Right.

MS. HOBSON: -- if under the new regs, as they are, you know, applied, understands and sees, oh, in order to continue doing this, I'm going to have to go and have this additional training.

CHAIRMAN CERQUEIRA: Well, they would --

MS. HOBSON: Wouldn't that discourage them?

CHAIRMAN CERQUEIRA: That would be grandfathered in, but -- for the people that are currently doing it. But for the new people, it would be a problem, and that's what we're trying to resolve. And Dr. Howe is going to tell us how we can do it.

Or, Jeff, do you know how we can --

DR. WILLIAMSON: Well, I think these transition issues really do bear on Neki's question. So a key one is to make sure, you know, in general terms that there are enough grandfathered AMPs and AUs of various flavors that there doesn't become a crisis in getting new people through the pipeline, and to also make sure the grandfathering is done. That's the ultimate goal.

I do think, though, this actually connects with the first issue that Ralph raised, because, you know, although I'm not a diagnostic practitioner, I am

now understanding that nuclear medicine practitioners -- up and coming ones now, not old one but new ones, who get trained in diagnostic radiology with their four- or seven-month training period -- four months, okay -- four months -- will have board certification pathway open to them for 200 uses not requiring a written directive.

And they're going to have to go through the alternative pathway of 35.392, in which case, you know, that's a change, and there will have to be some documentation kept.

DR. EGGLI: I just have to go through the --

DR. WILLIAMSON: No.

DR. EGGLI: -- not sodium iodide. We're talking about iodide-labeled --

DR. WILLIAMSON: Oh, I see.

DR. EGGLI: -- radiopharmaceuticals, which will put them --

DR. WILLIAMSON: Oh.

DR. EGGLI: -- into --

DR. WILLIAMSON: Within this --

DR. EGGLI: -- 390 for diagnostic imaging.

DR. WILLIAMSON: This is an important point that I think needs to be addressed maybe in

this.

DR. EGGLI: We have taken a portion of diagnostic imaging and taken it out of 290 and put it into 390, and they are low-dose diagnostic studies.

DR. WILLIAMSON: So the 35 -- the limited indication categories, the less than 33 millicuries and greater than 33 millicuries, specifically are limited to sodium iodide and not other compounds of iodine.

DR. EGGLI: 392 and 394 are specifically limited to sodium iodide.

DR. WILLIAMSON: Well, I think the staff better consider revising 392 and 394 to allow a broader spectrum of radionuclides to be used in these categories, so that there isn't this problem. It's quite unreasonable now to, you know, add this huge requirement on imaging physicists.

I think this is maybe a place where a motion is needed to advise the staff to seek a fix to the rule language.

CHAIRMAN CERQUEIRA: So what motion are you making, Jeff?

DR. WILLIAMSON: Well, I think the --

CHAIRMAN CERQUEIRA: Or Doug.

DR. WILLIAMSON: I'm not an expert in

this. I'm going to suggest one --

CHAIRMAN CERQUEIRA: John Graham used to be. He's no longer here.

DR. WILLIAMSON: -- of the nuclear medicine people make a motion to --

DR. HOWE: Can I make a quick point?

DR. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: Yes.

DR. HOWE: If you read 35.40, which is written directives, a written directive must be dated and signed by an authorized user before the administration of I-131, sodium iodide, greater than sodium iodide, 30 microcuries -- any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from a byproduct material.

So I think in the MIBG you may have greater than 30 microcuries, but it's not 30 microcuries of sodium iodide. And so I think if it is not considered a therapeutic dosage, then that particular use will still come under 200. But what we have to deal with that used to be under 200 that goes to 300 is the sodium iodide that goes over 30 microcuries.

DR. WILLIAMSON: So now what I'm hearing

-- I just want to -- is that other chemical forms of radioactive iodine, organically bound, whatever they are, that are more than 30 microcuries can still be administered by new 35.200 diplomates, so to speak, without a written directive, even though it exceeds 30 microcuries. It could be 10 millicuries, for example.

But if it's sodium iodide, 10 millicuries, that's needed for imaging or diagnostic purposes, that would have to be done through 390 -- 35.392, which means there is an extra documentation pathway that is not -- or a requirement that is not currently present that board-eligible candidates or board-certified candidates will have to keep.

CHAIRMAN CERQUEIRA: Okay.

DR. WILLIAMSON: Does everyone agree with that?

CHAIRMAN CERQUEIRA: Yes. Yes. All right. Now, we have someone in the back who has been standing there quite a long time, and I -- I didn't mean to overlook you.

I'm sorry. You've been standing there for a while to make comments, and I didn't recognize you. Please --

MR. MOORE: Thanks. I'm Scott Moore. I'm the Chief of the Rulemaking and Guidance Branch, and

I'm Dr. Miller's division.

CHAIRMAN CERQUEIRA: An important person.

MR. MOORE: Thanks. Our staff briefed you yesterday on the proposed rule comments and on the next steps in the rule.

And I guess I just want to mention to you all that I'm concerned about these transitional issues that you all are talking about now following the Commission briefing, and some of the comments that were mentioned this morning in the Commission briefing about the proposed rule and the tradition. And since that falls into my branch's domain, I need to bring them to your attention.

Dr. Lieto made comments during the proposed rules/public comment period, but I think it's important that the committee under that the committee as a whole did not officially comment during the proposed rule stage. Dr. Lieto did as an individual, but the committee did not.

And you all are talking about how you can best help us -- the staff -- out on the proposed rule, and how you can help us out over the next 30 days. And, you know, Dr. Williamson has said that the staff better consider revising the rule, and you'd advise the staff to seek a fix in the rule.

But the way you can best do that is to submit comments to us as a committee, and the comment period closed on Monday, February 23rd. We are just beginning to analyze those comments. Although we cut off the comment period on the 23rd, we are authorized to seek -- to accept comments after the end of the comment period if we're able to do so and it doesn't negatively impact our rulemaking process -- namely, it doesn't impact the schedule process for the rule.

So if we have comments trickle in after the comment period has closed, and we can take them, and it doesn't impact our rulemaking, then generally we'll consider them. So if the committee itself can get comments, and get combined comments from the committee to us as a committee set of comments, then we could consider them in the rule.

They would get docketed, and we would consider them as ACMUI comments with respect to the rule, and we would be able to consider them in preparation of the final rule as an ACMUI position with respect to the proposed rule. And that would carry a lot of weight, and it would allow us to consider where the ACMUI is.

But we could only do that if you got us something quick. And when I say "quick," I would be

thinking in terms of a few weeks. Anything beyond a few weeks, if it trickled out into the five-, six-week timeframe, it becomes less and less likely, and then beyond about six weeks I'd say we probably wouldn't be able to consider that.

I just want to let you all know how you can be most effective in interacting with us in the rulemaking process.

Now, if you remember our presentation yesterday, I mentioned to you the next step that we come back to you formally as a committee is, when we're in the draft final rule stage, we will come to you at the same point that we go to the agreement states with a draft final rule and seek your comments at that point.

But at that point, we'll have some prepared text, and you'll be less able to influence the process. I mean, we will have drafted words based on feedback that we will have gotten from Dr. Lieto and everybody else that commented on the proposed rule, and we'll have something crafted.

If you really want to influence us on the process, the way to do so is to get something on the record as soon as possible.

CHAIRMAN CERQUEIRA: Well, thank you for

those comments. And it's really -- yes, go ahead.

MR. ESSIG: I've been dying to hand out some material. I'm afraid we're going to lose a couple of people here, but I didn't want to interrupt.

CHAIRMAN CERQUEIRA: All right. Okay, if you can just -- yes.

MR. ESSIG: The material that we had talked about earlier -- and I just want to make sure -- I mean, I can always mail it to them, but as long as they're here, this --

CHAIRMAN CERQUEIRA: Well --

MR. ESSIG: Particularly to answer Rich Vetter's concern earlier, here is the letter that went to licensees on the interim source inventory I'll pass, and then the source inventory itself. I'll pass going in two directions.

Here -- because Commissioner McGaffigan mentioned that this morning in his presentation -- is the IAEA Code of Conduct for safety and security of radioactive sources. That I will pass in both directions.

And then, lastly, for information is the response letter signed by the Chairman that tasks the ACMUI with doing a review of the -- of the input from Marcus and Siegel. I don't know that you've seen

that, but it's the last sentence in the letter.

DR. HOLAHAN: And I'd like to clarify for the record, you were right when you said you got an e-mail. The letter was attached to the e-mail. It was a PDF file that was sent out by our contractor. So you didn't actually receive a letter from us. It was a letter signed by Marty Virgilio, but it was part of the e-mail.

MR. ESSIG: Okay. Sorry for the interruption.

DR. MILLER: Is that what you received, Ralph,or --

MR. LIETO: I got an e-mail, but I -- there was -- I am almost -- almost absolutely certain -- I don't remember a PDF attachment. I don't know if maybe --

DR. HOLAHAN: I have the actual file that was sent out in the inventory, and I can give you a copy of that. You've responded. Your institution has responded.

(Laughter.)

MR. LIETO: Oh, God. I can just imagine who did.

(Laughter.)

CHAIRMAN CERQUEIRA: Well, which really

brings up another point is --

DR. MILLER: That was my concern earlier.

CHAIRMAN CERQUEIRA: Who got the letter? There should be somebody --

DR. HOLAHAN: I asked Merri Horn to check, and she has indicated that she has received responses from all licensees and the ACMUI, except one.

CHAIRMAN CERQUEIRA: Yet some of the members were not aware of it. Okay.

DR. HOLAHAN: Well, it was sent to your RSO.

CHAIRMAN CERQUEIRA: Okay.

DR. HOLAHAN: So the RSO should have responded.

CHAIRMAN CERQUEIRA: Yes. A quick comment? Yes.

DR. WILLIAMSON: Well, I don't have a comment on these issues. I have a comment on the transition issues.

CHAIRMAN CERQUEIRA: All right. So --

DR. WILLIAMSON: We're going to go back to that.

CHAIRMAN CERQUEIRA: So we'll say good-bye to Dr. Vetter and Dr. Schwarz. Yes. We need to go back to the transition issues, because, you know, they

need our input. And a lot of these issues are very important, and we're certainly not going to be able to get it done by the end of this meeting, but we need to have some orderly format and assign individuals to get this back to them to get the committee's input.

Go ahead.

DR. WILLIAMSON: Yes. That is basically -- you've stated my point very eloquently. I am concerned that if we don't work through this list of issues today and figure out which ones really are issues that need to have group comment on, you know, we're going to be not in a position to make -- create an informed letter expressing our concerns.

So, you know, is this issue of the I-131 or I-125 imaging a real one or not? I --

DR. EGGLI: I think the issue there is there has been non-uniform requests on inspections, because the inspectors in Region I have required us to do a written directive for all radiopharmaceuticals that are iodine-labeled greater than 30 microcuries.

So if it's only sodium iodide, we have less of a concern. But as we did our quality management program under the old rule, we were required to do a written directive for every iodinated radiopharmaceutical over 30 microcuries.

DR. WILLIAMSON: Well, I would say that, you know, given there's this doubt, I think our -- I, first of all, think we should rise to the occasion and write a letter as a group, and make sure that within two weeks we're prepared to, you know, meet by federally noticed teleconference, or whatever, to finalize it.

So this should probably be one of the issues that's mentioned where we're getting ambiguous or ambivalent sorts of responses from various sectors of the Commission, and that this is a major concern that -- how are 200-level practitioners going to continue to do various forms of I-131 imaging that they have done in the past? As a profession -- new ones, I mean.

CHAIRMAN CERQUEIRA: Neki?

MS. HOBSON: Yes. I just have one quick comment. I'm still concerned about continued availability of these procedures to patients. And when I see that, you know, the experts on this panel -- and I'm very, very respectful of the qualifications of all the people, besides myself -- if they don't even understand what the regulations are really saying, how are licensees and the inspectors out in the field going to understand it?

How can -- like this clarification about the sodium iodide. Would the average licensee ever pick up on that, or just, you know, how are you going to deal with educating people and not have them just say, "Oh, well, never mind. We're just not going to do that anymore."

CHAIRMAN CERQUEIRA: That's a very important issue, and, you know, I -- I think it definitely needs to be addressed. The idea of workshops and sort of when people do site visits, it's an issue. And certainly the agreement states, which are the bulk of the sites out there, hasn't even been addressed.

So I think those are very valid points that we need to get addressed in really a timely fashion.

Ralph?

MR. LIETO: The point you made about agreement states -- Donna-Beth, when you -- in terms of the tact that's being taken right now, will that become the precedent for the agreement states to follow? Or will they be -- will they be allowed to --

CHAIRMAN CERQUEIRA: Transition.

MR. LIETO: -- develop their own?

MS. McBURNEY: Just speaking for one

agreement state, we would be looking at it from the standpoint of like for the -- for example, the iodine-131 issue. If it says sodium iodide above a certain amount, those -- those isotopes that are tagged with other material than for imaging would still be under our equivalent of 35.200.

We would probably do the grandfathering of those current authorized users in the same way that NRC is doing that. What other -- let's see. That's all, yes. And I would assume that the other agreement states would do likewise.

We're kind of paying attention to what goes up on the web on the Q&A to keep up to date on -- on how -- how these rules are being implemented in order to get an orderly transition into our rulings.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: Will it be up to the licensee -- I guess, you know, I don't necessarily need an answer right now, but will it be left up to the licensee to make that initial -- that initial request for change for the implementation of this new Part 35? Or will it be done as maybe their license is amended? Or is there going to be some other trigger for this license, only when it's renewed or --

DR. HOWE: I think you heard today that

Region I, which is our largest region right now, is revising the old licenses to the new Part 35 format as amendment requests are coming in.

And then, clearly, when we get a question from a licensee, because of the issue of being able to receive material when they're only authorized for 200 under their old license, and they are using I-131 over 30 microcuries, those come to the front pretty fast, and we -- we issue new licenses for those.

So I think it's -- it's happening on a day-to-day basis. We're not waiting for renewals. I think Pam was pretty clear on that. We're not waiting 10 years to bring the licenses into conformance with new 35. We're doing them as they need to be brought in. It goes without saying that we do it upon licensee request, too.

CHAIRMAN CERQUEIRA: All right. Well, now, Ralph, this is a very important issue, and I think certainly for the diagnostic community. And I -- does the NRC staff feel that they've got adequate input? And I guess in terms of your needs for the rulemaking, it has to be in writing, doesn't it? I mean, just -- this discussion doesn't really suffice.

MR. MOORE: Yes, sir, that's correct. We need it in writing. We need it on the docket. The

ACMUI discussion, although it's helpful to hear your thinking and it gives us background on where you're coming out, and it's helpful to hear various sides of the discussion. It's not the same, because it's not up on the record for other members of the public to hear.

It needs to be docketed, and it needs to be docketed through SECY, the same as all other comments. For instance, Dr. Lieto commented much the same as the comments that were presented to the Commission this morning, and that needs to be up on the docket and docketed through SECY. So we do need formal comments, yes, sir.

CHAIRMAN CERQUEIRA: Yes. And I guess all of the committee members got the material for comment, but that's really not a comment from the full committee, which really this meeting should have been sort of scheduled around trying to get that -- to get that done.

And I'd sort of like the committee and staff to give me some advice -- actually, give Dr. Malmud some advice on how to move forward with getting these comments to -- to them.

VICE CHAIRMAN MALMUD: Well, let's take a look at the bullet points on Ralph's page. The first

one is individuals currently in training programs. Now, the question that you raised, Ralph, was, do these individual -- if I understood you correctly, is, do these individuals require some form of attestation statement for the NRC? Is that correct?

MR. LIETO: I think more the -- related to the documentation of training and experience for the preceptor to make the attestation I think is -- it would be more the issue.

VICE CHAIRMAN MALMUD: And since the new rule goes into effect in October '04, is that correct?

DR. WILLIAMSON: It's October.

VICE CHAIRMAN MALMUD: October '04.

DR. WILLIAMSON: Yes.

VICE CHAIRMAN MALMUD: Would it seem reasonable that we recommend that those entering programs after June 30, '04, as you had suggested, Ralph, be furnished with these statements at the time of completion of their training?

That those entering the program after July -- after June 30th, meaning those that enter July 1st or after -- it's an approximately date, some residents start a week before June 30th, but those entering for the academic year, want to put it that way, beginning June -- beginning July '04, would require these

statements? Does that create a burden for anyone? Would that satisfy the NRC requirements?

DR. WILLIAMSON: I thought we had concluded with this long discussion previously that there -- other than this concern identified specifically about 392-type uses that there weren't any additional documentation requirements from the point of view of NRC for applicants coming via board-certified pathways, that it was the responsibility of the community or the individual preceptors to determine what level of documentation they were satisfied with, and that there is not a need for fixing the rule language at this time. I thought that was our consensus.

VICE CHAIRMAN MALMUD: Is that correct, Ralph?

MR. LIETO: Yes. I think the committee had decided that the individuals in training was no longer an issue.

VICE CHAIRMAN MALMUD: Does the NRC staff require that be in writing from this committee?

MR. MOORE: I'm sorry. I didn't hear the background to the question.

VICE CHAIRMAN MALMUD: I'm trying to resolve these issues that Ralph has brought up on the

transition issue page. The first one is individuals currently in training programs. This is an issue which we think really is not one of great substance.

It's simply a matter of documentation -- that those who enter training programs beginning July 1st of 2004 would require such statements to satisfy the NRC requirement from the authorized user at the time of completion of their training. Do you want a statement from us to that effect?

CHAIRMAN CERQUEIRA: Well, he needs something in writing, I think.

VICE CHAIRMAN MALMUD: That's what I mean.

CHAIRMAN CERQUEIRA: So I'm --

DR. MILLER: Scott, maybe you could go through what we just talked about with regard to what would be the easiest and fastest legal path --

MR. MOORE: Sure --

DR. MILLER: -- for the committee to get us their comments with the least impact on the committee.

MR. MOORE: We're looking for ways to simplify the process. What we need is a clear statement of what the position is, and if we look at the transcript there's going to be various comments about what the position should be.

If you can clearly articulate what the position is as a committee, it doesn't have to be signed by everybody. If somebody could clarify what the position is, it can be even -- we can even receive, I believe by e-mail, can't we -- we can receive a position by e-mail, and that can be e-mailed in by the chair of ACMUI or by an ACMUI member speaking for ACMUI to the SECY.

So as far as the individual positions, if you could just clarify what they are and send them in to SECY --

VICE CHAIRMAN MALMUD: I would like to do that while the committee is still here, and that's why I'm asking --

MR. MOORE: Yes.

VICE CHAIRMAN MALMUD: -- that question of you. So my question is, regarding the first item on the agenda -- individuals currently in training programs -- we have been told that we have no flexibility on the issue of the person signing off being the authorized user. So we're working from that as an axiom. Though we may not be happy with it, we're working with that as an axiomatic basis.

So do you want a statement from us which says that that authorized user documentation will be

provided to all those who enter training programs after July 1st?

MR. MOORE: Yes. We think you can pass a motion here as a committee, and then we could take the transcripts back and docket that and pull that as a comment from the transcripts.

VICE CHAIRMAN MALMUD: Yes. I understand that. And what I'm trying to ask you is, is the statement that would satisfy your needs, and our needs at the same time, one which states that this committee will take the vote, this committee wishes to authorize -- wishes to require, with you, that individuals who enter training programs July 1, 2004, or thereafter, will require statements by the authorized user certifying that they have had the requisite training.

DR. WILLIAMSON: I don't understand the substance of the motion. I mean, it doesn't matter whether they entered before or after. The way the rule is written now, come October 2004, everybody who is not grandfathered and who wants to be an authorized personage is going to require a preceptor statement.

So I think maybe if we disagree with that then we need to vote -- someone needs to make a motion saying that graduates who enter a training program on or before X date should be exempted from this

requirement. And we should just say it flat out, and then we vote on it, and it's in the record. And I think that will satisfy their needs if it's an official motion of this committee.

VICE CHAIRMAN MALMUD: Do you wish to make that motion?

DR. WILLIAMSON: Okay. I think somebody who is -- I -- all right. I'll make it, so that we can get going. Okay. So the ACMUI proposes that the staff add to the current regulation an exemption which allows matriculants into post-graduate training programs who enter on or before June 30, 2004, will not require a preceptor statement to become an authorized person through the board certification route.

VICE CHAIRMAN MALMUD: Is there a second to that motion?

MR. LIETO: Second.

VICE CHAIRMAN MALMUD: Ralph. Any discussion? Mr. Chairman?

CHAIRMAN CERQUEIRA: Yes, go ahead.

DR. WILLIAMSON: I don't think there's a need for this motion.

VICE CHAIRMAN MALMUD: There is a need. It has to go -- it has to be made public, and we --

DR. WILLIAMSON: Mr. Vice Chair, we have I think determined through conversation with the NRC staff that there isn't a problem to be solved, and there is really no need to modify the rule language.

DR. EGGLI: The original concern was the need for documentation that we would have to produce retrospectively. The NRC staff has now said that there is no specific required documentation, which I think resolves the issue of the people in that transitional status.

DR. WILLIAMSON: So I would recommend we not approve this motion.

VICE CHAIRMAN MALMUD: You can withdraw it.

DR. WILLIAMSON: I could withdraw the motion, but I've done it -- for the sake of discussion, I've put it out there.

CHAIRMAN CERQUEIRA: Ruth?

MS. McBURNEY: Okay. I agree, I don't think there is an issue to be commented on, and this is pertaining to the current rule. It's not pertaining to the proposed rule. So, also, there is not an issue in that with this reduced requirement for what goes into the preceptor statement. There shouldn't be a problem.

MR. MOORE: If I may? This is Scott Moore again. It is up to you as a committee to choose what to comment on in the proposed rule. One method would be to make motions and have them entered into the record in the minutes, and then we would get that docketed. Another manner would be to send us an e-mail. Another manner would be to send us a letter. That -- the mechanism is up to you.

VICE CHAIRMAN MALMUD: Those are the three mechanisms.

MR. MOORE: And they're --

VICE CHAIRMAN MALMUD: Are you proposing that since this committee is together now, and since we've had a discussion, and since we regard the first issue essentially as a non-issue, that we formalize our statement and get it into the minutes and give it to you now, rather than in an e-mail or by some other means of communication at a later date?

That's what -- that was the purpose of my motion, and you made that motion. Have you withdrawn the motion?

DR. WILLIAMSON: I will be happy to withdraw the motion. And if the chair wishes, I will try to make it in a more negative way, so that you can have something to enter into the record if that is

your desire.

VICE CHAIRMAN MALMUD: Ralph is very concerned about people -- about the transitional issues, and I'm trying to address the concerns of --

DR. WILLIAMSON: I think not every --

VICE CHAIRMAN MALMUD: We have to communicate this to the appropriate party. Here is a means of communicating it. We are sitting here. Would you rather send an e-mail than just make a statement right now?

DR. WILLIAMSON: No. I would rather we drop this issue and move on to the more important ones, because we've determined this one is not really a problem. That would be my suggestion.

VICE CHAIRMAN MALMUD: Does the NRC staff person here feel that there has been adequate communication from this committee to him with regard to the committee's desires, without the motion, and without the e-mail?

DR. WILLIAMSON: Just this transition issue. I do not mean to include the other --

VICE CHAIRMAN MALMUD: I'm referring to the first bullet point.

DR. MILLER: From the NRC staff perspective, what I'm hearing is you're not going to

comment on this issue.

DR. WILLIAMSON: Yes.

DR. MILLER: And if that's the committee's view, and that's what you decide --

DR. WILLIAMSON: I will retract the motion. I withdraw the motion, and I'll make a new one. The --

VICE CHAIRMAN MALMUD: No, you don't need to. So the -- go ahead. The absence of a comment means that we agree with whatever comes down with regard to the first issue.

DR. WILLIAMSON: Yes.

VICE CHAIRMAN MALMUD: Is that the agreement of the committee? Ralph, does that satisfy you? You presented this.

MR. LIETO: Yes, I presented this on behalf of the committee, but I -- I would agree that we should leave it as a non-issue and move on.

VICE CHAIRMAN MALMUD: Thank you.

Next item, AMP grandfathering. Do we agree to the issue as it is currently being dealt with? Or does the committee wish to make a comment for the record?

Dr. Williamson?

DR. WILLIAMSON: Well, I would like to

defer.

MR. LIETO: I'll just restate what my --

VICE CHAIRMAN MALMUD: Yes.

MR. LIETO: -- what the concern is.

VICE CHAIRMAN MALMUD: Yes, why don't you restate it.

MR. LIETO: The concern is is that in many states authorized medical physicists -- or that this is a new designation. So there is not a history to reference regarding individuals in this category.

In many state -- I don't know if I should say in many, but in several agreement states physicists -- authorized medical physicists -- individuals who are practicing and meeting the authorized medical physicist definition are not listed on the license. So there is not that designation that they can use as a grand -- to grandfather them.

So those are a couple of the major concerns. And I don't know -- Jeff, is there any other that you can think of?

DR. WILLIAMSON: Well, let's maybe do that one. I think that's -- that's an important one.

VICE CHAIRMAN MALMUD: So you've expressed the concern.

DR. WILLIAMSON: Yes.

VICE CHAIRMAN MALMUD: Do you have a motion to express beyond the concern?

DR. WILLIAMSON: Well --

VICE CHAIRMAN MALMUD: We have two physicists discussing this at the moment. Dr. Williamson?

DR. WILLIAMSON: I defer to Ms. McBurney.

MS. McBURNEY: I don't -- I don't think that a comment on the NRC rule would help this situation. It's more of a transition issue in those agreement states in which authorized medical physicist was not a -- a defined item, and those people were not already listed on the license.

VICE CHAIRMAN MALMUD: So if the NRC is looking for guidance, we have no -- no guidance to give except for a statement. And the statement is?

DR. WILLIAMSON: No. I think we do need to come up with something, so --

MS. McBURNEY: I mean, you could comment on -- on the concern, but how that would affect the final rules in this area I don't know.

DR. WILLIAMSON: Well, I think we need to say something. This is really an important issue. We need -- it's critical for the conduct of health care that there be a, you know, population of grandfathered

AMPs or, you know, the system is going to be in great difficulty.

So I think we need to make a motion to the effect that, you know, NRC needs to consider alternative language and/or guidance procedures to ensure that physicists currently practicing or playing the role of HDR physicists, gamma knife physicists, or cobalt-60 teletherapy physicists, or intravascular brachytherapy physicists, in agreement states are appropriately grandfathered, regardless of whether they are mentioned by name on agreement state or NRC licenses.

VICE CHAIRMAN MALMUD: That's a motion. Is there a second to that motion?

DR. EGGLI: Second.

VICE CHAIRMAN MALMUD: It's been seconded. Is there any further discussion of that motion? All in favor of that motion.

DR. MILLER: Can I ask a question?

VICE CHAIRMAN MALMUD: Please do.

DR. MILLER: Why is it only an agreement state issue?

MR. LIETO: It's not. It would be an NRC -- for example, if they're not listed in an agreement state, and they go into an NRC state to be added to a

license, there is nothing to reference that they've been doing this for -- you know, for X number of years, or whatever. So how would the NRC grandfather them if they've never been listed on a license?

MS. McBURNEY: It's a transboundary issue.

MR. LIETO: So there is --

DR. WILLIAMSON: And I consider it to be an important agreement state issue, too, because the compatibility level requires NRC -- the agreement states to adopt this language, which would disenfranchise their own physicists if they followed it literally.

VICE CHAIRMAN MALMUD: Was the suggestion, therefore, that this be augmented to be an NRC and agreement state issue?

DR. WILLIAMSON: Well, I think that -- I believe it's -- if it's addressed in the 3500 language, which is compatibility level B, the agreement states will be forced to follow suit.

So my -- the essence of my point was that the rule language and/or statements of consideration or guidance, whatever the mechanism is, because we don't know what that is right now, needs to somehow ensure that physicists who are playing the functional role in licensed activities for these authorized AMPs

of different flavors are grandfathered, regardless of whether they are mentioned specifically in the license or not.

So, and a mechanism needs to be found to identify and grandfather these individuals who are playing that legitimate role. That's the motion.

VICE CHAIRMAN MALMUD: Is there comment?

DR. HOLAHAN: Yes. Guidance is not a matter of compatibility. So only the rules are compatible.

MR. LIETO: So, Trish, then there would need to be something in the final rulemaking process that addresses that, is that correct?

DR. HOLAHAN: Yes, that's true, if you wanted to apply to agreement states as well.

DR. WILLIAMSON: So I think, then, it can be amended to say, then, I guess rule language or statements of consideration that may clear the intent, if you think the statements of consideration would give you enough of a lever to have transitional procedures that would conflict with the, you know, literal word of the rule. That's up to you guys. You're the regulators.

We have identified the problem and I think insist that it be fixed, and I think everyone agrees

around this table it's an important issue.

VICE CHAIRMAN MALMUD: So that the motion might sound like this. That the committee expresses its concern that current physicists in a variety of roles in the provision of medical physics be recognized for their current effort and grandfathered accordingly under the new regulations.

DR. WILLIAMSON: I preferred my statement, which was far more precise.

VICE CHAIRMAN MALMUD: Do you wish to repeat your statement?

DR. WILLIAMSON: Yes, I will repeat my statement.

VICE CHAIRMAN MALMUD: I was trying to get the motion.

DR. WILLIAMSON: Okay. All right. The ACMUI recommends that the NRC modify the language of the new training and experience rule and/or associated statements of consideration to ensure that medical physicists playing the functional role of authorized medical physicist for intravascular brachytherapy, high-dose rate brachytherapy, cobalt-60 teletherapy, and cobalt-60 gamma knife therapy, be grandfathered as AMPs in these respective categories regardless of whether they are currently mentioned explicitly in

agreement statement or NRC licenses at the time of the implementation of the new rule.

VICE CHAIRMAN MALMUD: Thank you. That's a motion. Is there a second to that motion?

PARTICIPANT: I second it.

VICE CHAIRMAN MALMUD: Is there discussion of the motion? All in favor of the motion? Any opposed to the motion?

MS. McBURNEY: Abstain.

VICE CHAIRMAN MALMUD: There's one abstention. The rest are affirmatives.

The next item is the authorized users of I-131 for diagnostic purposes meeting T&E for written directive use. Who wishes to address that concern for this committee to the NRC, so that it will be a matter of record? Ralph, do you want to tackle that one, or --

MR. LIETO: I'll give it a try.

CHAIRMAN CERQUEIRA: Or Doug.

MR. LIETO: I would move that licenses be amended to provide that current authorized users of sodium iodine-131 for imaging and localization greater than 30 microcuries be allowed -- or continue to be authorized for those purposes.

VICE CHAIRMAN MALMUD: That is a motion.

Is there a second to the motion?

DR. EGGLI: Second.

VICE CHAIRMAN MALMUD: Dr. Eggli. Is there any discussion of the motion? All in favor? Any opposed? Any abstentions? That carries unanimously.

All right. And the fourth item is --

DR. WILLIAMSON: I'm sorry, Mr. Chair. We -- we have a related issue on this point to consider. We have dealt only with the grandfathering of current practitioners of 35.200. I think we need to ensure that future practitioners in localization and imaging who current -- are able, through the normal training pathway of 35.200, be allowed to practice I-131 imaging when it's a non-iodated, non-sodium iodide radiopharmaceutical in excess of 30 microcuries. I don't know if I got it out right.

VICE CHAIRMAN MALMUD: Yes, you did.

DR. WILLIAMSON: Okay.

VICE CHAIRMAN MALMUD: So the committee --

DR. WILLIAMSON: The regulations, if necessary, need to be amended before being implemented, to ensure that that activity can be carried out under 35.200.

DR. EGGLI: Can I ask a question of staff

in that regard? The hours of requirement for 392, can they be done currently with the 700 hours in 290? Or do they have to be done in addition to the 700 hours in 290?

DR. HOWE: You have to look carefully at what the topics are and whether the topics should be addressing therapeutic or otherwise. And you have to make sure you meet your total number of hours for whichever category.

DR. EGGLI: You're saying your -- you say you're no longer distinguishing between therapy and diagnosis in -- and in 392, which is the less than 33 millicuries. We do not have a problem for future trainees for diagnostic purposes if the 700 hours in 290 can be done concurrently with the 80 hours in 392. However, if they have to be done sequentially, then we have a problem. So the question is: can these hours be done concurrently?

DR. HOWE: The requirements in 392 are that the -- they have to have training applicable to the medical use of sodium iodide for the procedures requiring a written directive. And they must include these topics, and they have to have 80 hours of classroom and laboratory training specific to that for sodium iodide use.

DR. EGGLI: Right. But could those 80 hours count as part of 290?

VICE CHAIRMAN MALMUD: Doug? Excuse me. The answer to your question is: by tradition, yes.

DR. EGGLI: I know by tradition, but --

DR. HOWE: But, by tradition, you're way over the 700 hours. It's minor.

DR. EGGLI: Except that the radiology residency is decreasing its required time to be more compatible with the new regulation.

DR. HOWE: Okay. Well, it says for medical use for unsealed byproduct material for imaging and localization studies -- their imaging and localization studies. And then you have to meet the criteria, so --

DR. EGGLI: Right.

DR. HOWE: -- I think as long as the objective is both imaging and localization, and I-131, then you're okay. But if there's one that's not in both of them, then you're going to have to add that little --

DR. EGGLI: And I do understand that. But we're looking at the overlap only. I'm looking, in my mind, at the overlap right now, not -- not -- nothing other than the overlap.

DR. HOWE: I think if you -- if it could be imaging localization, and it's also I-131 --

DR. EGGLI: Right.

DR. HOWE: -- and you're doing I-131, then it can cover into the imaging and localization.

DR. EGGLI: Okay. As long as the specific criteria from 392 are included.

DR. HOWE: Yes.

DR. EGGLI: Okay. Thank you.

DR. WILLIAMSON: I've just heard enough contradiction from the various headquarters and regional staff that I'm concerned about non-sodium iodide imaging when it involves doses in excess of 30 microcuries of I-131, that I thought maybe we should go on record, you know, recommending that staff comb through this new regulation with a fine-tooth comb and fix it if necessary to allow 35.200 practitioners in future to do whatever form of I-131 imaging they want to do, excepting sodium iodide imaging in excess of 30 microcuries, without additional training and experience. That would be my motion.

VICE CHAIRMAN MALMUD: That motion -- is there a second to the motion? I don't think we have --

MR. ESSIG: If I could bring up a procedural issue.

VICE CHAIRMAN MALMUD: We don't have a --

MR. ESSIG: You don't have a quorum.

VICE CHAIRMAN MALMUD: We don't have a quorum.

MR. ESSIG: You just lost -- Ruth McBurney left. You need seven.

VICE CHAIRMAN MALMUD: So we cannot present that as a motion, though it is meritorious. We could e-mail you on that issue, and Dr. Howe and staff are -- would happily accept an e-mail to that point.

DR. WILLIAMSON: I don't think we can act as a group without a noticed meeting. I don't think we can --

VICE CHAIRMAN MALMUD: At our next telephone conference call, we can deal with the issue.

DR. WILLIAMSON: Well, that will be too late.

VICE CHAIRMAN MALMUD: That's too late. All right.

DR. WILLIAMSON: I think we --

DR. HOLAHAN: You can send it electronically to -- and then send it in to us as --

when you get --

DR. WILLIAMSON: Without review --

DR. HOLAHAN: Yes, without a notice.

DR. WILLIAMSON: -- by the public? We can come up with a joint --

DR. HOLAHAN: Yes.

DR. WILLIAMSON: -- ACMUI position?

DR. HOLAHAN: Because it goes on the public document.

DR. WILLIAMSON: But we can't have a telephone conference about it.

MS. WILLIAMSON: Excuse me. It looks like you have a quorum now.

VICE CHAIRMAN MALMUD: How many constitute a quorum? We have seven. We now have a quorum. Okay.

MEMBER WILLIAMSON: Let's vote on this issue.

VICE CHAIRMAN MALMUD: Would you just quickly before we leave the quorum again make the motion? The ACMUI recommends that the staff carefully review the revised part 35 training and experience rule to ensure that future 35.200 practitioners will be allowed to provide I-131 imaging and localization, excluding sodium iodine, radiopharmaceuticals in any

dose needed without further training and experience.

MEMBER EGGLI: Second.

VICE CHAIRMAN MALMUD: I have a question. Do you mean any dose?

MEMBER WILLIAMSON: Any dose in excess of 30 microcuries.

VICE CHAIRMAN MALMUD: What about five millicuries?

MEMBER WILLIAMSON: If five millicuries are needed, then so be it. Five millicuries.

VICE CHAIRMAN MALMUD: That clarifies. Did you second the motion?

MEMBER EGGLI: I did.

VICE CHAIRMAN MALMUD: I will call the vote. Any further discussion of the motion?

(No response.)

VICE CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

VICE CHAIRMAN MALMUD: It is unanimous. We have dealt with all of the issues, Ralph, that you brought before us.

MEMBER EGGLI: Actually, I would like to codify in a motion a question for Donna-Beth.

VICE CHAIRMAN MALMUD: I just wanted to ask Ralph a question before we left this page.

MEMBER EGGLI: This is still on this issue of I-131 for diagnosis.

VICE CHAIRMAN MALMUD: All right.

MEMBER EGGLI: I would like to make a motion that the sense of the Committee be relayed to staff that diagnostic use of sodium iodide, which falls under 392 for diagnostic use only, that the ACMUI recommends that there be a clarification that that can be included in the 700 hours of training for 200 use as long as it is limited to diagnostic imaging and localization only and they meet the specific experience requirements listed in 392.

MEMBER WILLIAMSON: Second.

VICE CHAIRMAN MALMUD: Is there any discussion of that?

(No response.)

VICE CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

VICE CHAIRMAN MALMUD: So you have the spirit of the Committee. I think you already told us that it was okay, but it is now formalized, Dr. Howe.

MEMBER HOBSON: Dr. Malmud? These motions are going into the minutes. We don't get the minutes like for a couple of months. Now, will the NRC staff get the minutes in a timely fashion so that they can

be docketed and put into the record?

VICE CHAIRMAN MALMUD: The NRC staff? Three members of the staff have shaken their heads affirmatively.

CHAIRMAN CERQUEIRA: Yes.

VICE CHAIRMAN MALMUD: Let the record show that three members of the NRC staff have shaken their heads affirmatively that they will have received it.

Dr. Williamson?

MEMBER WILLIAMSON: Well, I think there are numerous more issues we might need to comment on. I think that I am not personally satisfied that the rule language defining preceptor allows the level of flexibility needed to accommodate the many scenarios that Ralph outlined in his presentation this morning.

Example, right now preceptor is defined as the individual who supervises and directs and provides the training of the authorized person applicant. I think I am concerned how that is going to fit with, just to give an example, for example, the practice which acquires a gamma knife and there is no authorized user on site.

So now I am worried that the restrictive way in which the preceptor requirement is written may prevent or preclude, for example, the medical director

of the one-week course in gamma knife from signing a preceptor statement on behalf of that person.

I am worried about a situation if a practice acquires an HDR device, in which case most of the training is provided, actually, by non-licensed personnel from the vendor, who are not necessarily even physicians. Who is going to sign the preceptor statement for both physicists and --

VICE CHAIRMAN MALMUD: Dr. Williamson, how is that being handled currently? Would you educate the Committee as to how it is occurring currently?

MEMBER WILLIAMSON: Currently, one way it is being handled is that now board certification provides the credentials. So there is no need for a preceptor statement at all. And basically the community goes and the practice goes and does these courses and begins the practice.

VICE CHAIRMAN MALMUD: Yes.

MEMBER WILLIAMSON: So there isn't a requirement. So I am worried more about the odd scenarios when a qualified practitioner in the sense that the community uses the word a "qualified" medical physicist, a qualified radiation oncologist, comes to acquire a new modality. Their training is many years, decades behind them. They have to acquire a new

modality. How is this to be handled?

I am not convinced at this point that the rule language is sufficiently flexible to basically systematize the processes that are in effect in the community now by which we get this done because new users, people, physicians, and physicists, move from practice to practice. And they have to acquire knowledge to competently perform new modalities. This happens all of the time.

VICE CHAIRMAN MALMUD: Ralph?

MEMBER LIETO: I would probably add that almost any use in section 1000 would apply because --

VICE CHAIRMAN MALMUD: It's new technology.

MEMBER LIETO: It's new technology, and your listing of authorized users and so forth on the license specifically lists those modalities in 1000 by application. So if you get a new modality in, whether it is a GliaSite or TheraSpheres or any of those modalities in pharmaceuticals as well as the machines that Jeff mentioned, I would see that licensee would be under that same situation.

MEMBER WILLIAMSON: So one thing I could propose maybe as a specific is to modify the definition of preceptor to include not only those who

direct and provide the training but have knowledge of the applicant's capability to successfully perform the safety duties associated with the modality.

VICE CHAIRMAN MALMUD: How could we have knowledge of the applicant's ability with the modality when the modality is new? Why don't we leave the definition as it is since the practice as it is has been unchallenged thus far?

MEMBER WILLIAMSON: Honestly, I am not sure how to handle this. I do think you may be right that it may not be a problem, but it might. I am concerned that perhaps without another 45-minute conversation or dialogue with the staff, we will never figure that out.

We have to go through these scenarios, painful as it is, one by one and determine whether there is a significant issue or not and then advise the staff how the rule might or might not need to be change.

VICE CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I know in a new technology issue for PET CT, most of the vendors are offering training opportunities at a site where there is someone who can preceptor your experience. Does that not occur while in radiation oncology?

MEMBER WILLIAMSON: I believe it is customary with the gamma knife but not for HDR. Would you agree with that?

MEMBER LIETO: I would agree with that, yes.

MEMBER WILLIAMSON: For intravascular brachytherapy, it is almost exclusively the vendor that performs the training. And they don't send a physician out there to do that. They send usually a customer support person who has been well-trained in the details of the protocol and the technical operation of the device.

VICE CHAIRMAN MALMUD: Dr. Williamson, isn't that issue generally dealt with at the level of credentialing within the hospital or the institution itself?

MEMBER LIETO: Well, you have to submit the preceptor.

MEMBER WILLIAMSON: The preceptor is required to be an authorized person practicing the same modality.

VICE CHAIRMAN MALMUD: Dr. Zelac may have some wisdom for us on the issue. Dr. Zelac?

DR. ZELAC: I will try to make a worthwhile contribution. What I am looking at is the

statements of consideration for the existing rule. This question of where training could be received and who could sign off on its being successfully completed was raised at that time.

I am going to read from the statements of consideration. It was the response of the NRC through the comment on this issue. "We," meaning the NRC, "do not believe that the rules should prohibit an individual from obtaining training at locations whose activities are supported by commercial manufacturers, suppliers, or the owners' investigators."

Here is the critical part, "We will rely on the preceptor's written certification for final assurance that an individual has completed the required training and experience and is competent to function independently as an AU."

What these words say to me is that the preceptor does not personally have to direct or provide the training, but he has to essentially be aware that appropriate training and experience has been received and is willing to attest to that in the preceptor statement.

VICE CHAIRMAN MALMUD: Thank you for that information, Dr. Zelac.

MEMBER WILLIAMSON: That is why I propose

the definition of preceptor be changed. So to follow, this has been great that Dr. Zelac brought this up.

So if I go to Nucletron and I have the training and treatment planning and I get all of the training in operating the device and then I go and talk to my colleague on the other side of town who has not personally been involved in the provision of this training to me and review my procedures and review the training I have gotten with the vendor and presumably by the relationship, this person already knows my background and experience in general, I think it would be reasonable that this person could attest to my competence to perform these duties.

So this is a person who has not directly provided the training but who has knowledge of my clinical capabilities and training and attests that I will do a good job.

So that is why I would propose inserting those words into the rule to really make sure that the rule has the flexibility to accommodate all of these bizarre situations.

CHAIRMAN CERQUEIRA: My only concern about that, maybe medical physicists work well together. I think for physicians, sometimes to find a colleague across town who is willing to assume any kind of

liability when he is going to be competing against you is going to be difficult.

So, even though that person may have gotten all of the adequate training, to find somebody who is willing to sign that preceptor statement may not be as easy.

MEMBER WILLIAMSON: But it might be easier if we make the rule more flexible. It could be somebody across the state line in another city.

MEMBER EGGLI: In the case of this 1000 new technology, the person who signs the preceptor statement has to be an authorized user or can it be some other authorized person? For instance, could it be the RSO of an institution that vouches for the fact that the medical physicist or the physician has gone and taken the training or does the authorized person have to be in the same category? You are shaking your head yes on "same category."

VICE CHAIRMAN MALMUD: I didn't understand the last thing you said. Who is shaking?

MEMBER EGGLI: Dr. Zelac is shaking his head yes that it has to be the same category.

VICE CHAIRMAN MALMUD: Same category.

DR. HOLAHAN: It has to be the same category.

MEMBER WILLIAMSON: So I really think does the staff find it objectionable or does it think it would help ease this transition if we substituted those words into the rule language?

VICE CHAIRMAN MALMUD: Substituted which words for which words?

MEMBER WILLIAMSON: Okay. Currently the definition reads, "The preceptor's person who provides or directs the training." I would say, "provides, directs, or has knowledge of."

VICE CHAIRMAN MALMUD: We have a comment from NRC.

MR. MOORE: At the risk of wading into this, I can imagine some potential implementation errors with people shopping for preceptors, especially if you get trans-boundary issues going out of state. I guess I can see, Dr. Williamson, out of state. You can imagine things going way, way out of state, across the country, people willing to sign off things far out of country and other states entirely.

I guess we would need to find a way in either implementation guidance or something to guard against that.

MEMBER WILLIAMSON: Well, is the alternative to do nothing and restrict the practice of

medicine? Nobody has made an argument that the way things work now is broken.

MR. MOORE: No. I am not --

MEMBER WILLIAMSON: You know, there is a shortage of radiation oncologists and physicists. So is my fix helpful or not?

VICE CHAIRMAN MALMUD: We have a comment from the American College of Radiology.

MS. FAIROBENT: I just wanted to point out an example of what we currently do through our accreditation programs. And I hate to bring this one in because currently it is not a modality that NRC regulates, but for PET, for example, positron emission tomography, in order for our physicians to become recognized for our accreditation program, they have to have 24 hours of training in PET.

Now, granted, a piece of that, they can get through the training programs, the didactic courses, but there is also an element that they have to go and do some clinical applications. They go to another facility. For example, one of our physicians in Texas went to a colleague's facility who was already accredited for PET in New Mexico.

It is not uncommon, at least for the ACR positions, to go to other facilities, which may even,

in fact, be across country. I don't see any prohibition in concept that that other authorized user should not be able to sign as a preceptor for the second physician.

There is a problem in the definition of preceptor as it is worded. And in our comments, we have recommended a simplistic fix. We talked and debated, Jeff, a lot about the type of language you are suggesting, but I think that the removal of the word "the" before "training and experience" in the definition broadens it so that it is not unique to a specific application and does allow the flexibility.

So I just point that out that it is not uncommon for physicians to go either across town to another colleague's facility across state in order to get that initial training in order to be able to do a new modality.

DR. HOLAHAN: But I would ask Lynne to comment. Is it the authorized user in the same field?

MS. FAIROBENT: Yes. For example, it would be --

DR. HOLAHAN: It is not like an RSO signing off?

MS. FAIROBENT: Yes. For example, it is physician to physician, who could then certify that

they did the clinical. It is not that dissimilar for what we do for a new physician who wants to do the three iodine cases.

If their facility is not currently doing the iodine therapies, they have to go somewhere to get their initial three cases. So they would have to go to a facility and work under an authorized user to do those types of therapies to get those three cases that are required under 394.

MR. MOORE: This is Scott Moore again.

I think what Lynne is describing makes a lot of sense. My comments had to do with the terminology "has knowledge of." I think you would probably want to be very careful about loosening the standards over broadly and being careful about what "has knowledge of" means. Is there a level of what "has knowledge of" means? I mean, if one doctor goes to another doctor and just describes what they did sufficient, is that "has knowledge of"?

VICE CHAIRMAN MALMUD: Thank you.

Yes?

MEMBER SULEIMAN: I hope this contributes. FDA's experience, will approve the device, will approve the drug, we really defer to the local institution for the credentialing in whatever the

local state.

But with any new technology, any emerging technology, the vendor really invests quite a bit in the training to get this thing off and running. So who is going to teach the very, very first person?

So I think in an emerging technology, new procedure and new protocol, you really have to defer to the expertise of the local facility and the manufacturer. Where that transforms into a more established new procedure and, all of a sudden, then you have enough bodies around to precept the others, that is the critical thing, but I think you have to cut a lot of slack early on.

I think people are excited about the technology. And nobody wants it to fail. So I think earlier on, there is probably a lot of attention. It is a case of getting it rolling out.

But where you make that transition, maybe when you decide to take it out of 1000, I don't know. Clearly you have got to rethink the concept of preceptor at that phase versus later on.

MEMBER WILLIAMSON: I think that is a good point. It certainly adds a big burden to the manufacturers to have to fly unnecessarily physicians from one part of the country to another just to have

a preceptor statement.

I guess I would question whether that is a good use of resources to significantly modify the pattern that is now existent within the regulated community unless you think it is a clear and present danger to public safety.

I have not heard anybody make that case. So that is why I am trying. I am arguing that I think these rules should be liberalized to accommodate the current practice as much as possible.

Yes, I suppose people could cheat and so forth. And maybe guidance could be an indication of consequences if people didn't take these duties seriously, but I think to add significant expense to becoming an authorized user for HDR or intravascular brachytherapy, which is not at this point found necessary by the community, why impose more costs and requirements to do this unless you really think there is a risk to public safety? And, as I say, I don't think anybody has made that case.

VICE CHAIRMAN MALMUD: Having said what you said, do you still feel that your motion is needed?

MEMBER WILLIAMSON: Well, I think it is a useful motion, yes. I would amend it to remove the

definite article "the," which would eliminate another concern with the preceptor definition, which is that the rule is not flexible enough to accommodate sort of multiple persons signing off on different modalities.

If you read it literally now, it sounds like for radiation oncologists and physicists, there has to be a single sort of training person who oversaw the training in all of these three or four different modalities, which the way medicine is changing so rapidly and dynamically, that is unreasonable.

So I think to eliminate the definite article "the" to allow explicitly for the possibility of multiple preceptors in different areas or even different maybe one for the didactic part and one for the practical part would be an appropriate thing to do.

VICE CHAIRMAN MALMUD: I am not familiar with the sentence or phrase in which it is suggested that the article "the" be deleted. Does anyone have that text that they could read to the Committee so that we might hear it? And would you share that with us? Which slide?

MEMBER LIETO: Actually, it was in the slides from this morning. If you look at slide number 4, it has the current definition in section 35.2. It

states, "The current definition of a preceptor is an individual who provides or directs the training and experience required for an individual to become" blah blah blah.

VICE CHAIRMAN MALMUD: And it's the "the training"?

MEMBER LIETO: And the suggestion was to change that to "an individual who provides or directs training and experience."

VICE CHAIRMAN MALMUD: That is a motion to change the --

MEMBER WILLIAMSON: I am looking for the text here so I can make it specific and focused for you. 35.2, isn't it?

VICE CHAIRMAN MALMUD: 35.2, "Definition. An individual who provides or directs the training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." And the word that we want to delete is the third word on the second line? Is that where the "the" appears?

MEMBER LIETO: Yes.

VICE CHAIRMAN MALMUD: And the preferred wording would be "An individual who provides or directs training and experience required for an individual to become an AU, an AMP, an ANP, or an

RSO."

Dr. Williamson has made the suggestion that the word "the" be dropped between the two words "directs" and "training." Is there a second for that motion?

MEMBER EGGLI: I'll give it a second.

VICE CHAIRMAN MALMUD: It is seconded by Dr. Eggli. Is there any further discussion of that phrase?

MEMBER LIETO: I guess I would ask NRC staff for an opinion. Another suggestion that we had made this morning was to use the words "an individual who provides, directs, or can verify the training and experience."

MEMBER WILLIAMSON: Which is very similar to my suggestion, "has knowledge of."

MEMBER LIETO: You think those are just equivalent statements of the same with different wording?

MEMBER WILLIAMSON: I think so. My initial motion was actually a little different. "Preceptor means an individual who provides, directs, or has knowledge of training and experience required for an individual to become" a dot dot dot dot.

DR. HOLAHAN: I, frankly, liked your

wording better.

MEMBER LIETO: Of the second on?

DR. HOLAHAN: Yes, "verify."

MEMBER WILLIAMSON: I accept that.

VICE CHAIRMAN MALMUD: Therefore, the preferred wording is "An individual who provides, directs, or verifies training and experience required for an individual to become," et cetera. Is that?

MEMBER LIETO: Yes

VICE CHAIRMAN MALMUD: That is a motion from Dr. Lieto. Is it seconded by Dr. Williamson?

MEMBER WILLIAMSON: Yes.

VICE CHAIRMAN MALMUD: Any discussion?

(No response.)

VICE CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

VICE CHAIRMAN MALMUD: It carries unanimously. Therefore, that is the last bit of material which I believe we want to convey to NRC staff with regard to communication by e-mail, other means, or this Committee.

MEMBER WILLIAMSON: I don't think so.

VICE CHAIRMAN MALMUD: Dr. Williamson would like to go on.

MEMBER WILLIAMSON: Unfortunately, our two

radiation oncologists aren't here, but if they were here, I would ask them if they were satisfied with the wording for the training and experience requirements for 35.300, which now read in sort of an ambiguous way but appear if you read it literally to allow radiation oncologists to continue being authorized users for 35.300 radiopharmaceuticals with board certification as it is currently administered. That is my understanding.

VICE CHAIRMAN MALMUD: May I suggest that in the absence of the two radiation oncologists that we not pursue this element of discussion but somehow communicate with them and get back to the Committee at the next meeting? Is that acceptable?

MEMBER WILLIAMSON: It will have to be. It will be useful to get the staff's perspective on the issue at this time so that we are prepared to do this by e-mail in a timely fashion.

VICE CHAIRMAN MALMUD: We have a full agenda for e-mail among us, you and I in particular. But in the absence of the radiation oncologists, I don't think we can really discuss it on their behalf. Do you?

MEMBER WILLIAMSON: I think we could find some useful information out from the staff that would

be material to the discussions.

VICE CHAIRMAN MALMUD: Do we want to ask a question of the NRC staff?

MEMBER WILLIAMSON: Yes, I do.

VICE CHAIRMAN MALMUD: May we limit that inquiry to no more than five minutes since we are now ten minutes beyond our agenda?

MEMBER WILLIAMSON: All right. Let me find the appropriate section. 35.390 currently reads that "An authorized user is certified by a medical specialty board whose certification process has been" blah blah blah blah. "To be recognized a specialty board shall require all candidates for certification to successfully complete the minimum of three years' residency training in irradiation therapy or a nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph B.1."

That is what the words say. They could be read as saying that if you have a residency under your belt in either nuclear medicine or in radiation oncology, that you need not satisfy to the letter all of the requirements in paragraph B.1.

I will mention the information to the Committee that paragraph B.1 includes the 700 hours of

training and experience and lists many varied and technical duties that you have to have experience with, including 12 cases of experience.

So my question is, is it the intent of the staff that the radiation oncology residency to be recognized by the Commission not be held to all of these detailed requirements in paragraph B.1?

VICE CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: I have to admit I had several conversations going in each ear at the same time. So I may not be able to answer exactly.

I think if we took a strict interpretation, we would say that the residency had to include 700 hours of training and experience in basic radionuclide-handling techniques applicable to unsealed byproduct material, which may not be in the residency program.

Now, the alternative -- and I am not as familiar with what the board certification criteria are going to be for 390. In the past, the board certification criteria for 930 I believe also included certifications that the radiation oncologists had. Therefore, they met the 300 criteria by the board certification route.

But the way the new board certification

criteria are written, I don't know if those same boards would meet the criteria that are going to be exclusively put into 390.

MEMBER WILLIAMSON: Well, I think this is a really important issue because it is not every radiation oncologist who practices radiopharmaceutical therapy, but certainly a significant minority has, I think. Unfortunately, my colleagues aren't here to represent the issue, but I think this is a messy and difficult problem.

DR. HOWE: And what happened under the old rule was that the requirements to meet training and experience requirements for 300 were 80 hours. We applied the I-131 model to other isotopes because 300 said 80 hours of radiopharmaceutical therapy and they had 3 cases of I-131 in either hypothyroidism and 3 cases in thyroid cancer.

We used the same model for going into strontium and zevlin or other isotopes. So there was an 80-hour criteria, where now 390 is a 700-hour.

So unless we had an equivalent to 392 or 394 for other isotopes, I believe you are right.

MEMBER WILLIAMSON: There is the problem. I do not think this can be resolved by e-mail. I think it is a sufficiently important issue that I

believe we may have to have within the time frame during which comments would be useful a teleconference that includes the radiation oncologists where we can attempt to come to a resolution and vote a motion on this issue because I think it is a key one that I think would dramatically change the practice of radiation oncology and basically close, make it much more difficult for radiation oncologists who are not grandfathered to be able to combine radiopharmaceutical therapy with the other therapies that they use.

VICE CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: From a 390 practitioner's point of view, I think whatever the reasonable requirement is for training and experience to handle 390 should be applied uniformly to anyone who wants to practice under the 390 rule. I don't think that a practitioner who practices in the 400 or 600 series should have a different requirement for handling 390 materials than anyone else who practices 390.

So what needs to be, there need to be appropriate training requirements. And then everybody needs to jump over that particular bar because the fact that you can do brachytherapy or external beam therapy doesn't mean that you have the experience to

do unsealed source therapy.

I think there should be one set of criteria for everybody. Whatever the right criteria are, they should apply across the board to all practitioners.

VICE CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: I am not sure this is going to add very much except to raise the level of discussion a bit. The proposed rule, which, of course, the comment period on which has now expired, reflected the recommendations that staff received from the Advisory Committee. They are almost identical to the recommendations that were received from the Advisory Committee with respect to what the qualifications should be for a particular board to become recognized.

So I ask the question of Dr. Williamson, is this now second thought as to what the previous recommendations were or am I misunderstanding something?

MEMBER WILLIAMSON: I think there was a mistake in the way the recommendations were communicated to you because the initial result of the subcommittee's deliberation was to have a sort of a much more general description and less prescriptive description of the technical training

requirements/content requirements in the 700 hours and put the 12 cases of experience as a requirement that would be imposed upon all 35.300 practitioners, regardless of whether they came through the board certification pathway or the alternate pathway. Somehow that got twisted around and converted back. I think in the staff rewrite of our position, it was not noticed.

So no, I think you will find if you examine the record closely, the last time I believe we even made a motion on this point that you might consider going back to the November meeting and look at the positions that we took, but I think that we had a discussion about that and again recommended that basically the core set of requirements that are not common to radiation oncology training are the 12 cases.

And so it was recommended by the ACMUI subcommittee that those be placed outside of the board certification pathway as common requirements for both alternate and board certification pathways so that at least the radiation oncology certification covered the didactic component.

VICE CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I believe that the 12 cases

is a common component, but I also believe that the safe handling of unsealed sources is an uncommon component and is not included in most therapy residencies.

VICE CHAIRMAN MALMUD: I don't know what the content of therapy residencies is. I can't address the issue. Once again, I believe that we should have this discussion with the two radiation oncologists who are members of this Committee available for their input.

MEMBER WILLIAMSON: I think that would be wise. At least we have found out the staff's perspective that basically if a motion is not made that is more favorable to the radiation oncologist's current status, they are basically going to be left out in the cold on this issue.

And that group of practitioners, which is able to provide the continuum of cancer care, is no longer going to be able to prescribe that modality. That would be a great loss to patients.

VICE CHAIRMAN MALMUD: You were addressing a subcommittee. Who did that subcommittee consist of?

MEMBER WILLIAMSON: The subcommittee was chaired by Dr. Vetter. It included myself, Ruth, Dr. Diamond. Were you in it, Ralph? I can't recall.

MEMBER LIETO: No.

VICE CHAIRMAN MALMUD: And Dr. Nag?

MEMBER WILLIAMSON: I am not sure if Dr. Nag was.

VICE CHAIRMAN MALMUD: So you may wish to --

MEMBER WILLIAMSON: Were you in it, Manny?

CHAIRMAN CERQUEIRA: No.

VICE CHAIRMAN MALMUD: You may wish to have just a telephone conversation with that subcommittee and get the consensus of that committee transmitted to the ACMUI Committee. All right?

MEMBER WILLIAMSON: Will do.

VICE CHAIRMAN MALMUD: Thank you for bringing it to the attention of the ACMUI, the entire Committee.

I will turn the microphone back to Dr. Cerqueira and to Angela Williamson.

CHAIRMAN CERQUEIRA: Actually, is Donna-Beth Howe going to be doing proposed changes to 10 CFR Part 35? I guess we still have that up.

MR. ESSIG: May I offer while Donna-Beth is setting up, if there are any matters of business that the Committee wishes to pursue in the near term, such as the one that involves the views of our two

radiation oncologists, we want to pursue it as a Committee, we have a 15-day lead time for noticing in the Federal Register, 15 calendar days.

So that if we wanted to schedule something now, we should be looking at a conference call about three weeks hence to give us time to notice it internally. That means go through the Office of the Secretary, get it over to the Office of the Federal Register, and allow for the 15-day time frame to be met. So what is one thing that you may wish to think about before we adjourn today? If we want to agree on a date for a conference call, it is about three weeks out.

CHAIRMAN CERQUEIRA: Now, Jeff, do you know if Dr. Nag or Dr. Diamond were aware of this?

MEMBER WILLIAMSON: I think they were aware. Yes, they definitely were aware.

CHAIRMAN CERQUEIRA: And the ACR is obviously aware.

MEMBER WILLIAMSON: And the ACR is aware, despite the fact they have said nothing.

MS. FAIROBENT: Dr. Cerqueira, there were discussions throughout ASTRO with the oncologists. Dr. Diamond and Dr. Nag are both aware of the issue. This was also reflected in our comment letter that was

signed by ACR, ASTRO, and others that was submitted to NRC on the proposed rule.

CHAIRMAN CERQUEIRA: So I think the appropriate course of action would be, Jeff, I think if you could speak to the other two radiation oncologists. And if they feel that it is a sufficiently important issue, then we should try to schedule a conference call.

MEMBER WILLIAMSON: I think one reason it hasn't come up maybe as much as it should have is if you read the current rule text, literally it looks like it would allow radiation oncologists to continue practicing just basically by board certification alone, which was the situation, is the situation at the present time and has been for many years now.

And there was a debate within the community about how much this needed to be commented on. I always felt it was a very high-risk situation to let it hang on the interpretation of grammar and a comma.

CHAIRMAN CERQUEIRA: I think Dr. Eggli's point is that basically dealing with unsealed sources is a unique experience which is not available to all radiation oncologists. And the addition of the cases would certainly strengthen up those requirements.

Your subcommittee had that in some form.

MEMBER WILLIAMSON: We had that. And that was recommended. And the rewrite, I believe, got lost. Unfortunately, our subcommittee didn't review the final draft closely enough.

CHAIRMAN CERQUEIRA: I think it will be important to find it. And then certainly the conference call after the input from the two radiation oncologists and the minutes would be --

MEMBER WILLIAMSON: I believe if the record is examined closely, the staff will find this has been brought up at least at the last two or three meetings by both Dr. Diamond and myself that we were concerned that the subcommittee recommendations were misrepresented.

CHAIRMAN CERQUEIRA: So, Tom, maybe if somebody from staff could try to dig up that information from the subcommittee, that would help speed up the process.

Last comment?

MEMBER EGGLI: I think, as a very minimum, it should be clear that current practitioners are not excluded.

CHAIRMAN CERQUEIRA: Right.

MEMBER EGGLI: So that if there has to be

a mechanism of accounting for people who are in practice, they currently have the appropriate experience at a very minimum.

CHAIRMAN CERQUEIRA: Good. I think that is a good point.

Dr. Howe?

DR. HOWE: Yes. If you will remember back to November's meeting, I brought ten issues that our working group had identified as we were working on the implementation of part 35 that I believe needed rulemaking.

Since that time, we have identified some additional issues. Some of them are relatively minor changes to the rules. Others may be more involved.

The first part of the rule that I am going to be addressing is 32.74, which is the part of the rule that authorizes distribution of sealed sources and devices by specific licensees to manufacture and distribute these items to persons licensed pursuant to part 35.

If you look at 32.74(a), you will find that this is limited to use as a calibration or reference source. That is going to be one issue. And if you look after the ore, you will see it is for medical uses listed under 400, 500, 600.

The effect of this in mentioning calibration or reference sources is that it specifically excludes our transmission sources that are now included in part 35, in 35.67 I believe. And so we are recommending that the rule be changed in 32.74 to be for use as calibration, transmission, or reference sources so that it parallels those sources in 35.67.

MR. ESSIG: Dr. Howe, I am going to interrupt just for a second. I am looking around the room and not seeing --

DR. HOWE: What you have to --

MR. ESSIG: It was under a different tab.

DR. HOWE: Yes. It was under an earlier tab.

MR. ESSIG: So it is under the seedSelectron?

DR. HOWE: Yes or am I moving out of 1000?

MR. ESSIG: Or maybe out of 1000.

DR. HOWE: Yes.

MR. ESSIG: Yes. We are moving modalities from 1000. It got misplaced.

DR. HOWE: That is where the slides are. Okay? So the first item for this particular change would be to add transmission.

Yes, Ralph?

MEMBER LIETO: If I understand this right, you are tieing it in to the 400, 500, and 600 uses, correct?

DR. HOWE: No. If you read the part that -- I don't have a pointer -- says, "Part 35 of this chapter for use as a calibration or reference source," then there is an "or." The calibration or reference sources are authorized under 35.67. So I am just talking about the 35.67 uses right now.

CHAIRMAN CERQUEIRA: So the suggestion has been made for a change. I mean, Jeff and Ralph, do you see any problems with those changes?

MEMBER LIETO: I would definitely support that.

CHAIRMAN CERQUEIRA: So do you want a vote from the Committee on that? So is that a motion?

MEMBER LIETO: I would move for approval of the change as suggested to section 32.74(a).

CHAIRMAN CERQUEIRA: A second on that?

MEMBER WILLIAMSON: (Raising hand.)

CHAIRMAN CERQUEIRA: Jeff? Okay. Second. Any further discussion?

(No response.)

CHAIRMAN CERQUEIRA: Call the question.

All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: Okay. Excellent. We do have a quorum, by the way. I saw you.

DR. HOWE: You do have a quorum.

MEMBER EGGLI: What about calibration sources that are used in other sections, like PET calibration and transmission sources that really don't fall under 400, 500, or 600?

MEMBER LIETO: That was my question she just answered. If you notice, there is an "or." Where it says, "400, 500, and 600," look at the line above. It is restated to say, "Calibration, reference, or transmission source or for the uses." It would allow for gamma CAMs.

DR. HOWE: And this is specifically for those byproduct material for persons licensed pursuant to part 35. Okay?

CHAIRMAN CERQUEIRA: Good. Next?

DR. HOWE: The next, we are still looking at the same part of the regulation, 32.74(a). Now we are focusing after the "or." we are looking at for the uses listed in 35.400 and 35.500, 35.600. The

point here is the effect is that it specifically excludes sealed sources and devices that are under uses listed, 35.1000. And so we are recommending that 35.1000 be added to those.

This would only include those sealed sources and devices that are under 35.1000. And 35.1000 had a radiopharmaceutical. It would not come under 32.74 because it wouldn't be a sealed source device. It would come under 32.72, which is where we regulate radiopharmaceuticals and biologics and those types of materials.

CHAIRMAN CERQUEIRA: Dr. Williamson?

MEMBER WILLIAMSON: I am a little confused about the intent of this. These are sealed sources actually used for intravascular treatment. They are not calibration or reference sources associated with it.

DR. HOWE: No. These are for the uses listed under 400, 500, 600, or 1000. So these would be your brachytherapy sources, --

MEMBER WILLIAMSON: I see.

DR. HOWE: -- your HDR units, your LDRs, your GliaSites, your --

MEMBER WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: So, Jeff, you support

that?

MEMBER WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: A motion to approve?

MEMBER WILLIAMSON: So moved.

MEMBER LIETO: Seconded.

CHAIRMAN CERQUEIRA: Discussion?

(No response.)

CHAIRMAN CERQUEIRA: Call the question. All in favor?

(Whereupon, there was a chorus of "ayes.")

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: Unanimous. Next item?

DR. HOWE: Now we are going to move into 35. And I have got a number of proposed changes that will address how we regulate and the information we get from licensees under 35.1000.

35.12(d) addresses essentially how we regulate 35.1000. And it was set up before we actually implemented the rule. We believe at this point that it doesn't accurately reflect what we are doing.

First, it appears as if -- well, it is

also 35.12(d)(1) that you have to meet the radiation safety aspects not addressed in subparts A through C. That seems to imply that the radiation safety aspects are all addressed in A through C. I believe that it is isn't clear that subpart M, which is your reporting for medical events and embryo/fetus and nursing infants also applies to 1000. So this is just to clarify that.

We expect the 1000 users to comply with subparts A through C and also the medical event and the other reporting requirements. So it is just a clarification. If you will let me continue, I will show you proposed language afterwards.

There is a second element to 35(d). It appears that, as I stated earlier, only the radiation safety aspects are all found in subparts A through C. What we are finding is that for some of these new technologies, there are certain parts in A through C that don't fit the new technologies.

We are also finding that most of our new technologies fit almost exactly in subparts D, E, F, G, H, which are the imaging localization, written directives required, manual brachytherapy, remote after-loaders, diagnostic devices. A through C are the general categories in the regulation.

MEMBER WILLIAMSON: So let me make sure I understand what the problem is. The problem is that the way one reads the current statement is that all of the measures mentioned in A through C must apply. And now what you want to do is introduce a fix that somehow relieves the licensee of having to comply with those provisions of A through C that don't have any relevance to the 35.1000 modality under consideration? I am sorry to be so dense here.

DR. HOWE: No. It's kind of the opposite. There is an implication that A through C should apply and apply without any changes. We are finding in some of the emerging technologies that there are some parts in A through C that don't apply to the emerging technologies.

MEMBER WILLIAMSON: I thought that is what I said.

DR. HOWE: It needs a revision to it. And there is also in the supplemental information an implication that the only information we need is the things that are listed under (d)(1).

In fact, we are finding that some of the written directive guidance needs to be modified for the emerging technologies. We are also finding that most of our emerging technologies fit almost exactly

in the other categories.

And so what I am proposing is that we add subpart M, in addition to A through C, and that we also recommend --

MEMBER WILLIAMSON: What's subpart M? I'm sorry.

DR. HOWE: Subpart M is the reporting for medical events. Just to make it clear, that also applies. The second part is that we revise 12(d) to specifically include appropriate radiation safety requirements in subparts D through H for a particular 1000 device. In the next slide, I will show you what I think that particular revision would look like.

We would say in D, "In addition to the requirements of paragraphs B and C, which is you must submit an application and provide a description of the facility and training experience, I believe, an applicant for a license to amend the medical use of 1000 must include information regarding any radiation safety aspects of the medical use of material that is not addressed in subparts A through C and M of this part. Commitments to follow radiation safety program requirements in subpart D through H that are appropriate to specific 35.1000 medical use." then we would continue exactly the same wording as currently

in the rule.

MEMBER WILLIAMSON: I think the original way it is stated is so broad any radiation safety aspects of the medical use of the material that is not addressed is sort of --

DR. HOWE: It's too broad?

MEMBER WILLIAMSON: Even those that haven't been imagined or mentioned anywhere in the regulations I find this statement has always bothered me.

DR. HOWE: Well, that was not the intent. The intent was that if we have a specific element in A through C and this one doesn't quite fit into how that is described, there could be a modification to somehow fit.

MEMBER WILLIAMSON: Somehow.

DR. HOLAHAN: I would like to add that if you agree in concept, the wording will be --

DR. HOWE: It will be totally different.

DR. HOLAHAN: It may be because we will come back to with the proposed rule at the time early on in the process. And it may change.

DR. HOWE: And as you deliberate, you may come to the conclusion later on that you don't believe there is a change needed.

CHAIRMAN CERQUEIRA: Ralph, you had a comment?

MEMBER LIETO: Yes. I am a little unsure as to what exactly is the intent to take something that is currently listed in 1000 and state that it has to meet all of the requirements of, say, subpart C plus these things or is it to take it out of 1000 and put it in subpart C with additional requirements?

DR. HOWE: Right now the basic radiation safety program things, you need a radiation safety officer, you need a written directive, you need a program to ensure you are administering therapeutic. All of that is in A through C, very general.

Those are general concepts. We aren't going to go beyond what is there. But it may be that this particular device doesn't fit the wording in this particular part.

MEMBER SULEIMAN: I hear what you are saying. And I read what you are intending. I agree because it says, "any radiation safety aspects." It is not saying, "other aspects." How can you anticipate what may be unique about some new medical device that maybe hasn't been addressed?

So I read this as sort of a catch-all to some new emerging technology which has got some very

unique characteristic that hasn't been addressed specifically.

CHAIRMAN CERQUEIRA: Good.

MEMBER WILLIAMSON: Well, I agree some fix is needed. Okay? The problems are there are aspects, safety aspects, of the device which certainly aren't captured in A through C and D through H and M that need to be specifically mentioned, which you have done in your guidance space. Okay. That is true.

There are also parts of these regulations that may or may not apply in all of the sections A through C, A through H, and M, though maybe the general concepts are applicable.

I think, as I read it, though, it is very confusing. And I think since you are planning to fix it, if you could think of some way in more ordinary language to express the intent so it is clear to practitioners, for example, you may want to just explicitly mention something to the effect that radiation safety aspects, as mentioned by NRC in their guidance for the appropriate device that aren't mentioned in blah blah blah parts must be addressed in the license application, somehow try to create phraseology that connects more with what we perceive to be the practical process for processing license

amendments.

I think this is a very legalistically written section that allows you the latitude to change all of these things that perhaps according to the Office of General Counsel, it is adequate. But as I read it as an ordinary working individual, it seems very obtuse what the intent is.

CHAIRMAN CERQUEIRA: So you have some problems with the language, but you have no problems with the addition of D through H and M as additional requirements. Is that correct?

MEMBER WILLIAMSON: I just wish the whole section were written in a more clear and concise form.

CHAIRMAN CERQUEIRA: Right. But I just think given the lateness, I am just not certain it is in our best interest.

MEMBER WILLIAMSON: No. I am making the recommendation that the whole section be rewritten, this whole paragraph be rewritten from top to bottom to make the intention clearer.

DR. HOWE: But potentially we look at 35.12(d) and we make revisions, maybe not these particular revisions, but we make revisions to more accurately reflect --

MEMBER WILLIAMSON: You know, you are

giving yourself the authority to exempt individuals from specific 35 rule requirements, which aren't applicable or meaningful for the new emerging technology. Plus, you are leaving yourself the authority to impose new ones via the licensing process.

I agree. That is good to state, and it is good to capture these other sections in here. I just think if you could find a clearer way of describing this --

CHAIRMAN CERQUEIRA: So are you making a motion to approve the addition of D through H and M to the new language that she is going to construct?

MEMBER WILLIAMSON: Subject to making the intent of the paragraph clearer.

CHAIRMAN CERQUEIRA: Okay. Ralph, more discussion?

DR. MILLER: Dr. Cerqueira, with regard to motions, I just want to throw this out just to let you know where are. Donna-Beth's presentation today I think throws out some concepts to get a temperature from the Committee. Okay? Anything we put out, what she is trying to do is to articulate that by taking a shot at what the language might be in a proposed rulemaking.

Anything that comes out of this I've got to take back and prioritize all of the other rulemakings that we have on the table. So where it would come out priority-wise would be dependent upon safety significance of the changes.

Given the lateness of the hour, I think we need to get some feedback from you with the concepts. Are we on the right track? Should we pursue this? Should she pursue this? Do you agree with pursuing this?

And then we would go to the rulemaking branch and get it prioritized and go from there. How soon that would be done would be dependent upon what the priority would be.

Scott, did I say that right?

MR. MOORE: Yes, sir. Donna-Beth's slides labeled "Potential Rulemaking" are just that. I am throwing these out conceptually. We have what we would call internally to the agency a user need memo from Tom Essig's branch to my branch requesting rulemaking on this. And that initiates the action.

CHAIRMAN CERQUEIRA: I understand. We are just trying to give you feedback.

MR. MOORE: Right.

CHAIRMAN CERQUEIRA: Taking a vote

sometimes I think just does force the Committee to focus. I don't think there were any objections to adding D through H and N. There were some concerns about the specific language.

MR. MOORE: On this, what would help us is a sense of where you are conceptually on the ideas. And then with respect to the specific language on these, we can certainly work it.

It is nowhere near proposed rule stage. And priority-wise, it will probably rank out somewhere in the medium to lower priority as a rule, probably behind some of our security-related rulemakings.

CHAIRMAN CERQUEIRA: So have you got enough feedback on this issue that you don't want us to vote on it? I think everybody was in agreement.

MR. MOORE: I think that is up to you all, but it sounds to me like conceptually you support the idea. It sounds like you would like us to work on the exact wording, especially any radiation safety aspects, yes.

CHAIRMAN CERQUEIRA: Okay. That's good. So, then, do you want to go to 35.41?

DR. HOWE: Yes. 35.41 is the requirement for programs to assure that things that require a written directive are administered in accordance with

the written directive.

If you look at B, this says, "As a minimum, you will have procedures required in A for the following things." When you get down to 4, it says that "You will have a procedure verifying that any computer-generated dose calculations are correctly transferred into the consoles for therapeutic medical units authorized in 35.600."

I believe at this time that it should be 35.600 or 35.1000 so that if you have a therapeutic medical unit and you have data being transferred into the console, that you do need this, regardless of where it is coming in the regulation.

CHAIRMAN CERQUEIRA: Jeff, do you have any problems?

MEMBER WILLIAMSON: No.

CHAIRMAN CERQUEIRA: Any other comments?

(No response.)

CHAIRMAN CERQUEIRA: I mean, we are just basically adding the 1000. And I think that is certainly appropriate, emerging technologies. Okay. 35.610(d).

DR. HOWE: Do you want to go back, Ralph?

MEMBER LIETO: Well, I am trying to think of where we might run into a problem. Are we

concerned about 35.1000 applications involving therapeutic treatments?

DR. HOWE: It only involves transferring. You have got computer-generated dose calculations and having them directly transferred into consoles of therapeutic medical units.

So it is not all of 1000. It is just those therapeutic ones with the computer-generated --

MEMBER LIETO: My concern was if, say, for example, they were going to get into doing treatment planning calculations for radiopharmaceuticals. And you would have to do the same thing. I am just going to be worrying about something that is really not an issue right now, but this is potential.

CHAIRMAN CERQUEIRA: All right. Next?

DR. HOWE: So is everybody agreed on that one?

CHAIRMAN CERQUEIRA: Yes.

DR. HOWE: The next issue is 35.610(d). That is where a licensee is required to provide instruction initially and at least annually. And then it goes on to describe who it has to be given to and people that use therapy units.

This is specifically for remote after-loader units, gamma knife, and teletherapy

units. We find that it is confusing to certain people about the initial training. We think that there are several different meanings to initial training. There can be initial training when you get a brand new device into a facility in which the initial training should be provided by the vendor.

And then there is initial training when you have an established program and you are bringing a new person in. That initial training could be done by the licensee. So what we are recommending is that we add a new section to address vendor training and distinguish it from the training a licensee provides, initial training, and make that difference based upon the licensee's experience with the unit; i.e., new units or units with significant manufacturer upgrading.

And so this would be an example of recommended rule language, where we say "Vendor training would be provided for all operators of a new therapy unit or therapy unit" -- yes, Jim?

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: Yes. I am trying to think. In the 35.600, it doesn't specify what training the vendor has to provide versus what the licensee can provide without the vendor's support. Is

that correct?

DR. HOWE: It doesn't address vendor at all.

MEMBER WILLIAMSON: So my question is right now it is left at the discretion and responsibility of the licensee. So is that you consider the current regulation inadequate now that it is sort of left to the licensee based on their judgment if an upgrade, for example, is significant enough or they buy a new system, that they will get the vendor training or not or make some other arrangements that are suitable to themselves?

Right now it is a very nice, not very prescriptive rule that allows the users a fair amount of flexibility in determining what source they access for the training. Do you really feel it is such a problem that a more prescriptive rule identifying exactly when the vendor has to be involved is necessary?

DR. HOWE: We do believe for therapy devices that are new, new technology, new therapy devices, that vendor training is essential because the vendor is really the only one that has the experience with the unit at this particular time.

On certain new significant modifications

to therapy devices, again, the vendor is the one with the experience on what it is doing. We have actually had a misadministration where the vendor was going to provide training but didn't provide training before first patient use and they didn't understand exactly the new changes in the device from the preceding one.

MEMBER WILLIAMSON: Well, I guess I am wondering. You now have a performance-based rule. If you want to put more detail and complexity into it to specify exactly when the vendor has to be involved, why not leave it as a performance-based rule?

Okay. So there is one anecdotal experience of where a licensee could perhaps have benefitted from this, but in general, my perception would be licensees are making good decisions when to involve the vendors and when to make the changes themselves. In the training and experience criteria, there is now a role for the vendor in providing experience for the authorized personages, the physicist and the authorized user for 35.600.

I guess I am questioning the necessity of this.

CHAIRMAN CERQUEIRA: Have there been problems or are you just anticipating?

DR. HOWE: Yes, there have been problems

and not only that, but one of the major differences in new technologies and some of the older technologies is that we do require vendor training in the guidance because those are the people who have the experience.

CHAIRMAN CERQUEIRA: Right.

DR. HOWE: Moving it into the regulation may make some of the new technologies less foreign to the regulations. And we would already have vendor training for the new devices.

CHAIRMAN CERQUEIRA: Yes. Ralph, you had a comment?

MEMBER LIETO: I keep reading this, trying to understand the exact issue that we are trying to address in a long-term basis so that we are not just trying to address this one incident that occurred.

I guess maybe if we change this to maybe "vendor-authorized" because I am not necessarily absolutely positive that you might not have the licensee, an individual with a licensee or another licensee that might come and provide that that is not the vendor but maybe the vendor-authorized individual. That is I think some fine tweaking here.

DR. HOWE: We kind of covered that.

MEMBER LIETO: Look for that. So that was pretty much my --

MEMBER WILLIAMSON: I think it is very difficult.

CHAIRMAN CERQUEIRA: We have another comment.

MEMBER SULEIMAN: I will keep it short, but I think it does happen. I think, no matter how new the technology or how familiar the users think they are with the modified version of the new technology, if you don't require it or mandate it, there will be situations where it may be used before it should be.

And so I think this is just sort of putting it down as a regulatory requirement that thou shalt not start using this unless you have proper instruction.

By taking it out, somebody is going to say, "Well, it wasn't required." I can give you some examples, but it is human nature. They will feel comfortable. They will think they know what to do, and it will be used improperly.

CHAIRMAN CERQUEIRA: Jeff, do you have a last comment?

MEMBER WILLIAMSON: Yes. I guess in the spirit of performance-based regulation, I am opposed to changing it from the relatively broad way it is

written, which leaves a fair amount of discretion and responsibility for the user to appropriately involve the vendor.

I am thinking of situations where it is very difficult to get 12 radiation oncologists or physicists together at one time to have the vendor give the training. I think that perhaps by safety as not being marginalized in any way, for example, the majority of individuals who operate the system get vendor training. And then the physicist or lead authorized user is able to sort of train as new individuals on the new device others who follow. You just create I think somewhat of a burden on everybody for what I am going to speculate is a fairly small number of incidents.

DR. HOWE: Now, we are not addressing the "and others follow" because the "and others follow" is in part 2. In other words, the licensee now has experience with the unit. It is not new. It hasn't had any major revisions. So that is the licensee.

MEMBER WILLIAMSON: But you have in number one, "all operators." So that means if you miss one, if one is sick that day on the one time the vendor can come, you have created an incident now where the whole operation is out of compliance because one operator

was not here.

MEMBER SULEIMAN: I hear you. I think the NRC staff should just make note of that and maybe consider that.

CHAIRMAN CERQUEIRA: Doug and then Leon? Do you have any comments?

DR. HOWE: So it may be more on wording.

MEMBER EGGLI: In support of Jeff's comment, in new technology, train the trainer is a very common vendor approach, where the vendor will come out and train two or three people extensively for a two or three-week period. And then those same two or three people train everybody else in the institution on that new piece of equipment.

It may be appropriate to have initial vendor training of some portion of the staff, but it is virtually impossible to get the vendor to train 100 percent of the staff. I am in support of Jeff' comment.

MEMBER WILLIAMSON: Yes. And if you think about the kind of training that is required for gamma knife, it is very extensive and expensive. And if you think about the sort of one or two-hour sessions the vendor has, they are useful, but it is by no means a replacement for licensee-initiated training and

testing and observation of workers. So it is really missed.

DR. HOWE: And I recognize the limitations on putting all operators in there. We just really would like to have vendor training provided at the licensee's facility.

And then we generally have no problem as a policy for vendor-trained individuals training others. We do have policy problems when we get to the other people who are three or four generations down providing training on something new.

CHAIRMAN CERQUEIRA: I think you have heard some of the concerns. It is difficult to get everybody there. Ralph?

MEMBER LIETO: I don't interpret it that they all have to be there at that time. It is just that it has to be provided to them before they operate the device. So if they are not there that first whatever, then what I am interpreting is the vendor has got to come back and get these others or, as it says there, individuals certified by the device manufacturer. He may train 20 people, and then he certifies one of those people and they train the others.

So, I mean, I guess basically I endorse

it. And I think the wording can be massaged to achieve I think Jeff's concerns.

CHAIRMAN CERQUEIRA: Good. All right. Next?

DR. HOWE: As you know, we added a section to each emerging technology up on the Web site that allowed individuals that had authorization for the 35.1000 use that if the Web site guidance changed, they could change their radiation safety program to be in conformance with the new Web site guidance without coming in for an amendment. They had to have approval for that, essentially, in the tie-down condition of the license.

The next step is to move this into the regulations, make it clear that anybody with a 1000 use can revise their radiation safety program to conform with the guidance as the guidance is being updated without needing an amendment.

So this would involve revising 35.26 to permit changes based on current 1000 guidance. And this would probably look like this. The revision is compliance with the license or is based on current guidance for the 35.1000 medical use posted on the NRC Web site. Once again, the wording is just a straw man on there.

DR. HOLAHAN: And I would like to add we have to look at that seriously because I don't know if it can be done because of guidance being changed. So it is making our guidance into a requirement.

DR. HOWE: But what it does is the first question came up because of intravascular brachytherapy. Intravascular brachytherapy before it moved into 1000, it was done by license condition. At that point, we required the authorized user, the cardiologist and the medical physicist, to be physically present. Those were license conditions. The licensee had to come in for amendments.

Now, under 1000, we no longer require all three people to be physically present. So generally as we relax the guidance, this allows licensees to also relax their program to meet it without having to ask for an amendment.

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: Well, I think is very clearly written and indicates the dynamic role of the Web site and guidance. So if it could be legally done this way to allow some sort of dynamic character to the regulations, I am all for it.

I think this if it, again, passes muster with your Office of General Counsel might indicate a

model you could use to rewrite the earlier section that I objected to, which mentions specifically the role of the guidance Web site in indicating which sections or provisions of A through H are to be abrogated or to be enhanced in light of the specific features of the new modality.

So I think if it is possible, this is good. It is very clear. It relates in an obvious way to the process. And everybody can understand it.

CHAIRMAN CERQUEIRA: Any other comments? Usually if Jeff likes it, then --

(No response.)

CHAIRMAN CERQUEIRA: Okay. The last item, 35.2026?

DR. HOWE: And in 35.26, there was a requirement to keep records of the change. And so this is a conforming change to 35.2026, where originally it asks that you keep a copy of the old and new procedures in the effective date of the change.

And we would recommend that you would also keep a copy of the appropriate 35.1000 medical use Web site guidance that you were making your change based on.

CHAIRMAN CERQUEIRA: It sounds straightforward.

DR. HOWE: And I think that is the end, isn't it? Yes.

MEMBER SULEIMAN: Why five years?

DR. HOWE: Five years is the current I think inspection frequency for most medical use licensees. And that is in the current regulations.

Thank you very much.

VICE CHAIRMAN MALMUD: Thank you, Dr. Howe.

NEXT MEETING DATE, AGENDA TOPICS, MEETING SUMMARY

VICE CHAIRMAN MALMUD: Can we schedule our next meeting now?

MR. ESSIG: The piece of paper that you were handed has ACRS and ACNW meetings on it. The purpose in handing this out -- and we didn't have time to explain it at the time -- this just shows you when the room that we prefer to meet in, T2B3, is occupied; that is, it is spoken for by either the ACRS or the ACNW. And so, as you can see, September 8 through 11, October 7 through 9, November 3rd through 6.

So if we meet in the latter half of October I would think would be a good time because the room would not appear to be spoken for in that time. The ACNW is meeting in October, but they are meeting in Las Vegas. So I would say any time after, say, mid

October.

VICE CHAIRMAN MALMUD: Mid October?

MR. ESSIG: Yes.

VICE CHAIRMAN MALMUD: Which days of the week?

MR. ESSIG: Probably Tuesday, Wednesday seems to --

VICE CHAIRMAN MALMUD: Monday, October 11th is Columbus Day.

MEMBER WILLIAMSON: When is ASTRO? It is always in October.

VICE CHAIRMAN MALMUD: I don't know.

MEMBER WILLIAMSON: I don't know either.

VICE CHAIRMAN MALMUD: October 12th and 13th good?

MEMBER WILLIAMSON: I don't know.

VICE CHAIRMAN MALMUD: Shall we not set the date today?

CHAIRMAN CERQUEIRA: Is the 11th a holiday? People tried not to travel.

MR. ESSIG: Yes. It is Columbus Day.

VICE CHAIRMAN MALMUD: The 11th is Columbus Day.

MS. WILLIAMSON: If at all possible, let's schedule it now because we don't know what is going to

come up in the future. And we might just have to wind up taking what we can get later.

VICE CHAIRMAN MALMUD: Then why don't we try for the 12th and 13th of October, Tuesday-Wednesday?

MR. ESSIG: Or maybe Wednesday-Thursday.

VICE CHAIRMAN MALMUD: Oh, I see. Wednesday-Thursday, 13-14. Is that all right?

DR. HOLAHAN: And can you find out the dates of the ASTRO meeting and get back to Angela or Jeff?

MEMBER WILLIAMSON: Yes.

VICE CHAIRMAN MALMUD: So make it Wednesday and Thursday, October 13th and 14th?

MR. ESSIG: And do we also want to pick a date for, call it, a mid-cycle conference call?

VICE CHAIRMAN MALMUD: Yes.

MR. ESSIG: And that would be halfway between now and October, so say about three months out, four months out?

VICE CHAIRMAN MALMUD: Well, summer is a problem.

CHAIRMAN CERQUEIRA: Towards the end of May.

VICE CHAIRMAN MALMUD: End of May? All

right.

CHAIRMAN CERQUEIRA: Or June.

VICE CHAIRMAN MALMUD: What about June? Early June?

CHAIRMAN CERQUEIRA: It's just a conference call. It's a conference call. It's not a meeting.

MR. ESSIG: Yes, just an hour or two conference call.

VICE CHAIRMAN MALMUD: What about Wednesday, June 16th?

MEMBER EGGLI: That is the last day of SNM. If you could make it Thursday?

VICE CHAIRMAN MALMUD: Thursday, June 17th?

MEMBER EGGLI: That would be after SNM.

VICE CHAIRMAN MALMUD: Okay. Yes. A conference call. And that would be --

MR. ESSIG: You should probably schedule it for the afternoon to --

VICE CHAIRMAN MALMUD: Afternoon.

MR. ESSIG: -- accommodate those that are in the Pacific time zone.

VICE CHAIRMAN MALMUD: Great.

CHAIRMAN CERQUEIRA: What day are we

considering?

VICE CHAIRMAN MALMUD: Thursday, June 17 at 1:00 Daylight Saving Time in the East.

DR. HOLAHAN: Excuse me? Dr. Malmud?

VICE CHAIRMAN MALMUD: Yes?

DR. HOLAHAN: May would work better if you want to talk about the final rule going out because it is planning on coming out approximately the end of April. So that would give you time, a couple of weeks, to look at it. So I would look at meeting sometime in mid to late May.

MEMBER WILLIAMSON: That is a reasonable situation under the circumstances, mid to late May.

MR. MOORE: I commented that the next opportunity for comment on the draft final rule would be when we issued to you in the agreement states in draft final form for 30-day comment. We are projecting that that will happen on April 26 approximately.

VICE CHAIRMAN MALMUD: So this should be after that?

MR. MOORE: In between April 26 and approximately May 26.

VICE CHAIRMAN MALMUD: How about Thursday, May 20th in the p.m.? Thursday, May 20th? Thursday,

May 20th, any objection?

CHAIRMAN CERQUEIRA: Staff should probably send out notices on this so people can check their calendars, talk to their spouses, too.

MEMBER WILLIAMSON: How about the 13th of May, then?

VICE CHAIRMAN MALMUD: The 13th of May? Is that better for everyone? Thursday, the 13th of May, 1:00 p.m.?

DR. MILLER: Would that give you sufficient time if you get the packages around the beginning of May to be able to digest them?

MEMBER LIETO: Or you could use one as a primary and the other as an alternate.

VICE CHAIRMAN MALMUD: May 13th is the date. The 20th is the alternate.

MEMBER WILLIAMSON: So 1:00 p.m. Eastern?

VICE CHAIRMAN MALMUD: 1:00 p.m. Eastern Daylight Time, which will allow us to bring in our brethren in from the West Coast. Thank you.

MR. MOORE: Thank you.

MR. ESSIG: And is there a need to have a notice to conference call within the next three weeks?

MEMBER WILLIAMSON: I think it is possible.

MR. ESSIG: Because we can go ahead and schedule it and then cancel it if need be. If you want to meet within the next three weeks, we should take the action now, start the action tomorrow.

VICE CHAIRMAN MALMUD: That would be --

MR. ESSIG: If you want to do it on a Thursday, that would be Thursday the what, 18th?

VICE CHAIRMAN MALMUD: Thursday.

MR. ESSIG: No. That is two weeks out. Better make it whatever the Thursday is after. Thursday, the 25th?

VICE CHAIRMAN MALMUD: I will be away. March.

MEMBER EGGLI: I will also be away that week.

MEMBER WILLIAMSON: March 25th I will be away, too.

MR. ESSIG: You'll be away, too? Okay. Well, that is not a good week, then.

VICE CHAIRMAN MALMUD: What about Tuesday?

MEMBER WILLIAMSON: Monday-Tuesday I will be here.

VICE CHAIRMAN MALMUD: Tuesday afternoon, the 23rd of March?

MEMBER WILLIAMSON: Yes. I think that

could work.

MEMBER EGGLI: Is that the last week of March?

VICE CHAIRMAN MALMUD: No. That is a conference call Tuesday, the 23rd of March at 1:00 p.m.

MEMBER WILLIAMSON: I am leaving at 3:00 p.m. on a flight. I could do it earlier in the day, but I can't do it at 1:00 o'clock.

MR. ESSIG: Is Monday okay?

MEMBER WILLIAMSON: Monday is okay.

VICE CHAIRMAN MALMUD: Monday afternoon?

MEMBER WILLIAMSON: Monday is okay.

VICE CHAIRMAN MALMUD: Monday afternoon, March 22nd at 1:00 p.m.

MR. ESSIG: Okay. And what would we like to have on the agenda so that we can put something in the Federal Register?

MEMBER WILLIAMSON: I guess training and experience for 35.300.

DR. HOLAHAN: And do you need to make sure that the radiation oncologists are available?

MEMBER WILLIAMSON: Yes, yes. Good point

VICE CHAIRMAN MALMUD: And what about, will we have any follow-up, then, on the issue at the

hospital in Michigan?

DR. MILLER: Yes. You're going to need to have a conference call to formulate the Committee's view based on the subcommittee report in dose reconstruction.

VICE CHAIRMAN MALMUD: Right, right. Is that okay for you, Jeff, since you will have the dose reconstruction task?

MEMBER WILLIAMSON: Is what all right with me?

VICE CHAIRMAN MALMUD: That date, Monday, the 22nd, to discuss it.

MEMBER WILLIAMSON: Oh, in addition to this other item?

VICE CHAIRMAN MALMUD: Yes.

MEMBER WILLIAMSON: Yes, I guess. That depends what information we have, I guess.

MEMBER LIETO: Give a status report?

MEMBER WILLIAMSON: We could certainly give a status report at the very least.

MR. ESSIG: Jeff, the only other information that I am aware of currently that you haven't been already given would be results from any insights from any interviews with the daughter. That is all there is available.

MEMBER WILLIAMSON: I think that is correct. Also, if we would hear the factual testimony of Ralph as well, I think, would be useful, what he may be able to tell us.

VICE CHAIRMAN MALMUD: Do you have the data that you need to evaluate, Jeff?

MR. ESSIG: Yes. I can get the data.

VICE CHAIRMAN MALMUD: Do you have the data that you need to evaluate the dosimetry calculations and the letter from Dr. Marcus and Dr. Siegel?

MEMBER WILLIAMSON: Do I have the data that I need? I mean, there is no data now. There is an inspection report with the result. And there are some arithmetic calculations and assumptions. And there is the report by Marcus, et al., which raises some general criticisms but is not much more information. Right now there is no basis.

CHAIRMAN CERQUEIRA: I guess the only other issue related to that is I think Dr. Malmud mentioned that Ralph may be included on that subcommittee, which is fine, but I think his involvement by being employed at the hospital needs to be sort of kept in mind and considered.

What is the feeling of the Committee and

staff? Should he be on it? Should he not be on it?

MR. ESSIG: I believe my recommendation would be that you not have him officially on the Committee but that you could use him as a source of factual information. He cannot participate in any decision-making or any recommendations.

MEMBER WILLIAMSON: That was my request, that we just be allowed to interview him and find out what he knows.

MR. ESSIG: Certainly there is no problem with that.

MEMBER LIETO: I could work on that task, too, some part of it, with Dr. Malmud in terms of the future recommendations.

MR. ESSIG: Sure, sure, no problem with that.

CHAIRMAN CERQUEIRA: Thank you. The meeting is now adjourned. Thank you.

(Whereupon, at 5:08 p.m., the foregoing matter was adjourned.)