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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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MONDAY,

JULY 8, 2002

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ROCKVILLE, MARYLAND

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The ACMUI met at the Nuclear Regulatory Commission, Two White Flint North, Auditorium, 11545 Rockville Pike, at 1:00 p.m., Manuel Cerqueira, M.D., Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL CERQUEIRA, M.D., Chairman

JEFFREY A. BRINKER, M.D., Member

DAVID A. DIAMOND, M.D., Member

DOUGLAS F. EGGLI, M.D., Member

NEKITA HOBSON, Member

RALPH P. LIETO, Member

LEON S. MALMUD, M.D., Member

RUTH McBURNEY, Member

SUBIR NAG, M.D., Member

COMMITTEE MEMBERS: (cont.)

SALLY WAGNER SCHWARTZ, Member

RICHARD J. VETTER, Ph.D., Member

JEFFREY F. WILLIAMSON, Ph.D., Member

ACMUI STAFF PRESENT:

ANGELA WILLIAMSON

LLOYD BOLLING

JOHN HICKEY, Designated Federal Official

ALSO PRESENT:

WILLIAM R. UFFELMAN, ESQUIRE

LYNNE A. FAIROBENT

C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S

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

1:04 p.m.

CHAIRMAN CERQUEIRA: On behalf of the ACMUI Committee, I would like to bring this telephone conference to order.

The main purpose of today's meeting is to go over the recommendations of the NRC ACMUI Subcommittee on Training and Experience Requirements that were submitted to the main Committee and to the NRC, and are now going to be discussed by the main Committee, and, hopefully, we will be able to reach some conclusions on these revised training and experience requirements, so we will fix some of the problems with the Part 35 revision.

Before we get into that, on behalf of the Committee, I would like to thank John Hickey for all the work that he has done with the Committee over the last year and a half, John. He's going to be moving on to other areas within the NRC, and we appreciate all the work that he has put into it. I personally would like to thank him for helping us through this fairly elaborate process. Thank you, John.

MR. HICKEY: Thank you, Dr. Cerqueira.

CHAIRMAN CERQUEIRA: Does everyone here have the version that is dated June 27th, 2002? Now

there's an introduction and a rationale which goes into some of the background material as to why this was necessary. Does anybody have any comments or changes they would like to make to the introduction or the rationale?

MR. HICKEY: Dr. Cerqueira, this is John Hickey. If I could just go over the arrangements with the members?

I believe some more people just came on the bridge. Is Dr. Nag on?

DR. EGGLI: No, this is Dr. Douglas Eggli.

MR. HICKEY: Okay, thank you, Dr. Eggli. Is Dr. Nag on? Is Ms. Hobson on?

MS. HOBSON: Yes.

MR. HICKEY: Okay. This is John Hickey from NRC headquarters. We would like to welcome Dr. Eggli, participating in his first meeting. He was recently appointed as a nuclear medicine physician. He's from Pennsylvania State University, Hershey Medical Center.

Also, we will welcome Dr. Brinker, as a new appointee interventional cardiologist. He has participated in previous meetings as a guest, and he has already met the other members of the Committee.

This is an open meeting. There are

members of the public present here in NRC headquarters, and the meeting is being transcribed.

Dr. Cerqueira, I will turn it back to you.

CHAIRMAN CERQUEIRA: Okay, thank you very much, John, for those comments.

We have four hours for this telephone conference. Hopefully, we will be done much sooner than that.

Does the Committee feel comfortable just going through the various sections and giving comments and criticisms? I think that would be the most logical way to approach it.

Again, going back to the Introduction and Rationale, any unhappiness with that or changes that people feel would be appropriate?

(No response.)

Okay, the no comments is an acknowledgment of acceptance of what's been stated.

MR. HICKEY: This is John Hickey. Those on the phone, when you do speak, please identify yourselves for the transcriber.

CHAIRMAN CERQUEIRA: All right, so the next section will be 35.50, Training for Radiation Safety Officer. I think the changes here reflect the Subcommittee meeting that was held in June.

DR. WILLIAMSON: This is Jeff Williamson. May I make a suggestion then?

CHAIRMAN CERQUEIRA: Yes.

DR. WILLIAMSON: I think it might be helpful if the Subcommittee member who is responsible for each section perhaps briefly outlined what the changes were.

CHAIRMAN CERQUEIRA: That would be worthwhile. Who is responsible for the Radiation Safety Officer's section? Was that --

DR. VETTER: Richard Vetter was responsible for that, speaking.

Just to clarify, if I may, Jeff, when you said, "outline the changes," do you mean from the June 21st document?

DR. WILLIAMSON: No, I think that this is a broader group. So I think it would be useful if you just basically went over the new training and experience requirement and highlighted the changes relative to the recently-published Part 35.57.

DR. VETTER: Right, okay. The recently-published 35.50 -- actually, 35.57 is the grandfather clause, but the recently-published 35.50, that is the revised Part 35, did not list boards. The Subcommittee, as we discussed whether or not to list

boards, decided that -- we didn't actually take a vote, but I think the consensus was that we would like to recommend that some boards actually be hard-wired in, if you will, to the regulation. That is, those that meet the specific criteria that are identified be hard-wired in, and that is paragraph (a).

So relative to the issue of radiation safety, there are three boards that meet those requirements, and they are listed here. Those three boards meet the requirements of paragraph (b).

Now the recently-published Part 35, as you recall, required that any board that would be recognized by NRC satisfy the requirements, the very specific training requirements, which are now paragraph (c), and, in addition -- I'm sorry, the boards must require that applicants meet those requirements and also require that the applicant provide a preceptor letter that is signed by someone who testifies, if you will, that the individual is competent.

In the charge to the Committee, we were asked to develop a recommendation where being board-certified would be the default. So this first section is written in that way, that anyone who would fulfill the responsibilities of Radiation Safety Officer must

be certified by one of the listed boards or by another board that meets the requirements of paragraph (b).

That is, in this particular case you hold a degree; you have a certain number of years of experience, and you have a supervising physicist or RSO testify, if you will, that you, in fact, have completed that training requirement. That is, the board would have to have a letter from the supervising physicist or RSO testifying that you have completed, that the RSO has completed -- that the applicant has completed the training.

Then, finally, the Committee felt very strongly that if individuals could pass the examination of a board of peers that tested in the subject area -- and in this case it is primarily radiation safety, but also it is some physics implementation, and so forth -- that that, in fact, demonstrates that the individual has the knowledge to do the job.

So paragraph (b) is actually a list of the criteria that any new board would have to meet in order to be recognized by the NRC, and the three boards listed in paragraph (a) do, indeed, meet those criteria.

Paragraph (c), then, is unchanged. That's

basically the alternate pathway. We did not make any changes in that, with the exception of the very last item in paragraph (c) which has to do with written certification. There again, we removed the -- let's see, was there -- I need clarification. Was there a requirement? Yes, there was, in that paragraph there was a requirement that the preceptor sign that the individual is competent to practicum. So this paragraph (c)(3) does not have that in it.

Then paragraph (d) is the basically unchanged certainly philosophy. That is, anyone who can be approved to be an authorized user, medical physicist, or nuclear pharmacist can also serve as the Radiation Safety Officer.

Then a second charge of the Subcommittee was to decouple the modality-specific training from the board. Paragraph (e) does that. So this is new.

So, in other words, paragraph (e) says, it doesn't matter whether you're board-certified or go through the alternate pathway; you must demonstrate that the licensee must assure that the individual who will serve as Radiation Safety Officer has the training in radiation safety, regulatory issues, emergency procedures, proposed clinical procedures, and so forth, for any modality for which the licensee

is licensed or seeks authorization.

So that, in a sense, decouples it from the board, but the board doesn't have to assure that the individual has the experience in the specific modality, but the licensee must assure that the Radiation Safety Officer has that experience.

MS. HOBSON: I'm not sure there's anything about that on my copy.

MR. HICKEY: Excuse me, Ms. Hobson, could you speak up or try to increase the volume in some way?

MS. HOBSON: Well, I was just saying that my copy as my computer downloaded it does not include the (a), (b), (c), (d), and (e) that Dr. Vetter was referring to. Am I the only one that has that kind of a copy? Is it a peculiarity of my computer?

MS. McBURNEY: Are you on 35.50?

MS. HOBSON: Yes.

MS. McBURNEY: Training for Radiation Safety Officer?

MS. HOBSON: Yes.

MS. McBURNEY: It should have.

MS. HOBSON: No, no.

DR. VETTER: It must be your system. If you have a specific question on a specific paragraph,

just mention that.

MS. HOBSON: Okay, I did have a question about if any additional boards besides the three that are listed here would go through a process of becoming accepted by the NRC before their certification would be accepted?

DR. VETTER: That is our recommendation, yes.

MS. HOBSON: Okay, all right. Thank you.

CHAIRMAN CERQUEIRA: Again, this is Manuel Cerqueira. If people could identify themselves, it will make it easier for the transcriptionist.

I would like to add one point that is the result of a Subcommittee meeting. We had quite a discussion about competence, and everyone agreed that completing the training and experience is what, with the certification from the supervising individual, would be required. This is somewhat different than we had included in the original, but I think, as a result of listening to the boards and as a result of the discussions, most of us felt comfortable with "completed the training and experience," and this would be used throughout the document, not just for the Radiation Safety Officer, but for the other individuals as well.

Okay, any other discussion on the Radiation Safety Officer?

MR. LIETO: Are we opening it up to specific comments? This is Ralph Lieto speaking.

CHAIRMAN CERQUEIRA: Yes.

MR. LIETO: I have a comment, and I am just going to repeat some of the things that I had sent previously to the NRC. This was a comment throughout all the training.

For example, if we go to 35.50, Part (b), No. 3, which says, "to provide a written certification from the supervising physicist or RSO," individuals don't certify, and I think Dick recognized this.

My suggestion was that using the word "attestation," or if there is another term that the NRC would prefer that for now I guess to the preceptor concept, I think we maybe want to change that all the way throughout, because I don't think anybody is going to want to sign a statement that they certify an individual. I don't even know if they can, but that is a comment for this specific part and also throughout the training requirements for the authorized users.

DR. VETTER: Richard Vetter.

I think that is a very good point,

particularly since it falls within the paragraph that is talking about certification boards, using the word "certification" in two different contexts there. So I would support Ralph's suggestion that we change it from "certification" to some other word, "attestation" or "written documentation." I don't know what is the best word, but I do agree with what he said.

MR. LIETO: My next comment has to do with the paragraph above it on No. 2 and maybe also to Dick and to the NRC staff. I guess there is some wording in there that I thought I'm a little confused by, the word "responsible professional experience." I guess I am kind of bothered by that word "responsible" being in there and would maybe recommend that we just delete that word.

DR. VETTER: Where's the word "responsible"?

MR. LIETO: It's No. 2. It would be (b)(2) where it says, "to have five or more years of responsible professional experience." I don't know if that is maybe taking verbatim from some other reference.

DR. VETTER: That is verbatim from one of the boards.

MR. LIETO: Okay.

DR. VETTER: But we don't need to go verbatim from the board. I don't have a problem with deleting that.

MR. LIETO: The other thing was, in that same paragraph, was professional experience versus applied health physics. I should say professional experience in health physics versus applied health physics. Is there some place where that is clarified? I know it is not in here, but, I mean, is there a reference that can be cited where there is that distinguishment between those two terms of radiologies.

DR. VETTER: This is Richard Vetter.

I think the reason the word "applied" is there is so that we assure that the person applying to become certified is not someone who is simply a book-learner; that is, they have never been in an actual operating environment.

We are suggesting that the individual actually has to have worked in the environment. In other words, it would be difficult for a person who went right from graduate school into a faculty position, never actually practiced, to meet this requirement.

Just let me expand on that a little bit

more. It is not that we are trying to exclude anyone.

MR. LIETO: Right.

DR. VETTER: It is just that we felt that it was important that the individual actually has been in an actual environment practicing health physics, taking measurements, doing calculations, doing all those sorts of things, doing surveys, so that they actually have some real experience. That was the purpose of that.

MS. SCHWARTZ: Maybe you could change -- Sally Schwartz -- change the wording to "three years working in health physics"?

DR. VETTER: This is Richard Vetter.

You're also working if you are sitting at a desk doing calculations, and you've never actually took on a survey meter.

CHAIRMAN CERQUEIRA: This is Manuel Cerqueira.

Ralph, I mean you see the intent, what we are trying to get at. Do you agree with requiring some practical applied requirement as opposed to classroom?

MS. McBURNEY: This is Ruth McBurney.

I think that goes also to the start of that No. 2, where you can have graduate training

substituting for two years, but you've got to have at least three of those years in applied health physics. You couldn't just have graduate training or, as Rich mentioned, faculty-type work.

MR. LIETO: But the applied would not, if I am understanding correctly, would not necessarily have to be in a medical or modality-specific environment, is that correct?

DR. VETTER: This is Richard Vetter. That is correct.

MR. LIETO: Okay.

DR. VETTER: Paragraph (e) takes care of that.

MR. LIETO: Okay, right. Okay. All right.

CHAIRMAN CERQUEIRA: So can we keep that as is, Ralph?

MR. LIETO: I'm sorry?

CHAIRMAN CERQUEIRA: We can keep that as through using "applied health physics"?

MR. LIETO: That's fine.

CHAIRMAN CERQUEIRA: We'll take "responsible" out.

Okay, other comments?

MR. LIETO: This is Ralph Lieto again.

On the last paragraph, that Section (e), where it decouples from the board certification, just to be sure that I understand this correctly, because there has been a question brought up. This would allow, then, say, a teletherapy physicist to be an RSO over, say, a nuclear medicine area if they can demonstrate the training that meets the requirements of Section (e)? Is that correct, Dr. Vetter?

DR. VETTER: Yes, that is correct.

MR. LIETO: Okay.

DR. WILLIAMSON: This is Jeff Williamson. I would like to ask Mr. Hickey if he agrees with that interpretation.

MR. HICKEY: This is John Hickey.

The intent was -- I believe this is not the Subcommittee's wording. I think this is from the existing regulation. The intent was if they have experience with similar types of materials. So if you include a paragraph (e) which says they have to have -- this, taken in total, would say that they have to have the right training experience and experience with the radioactive material. So I would agree with Dr. Vetter.

DR. WILLIAMSON: Because why I asked, it says in (d), "has experience with the radiation safety

aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities."

I guess, then, what it also means is, by extension, a nuclear medicine physician could become the RSO of a broad scope licensee?

DR. VETTER: This is Richard Vetter.

The answer, my opinion, the answer to that is yes, if he or she meets the requirements of (d) and (e), or specifically (d).

DR. WILLIAMSON: Yes, you know, it is not clear to me, I guess what I am saying, it is not clear to me that the requirements in (d) are the same as the requirements in (e). I mean, one interpretation of (d) and (e) is that (e) provides for the less stringent training and experience that's modality-specific, and the intent of (d) is kind of to limit the person to be an RSO of an operation that is more or less limited to what the person is already authorized to do as an authorized user or AMP.

DR. VETTER: Yes, I agree with that. This is Richard Vetter. I agree with him.

DR. WILLIAMSON: And, you know, its intention is to serve the small single or small licensees that have maybe one or two modalities

available, such as only nuclear medicine or only teletherapy or only brachytherapy, in which the most qualified person available to do that is probably an authorized user or AMP working with the specific modality.

MS. McBURNEY: This is Ruth McBurney, and it is probably a medical physicist in a therapy that was a trained therapy physicist would probably meet the alternative pathway of (c) by virtue of their education and most of the experience, and if they had just a little extra in nuclear medicine, probably they could be authorized as an RSO for nuclear medicine.

MR. LIETO: This is Ralph Lieto.

The comment that Jeff brought up, that seems to present sort of I guess a danger, for lack of a better word, that would allow someone with minimal qualifications to be RSO over extremely multiple-modality-type licensees. Well, you know, do we want to do anything about that?

DR. WILLIAMSON: It would be some concern, I guess. I can see it cutting both ways, but I want to remind the Committee and Subcommittee of one of the positions that Bill Hindee presented in behalf of the ABR. He basically notes that in Subpart (c), the old requirement, they list in there anybody boarded by the

American Board of Radiology, American Board of Medical Physics and Radiation Oncology, and a bunch of other things. They are listed as members of the -- they can be RSOs.

So on the negative side, it seems to me we are making it more difficult for certified therapy physicists to be RSOs of broad-scope licensees, and maybe in some cases that might be the best and most -- how could I say? -- safety-conscious decision for a given licensee to make, as the alternative being somebody who is not onsite, who's a consultant RSO, and is not there, and so on. That is kind of an awkward dilemma to be put in. So I think it's possible that it cuts on the negative side a bit.

In another direction, it can cut on the negative side by, as you pointed out, Ralph, allowing somebody that really doesn't have the basic education and technical knowledge to absorb all of these modalities and their safety aspects, and doesn't have a global enough knowledge of the regulations, and so on, to be the RSO of a really complex program. That is another concern. So it could also let in some underqualified people, and it might also cut out some mainly well-qualified people.

MR. HICKEY: Could the last speaker

identify himself?

DR. WILLIAMSON: I'm sorry, I couldn't understand what you said.

MR. HICKEY: Could you identify yourself, please? Didn't catch your name.

CHAIRMAN CERQUEIRA: Jeff Williamson.

DR. WILLIAMSON: I'm sorry, Jeff Williamson.

CHAIRMAN CERQUEIRA: This is Manuel Cerqueira.

So how do you want to handle this, Ralph --

MR. LIETO: I guess I have been answered satisfactorily on that. I see this as, I guess, a double-edged sword here, but I guess we don't want to make it overly restrictive in the sense that we do cut out viable candidates for this position.

One thing that I would just want to add to this, as I had in my previous comment, was that it talks about training requirement being satisfied and by training under a supervised individual. I guess I would just like to add that there be some attestation statement, again, about the satisfactory completion of that training under Item (e).

(Pause.)

In other words -- this is Ralph Lieto again -- maybe a statement to the effect that, quote, "supervising medical physicists or Radiation Safety Officer must attest in writing to the satisfactory completion of the training."

DR. VETTER: This is Richard Vetter.

Our intent here was to put the responsibility on the licensee to assure that the Radiation Safety Officer had the training needed. We assume that licensing, if they wanted to pursue it, would ask the licensee to verify that they, in fact, did have the training.

So what training are we talking about? The last sentence, "the training requirement may be satisfied by meeting training supervised by an authorized medical physicist," et cetera, "who is authorized for the modality." So a licensee would then have to be able to demonstrate that that training occurred.

I am not arguing against what you are saying, Ralph. I am just saying that it is our intent here was for the burden to be put on the licensee, and not to prescribe how, in fact, they could demonstrate that the training had occurred.

MR. LIETO: So you're suggesting that --

DR. VETTER: I guess I was just making it a little bit more explicit that there needs to be a documented -- in other words, I could see the licensee could get this from the supervising physicist or RSO, yet it might not be in writing. I guess I was just saying that there needs to be a documentation that the training was completed satisfactorily; that's all.

CHAIRMAN CERQUEIRA: Well, Ralph, this is Manuel Cerqueira.

On (b)(3) you had us take certification out for completed the training and experience, and now here you want to put it back in some way that there is a documented competency or satisfactorily conclusion. Why would it be different in (b)(3) than in --

DR. VETTER: Well, in (3) you're asking for -- it uses the word "certification."

CHAIRMAN CERQUEIRA: Right.

DR. VETTER: I'm just kind of using Webster's definition of attestation and just saying that the licensee needs to have this document that the person has received, completed this training satisfactorily; that's all.

DR. WILLIAMSON: This is Jeff Williamson.

But isn't it the case that, if this is required, there is an understood obligation of the

licensee to be able to provide documentation that this training occurred if an inspector asks for it?

DR. VETTER: Right, but who does it come from? Let's say you hired a person and he says, "Yes, I have it. I'll write you a document that says I have it," as opposed to the person that did the actual supervision of the training. That is what I was saying.

DR. WILLIAMSON: I am just concerned that we are making more complexity and bookkeeping and making it more prescriptive than it needs to be. I mean, there is kind of a not-so-well-established for RSO, but I think there are fairly well-accepted pathways for getting this modality-specific training for authorized users and authorized medical physicists with the different modalities.

I think to put in place another sort of level of formal letters, I just don't see why it is necessary.

MR. LIETO: Well, this is Ralph Lieto again.

I seem to recollect that there was a concern -- I don't know if it was brought up in the Committee meetings or at the hearings or where -- that there was a problem and there were requirements for

these trainings, and so forth, but no one had to necessarily attest to the fact that the person completed it satisfactorily. In other words, they could say, "Yes, this person did the training, but they're really not competent to function independently."

I think that was a concern that was raised several times in the past. My recommendation was simply to address that issue: that if you're going to say that this person is competent to be an RSO, then you should be willing -- and you supervised that training -- then someone should be willing to put their name that they were competent.

DR. WILLIAMSON: This is Jeff Williamson again.

We actually did discuss the general issue a lot. This is far more general than this paragraph (e), because the general position that the Subcommittee took was that the preceptor statement definition as written in the recently-published Part 35 was so strong it required the preceptor to attest to the clinical competence of the applicant and the ability to practice independently; that we felt that there would be a problem because preceptors would be unwilling to sign such vague and unquantifiable

statements, for fear of taking on -- for fear of future liability, if it turned out there were some incident down the line involving the applicant.

So we backed off and wanted to go with nothing more strong than satisfactorily completed the training program, which, you know, is black and white and can be quantified that they did or did not, and leave it at that.

CHAIRMAN CERQUEIRA: This is Manuel Cerqueira.

I would like to hear some other Committee members kind of give us their view on this. Ruth, what do you think would be -- I mean, we had this discussion through multiple years of developing Part 35 revisions and then also during the Subcommittee. I thought that this language had sort of finally captured what we felt was putting enough teeth into it, but not making it so restrictive. Ruth?

MS. McBURNEY: Yes, this is Ruth.

I think that, from a regulatory standpoint, if somebody wants, if an inspector wanted to see that somebody had completed that training, that there might be some sort of document available. But I think we decided not to put it into rule as far as requiring that to be submitted as a licensing, as a

part of the licensing process.

CHAIRMAN CERQUEIRA: Well, I think that was the general --

MS. McBURNEY: For the modality-specific training.

CHAIRMAN CERQUEIRA: Dr. Eggli, this is a whole new issue for you in some ways. Do you have any comments on this particular requirement?

DR. EGGLI: Well, I participated in one of the early Part 35 workshops. The issue is, wherever you set the bar for training and experience, no one should be able to crawl under the bar rather than leap over it. Having no defined documentation pathway leaves the potential for people to crawl under the bar.

CHAIRMAN CERQUEIRA: Okay, although, again, the SNM gave us pretty strong language that none of this should be required. So that runs a little bit against what some of the earlier recommendations have been.

Dr. Malmud, your comments? Dr. Malmud?

DR. MALMUD: Yes, my feeling is that, when we are overly prescriptive, we create new problems that would not otherwise have occurred.

Are you able to hear me?

CHAIRMAN CERQUEIRA: Yes, yes.

DR. MALMUD: My own feeling is that it would be better to certify that the individual had completed a training program. What the individual has done subsequent to the training program is not, in my mind, something that can be attributed to the training program itself, which addresses the issue that was raised about a liability of the person who certifies for the training program being held responsible forever.

I think we are responsible for that which we did while we were in charge of the training program. If the individual loses his capability for one reason or another beyond that, I don't think we can be held responsible for that.

So I would lean toward the less prescriptive, and running the risk, I agree, of someone crawling under the line rather than jumping over it. But I don't know that there is any way in human behavior that we can prevent every possible breach from occurring.

My preference would be to be less prescriptive.

CHAIRMAN CERQUEIRA: Okay, let's have David's comments then. Thank you.

DR. WILLIAMSON: This is Jeff Williamson.

Another point to be made is that this is a new requirement. It is not present in the Subpart (j). It does not seem that there is any evidence that this has caused a crisis in public safety. Like are these whole lines of people crawling under the wire endangering the radiation safety of numerous operations? The existing system works. So why make it more difficult?

DR. MALMUD: Yes, the most significant issue that we had at our institution was with a very well-trained person who, for some reason or another, wasn't behaving well. So I don't know that the issue of being overly prescriptive would not have dealt with that issue, while at the same time I agree we can't leave the door wide open.

So my tendency would be to go with those members of the Committee who prefer being less prescriptive.

CHAIRMAN CERQUEIRA: Okay, David Diamond, do you have any feelings on this issue?

DR. DIAMOND: I actually rather like the language as it is right now. I think that it is not too overly prescriptive. I think it gives enough guidance, and I like the way it is right now.

CHAIRMAN CERQUEIRA: Okay, good. Dr. Nag?

(No response.)

I guess he's not on at this point.

Sally, do you have any comments?

MS. SCHWARTZ: No, I think that as it is written is an acceptable --

CHAIRMAN CERQUEIRA: Okay. So I think we have had a fairly good discussion on this. I think people understand your concerns, but I think the feeling is that, as it is currently written, it would still deal with some of the issues that you have brought up.

DR. MALMUD: And that's my interpretation as well. This is Malmud again.

CHAIRMAN CERQUEIRA: Yes. Okay, well, again, just on behalf of my constituency, the nuclear cardiologists, again, I would love to get a clarification also, but if someone is an authorized user so that a private practice cardiology office, an authorized user under (2)(D) of this section would be able to qualify as a Radiation Safety Officer. That was brought up during the discussion, but I just wanted to make sure that that was agreed upon by everyone.

Okay, well, I think we have had a fairly

good discussion on this. Some of these issues will come up with some of the other ones, and we will probably won't have to go into it in as much detail.

So other than a few changes under (b)(2), taking out "responsible" and then trying to come up with a different word under (b)(3) for certification, I think the feeling is to leave the rest of it as is. Richard, is that your understanding also?

DR. VETTER: Yes, that is my understanding.

CHAIRMAN CERQUEIRA: Okay. John?

MR. HICKEY: Dr. Cerqueira, John Hickey. I just wanted to clarify an important point with Dr. Vetter that will apply to all the sections.

I want to clarify that it is the intent of the Subcommittee that the boards that would be listed would have to be evaluated against paragraph (b) and meet paragraph (b) in order to continue to be listed.

DR. VETTER: This is Richard Vetter.

Yes, that is the intent of the Subcommittee.

MR. HICKEY: Thank you.

DR. MALMUD: This is Malmud.

Going back to (b)(3), might the word "statement" suffice instead of "certification"?

"Provide a written statement from a supervising physicist" --

DR. VETTER: This is Richard Vetter.

I would certainly support the use of that word.

CHAIRMAN CERQUEIRA: I think we will probably have to get some idea from counsel on the appropriateness, but on that I think everyone agrees that maybe "certification" is too strong a word to put in there, but "attestation" or some other appropriate word or "a written statement" would be fine.

Okay, should we go on to 35.51, Training for an Authorized Medical Physicist?

DR. DIAMOND: Excuse me, Dr. Cerqueira. This is Dr. Diamond.

CHAIRMAN CERQUEIRA: Yes.

DR. DIAMOND: I was under the impression we would be able to do the therapy sections first. I have a fairly limited amount of time I can be on a conference call today.

CHAIRMAN CERQUEIRA: You're right, that had been requested. If no one else has any objections, then why don't we do that?

DR. DIAMOND: So let's please direct our attention to 35.390, which is the first section that

I worked on. This is Training for Use of Unsealed Byproduct Material for Which a Written Record is Required. This is about 5-d-iodine, which I will address in a minute. I will give you a second to get to 35.390.

For those of you who aren't familiar, there is a parallel structure to all of these therapy-related sections; simply, small paragraph (a) addresses the board pathway. Small paragraph (b) discusses the alternative pathway, and then small paragraph (c) enumerates the boards that are listed.

So just to highlight the changes, basically, small paragraph (a), this is indicating that there must be successful completion of a residency program, either radiation oncology or nuclear medicine.

Paragraph (b) is essentially exactly the same.

DR. MALMUD: Dr. Diamond?

DR. DIAMOND: Yes?

DR. MALMUD: This is Leon Malmud.

May I ask a question about --

DR. DIAMOND: Yes, sir.

DR. MALMUD: -- that paragraph? It says -- this is Section (a)(1).

DR. DIAMOND: Yes, sir.

DR. MALMUD: "A minimum three-year residency program in nuclear medicine." Now what would happen to a radiologist who is board-certified in radiology and a one- or two-year program in nuclear medicine to augment that and become certified? Would that qualify as a three-year program?

DR. DIAMOND: My understanding, Leon, is that a radiologist who is currently board-certified in practice would be grandfathered from these changes.

DR. MALMUD: Thank you.

DR. DIAMOND: And I'm sorry, small paragraph (c) is just my attempt to enumerate the boards in nuclear medicine or radiation oncology currently recognized by the Commission. As Dr. Hickey just mentioned, in all these sections, of course, the staff would go back and assure that all the paragraph (b) requirements were met by that particular board before they were included in the regulation.

So I would be appreciative to hear the -- oh, by the way, Ralph, I noticed that on the alternative pathway, I used the word "attestation" for you.

MR. LIETO: Right.

DR. DIAMOND: Okay. At least it would be

good to hear any comments from those folks who weren't on this working group or Subcommittee, please.

DR. WILLIAMSON: Jeff Williamson.

The currently-published training and experience requirement lists as a requirement 12 cases of iodine greater and less than 30 millicuries, and I have forgotten what the other two categories are. But you've dropped that out?

DR. DIAMOND: I used what I thought was the currently-recommended language. Jeff is referring to paragraph small (b), capital (G), where there are four subsections of 1, 2, 3, and 4.

DR. WILLIAMSON: Here they are, yes.

DR. DIAMOND: And they are enumerated there for you, Jeff.

DR. WILLIAMSON: Yes, but I guess the question is, do you think that --

DR. DIAMOND: That was supposed to be verbatim from what's --

DR. WILLIAMSON: Yes, I know that there, but my comment is that one could get through, you know, be board-certified in radiation oncology, have come through a program where they didn't even do one radionuclide application, and be an authorized user for this.

I am wondering if it wouldn't be wise to take the paragraph small (b)(1)(G), 1 through 4, and put it as a separate section and say, regardless of which of the three pathways you come from, a listed board, a new board to be vetted in the future, or alternative pathway, you need to do these 12 cases.

DR. DIAMOND: Right, that's one option. The other option is simply to say that any doctor coming on staff to a medical center who wishes to go and have a specific privilege -- let's say you're a radiation oncologist and in your training you've never used radioactive iodine. Well, in that case you would have to go, when you apply for privileges and they will ask you, "Have you done this," and you say, "No," then you will not be granted privileges for that particular submodality. That is the more straightforward way to handle it, in my opinion.

MR. LIETO: This is Ralph Lieto.

Dr. Diamond, I kind of agree with Dr. Williamson because my concern is that -- and correct me if I am wrong -- but most radiation oncology residencies don't involve the unsealed radiopharmaceutical end of therapy. How would, say, someone applying to the NRC, how would they know whether their training program included

radiopharmaceutical therapies?

DR. DIAMOND: Well, Ralph, there is a tremendous disparity in radiation oncology programs. I can't give you a breakdown --

MR. LIETO: Okay.

DR. DIAMOND: -- but I would say it is a 50/50 mix. I have no specific objections in principle to changing this around to be more prescriptive, in other words, to tell the American Board of Radiology, Section of Radiation Oncology, that they must go and meet requirements 1 through 4 to grant board certification.

DR. WILLIAMSON: No, I didn't say that, David. I'm sorry, this is Jeff Williamson again. I said that an authorized user is one who is certified by the American Board of Radiology and Radiation Oncology or some other board for nuclear medicine or has this following alternative experience.

The last paragraph would be, "In addition to the above paragraphs (a) through (b), an authorized user for radiopharmaceutical therapy should have this distribution of case experience."

DR. DIAMOND: And what I would propose, Jeff, is I would go and add simply a small paragraph (d), as in "dog," which we have done in other therapy-

related sections. Basically, again, to remind you of the structure, small paragraph (a) is the board pathways; small paragraph (b) is the alternative pathway; small paragraph (c) is the currently-recognized or is enumerated, and small paragraph (d) would be basically a notation or a specification that certain specific modality training for that particular area in which they wish to function must also be present, regardless of their board certification.

DR. WILLIAMSON: That's essentially what I was suggesting.

MR. LIETO: Yes, this is Ralph Lieto. I thought that's what Jeff said, too, because I would agree with that, Dr. Diamond. I think that would answer at least my concerns because, knowing that someone was board-certified in radiation oncology, yet had no unsealed source experience, and yet got approved for that, I think it is just a disaster waiting to happen.

DR. DIAMOND: As I think this proves, Jeff and Ralph, this may be a very clear way to proceed, and it would bring it in parallel, for example, with Section 35.690, which is simply exactly that. For any specific modality with which you wish to work, you must have training experience in that specific

modality.

CHAIRMAN CERQUEIRA: This is Manuel Cerqueira.

I think that would solve, though, the problem. Really it almost sounds like (2)(E)(1), the Radiation Safety Officer requirement, where we try to put some more specific training requirements in there.

So, Ralph, you are happy with that?

MR. LIETO: Yes. This is Ralph Lieto. I would agree with that.

DR. WILLIAMSON: Jeff Williamson. I think also it is a less radical restructuring of this part, so less likely to provoke a negative response from the regulated community.

DR. MALMUD: Leon Malmud. I agree.

CHAIRMAN CERQUEIRA: Any other comments from other members of the Committee?

DR. VETTER: This is Richard Vetter. I agree as well.

CHAIRMAN CERQUEIRA: Okay.

MS. SCHWARTZ: Sally Schwartz. I agree also.

DR. BRINKER: This is the other Jeff. I agree.

CHAIRMAN CERQUEIRA: All right, so, David,

I think if we add that small (d) at the end --

DR. DIAMOND: Would you like me to move onto the next two sections --

CHAIRMAN CERQUEIRA: I'm sorry, what?

DR. DIAMOND: Would you like me to move onto the next two sections?

CHAIRMAN CERQUEIRA: Yes.

DR. DIAMOND: The next two sections, 35.392 and .394, respectively, have to do with the use of sodium I-131; we find these less than or greater than 33 millicuries, respectively. Basically, all that was done is a competency statement was removed.

As was mentioned earlier, there was a very strong sense by the Subcommittee that it is not appropriate to have a preceptor attest to competency. Therefore, I simply removed the competency statement for both of those two sections and left the remainder of the sections unchanged.

CHAIRMAN CERQUEIRA: Except we may want to change some of that to "written statement" instead of "certification." Ralph, would that be in line with your earlier comment?

DR. MALMUD: You're referring now to Sections 35.392 and 35.394?

CHAIRMAN CERQUEIRA: Right.

DR. MALMUD: Agreed. Malmud.

CHAIRMAN CERQUEIRA: Okay. Any further discussion on these sections then?

DR. VETTER: This is Richard Vetter.

So did we decide to not use the word "written certification" but something else a little less strong, or what did we -- is that a theme we want to follow in this whole section?

DR. EGGLI: I understood so then, "attestation" or "statement."

MS. McBURNEY: "Notation."

DR. VETTER: Okay, so we will find a new word for that.

CHAIRMAN CERQUEIRA: Okay.

MR. LIETO: This is Ralph Lieto.

On the copy here it doesn't have what the hour requirement -- is there still the hour requirements?

DR. DIAMOND: Everything is exactly the same, Ralph, other than the removal of the competency statement.

CHAIRMAN CERQUEIRA: Okay, any further discussion on .392 and .394?

(No response.)

Again, if people have, you know, late,

late thoughts about some of these issues, they can still send us written comments while the staff is reviewing some of these changes.

Shall we go to 35.490?

DR. DIAMOND: Okay, 35.490 is Training for the Use of Manual Brachytherapy Sources. This we did not discuss in our June meeting. Basically, what I have done is I have gone back and made it parallel in structure to 35.690, which we did, in fact, discuss at great length. So, once again, there is that format of a board pathway, small paragraph (a); an alternative pathway, small paragraph (b), and the small paragraph (c), which is the enumeration of boards.

The only really changes in this whole section is just, again, listing the residency programs. Paragraph (a) continues also the residency program director's statement attesting that the training requirements have been met.

The examination, the hours on paragraph (b), both for work experience and classroom experience are unchanged.

DR. WILLIAMSON: Now (b) handles alternative pathway, correct?

DR. DIAMOND: Correct, Jeff.

DR. WILLIAMSON: Okay.

MS. McBURNEY: This is Ruth.

This is the 20-hour requirement for manual brachytherapy?

DR. DIAMOND: It is 200 hours of classroom and laboratory.

MS. McBURNEY: Yes.

DR. DIAMOND: That's paragraph small (b) on little Roman numeral (i), and then right after that is 500 hours of work experience.

MS. McBURNEY: Right.

DR. DIAMOND: So that is unchanged. Again, this was simply reworded to be parallel with .690.

DR. WILLIAMSON: Could I just make a comment about the sort of style of paragraph (a), I guess? It is not really a substantive comment.

Jeff Williamson speaking.

DR. DIAMOND: Okay.

DR. WILLIAMSON: I wrote the --

DR. DIAMOND: The Williamson manual style.

(Laughter.)

DR. WILLIAMSON: Yes, right. To me, paragraph (a) is not terribly clear that the board has to meet features or has to exhibit features 1 through 4.

To give you an example, I wrote it in the physicist part as, "if certified by a specialty board in radiation oncology, certification has been recognized by the Commission and requires all diplomates," and then bang, bang, bang, bang, and it's very clear that the 1 through 4 then are essential features of a recognizable board, or one recognizable by the Commission.

So it is just an issue of how it is phrased rather than substantive.

DR. VETTER: This is Richard Vetter.

I actually support what Jeff just said. If you moved those few words out of paragraph (a)(1) into the major paragraph, then you eliminate room for argument about whether 2, 3, and 4 go along for it or if they are separate.

DR. DIAMOND: That is an easy fix.

CHAIRMAN CERQUEIRA: This is Manual Cerqueira.

Any other comments on those changes that have been proposed by Jeff and Richard?

MR. LIETO: This is Ralph Lieto.

I have one point for clarification. Under the alternative pathway, (b), at the end of No. 2 you say that the "experience may be obtained concurrently

with the supervised work experience." Did you want that to state paragraph (b)(1)(ii) or did you just want it to be (b)(1)? In other words, do you want the 700 hours to be concurrently with the three years of supervised experience? Because right now you are just saying the 500.

DR. DIAMOND: Oh, I see.

MR. LIETO: I think your intent is to have just --

DR. DIAMOND: It is a lot clearer just (b)(1).

MR. LIETO: Yes, drop the Roman numeral --

DR. DIAMOND: Well, that last sentence is referring specifically to the supervised work experience --

MR. LIETO: Right.

DR. DIAMOND: -- which is that paragraph small Roman numeral (ii). Small Roman numeral (i) is all classroom/laboratory time, Ralph.

MR. LIETO: Okay. Well, I'm just checking for clarification. Did you want the classroom experience to be also concurrent with the supervised -- you know, with the three years of clinical experience? In other words, I guess what I am asking is, couldn't you or wouldn't most programs have their

classroom and work experience as a part of the three years with the residency program?

I don't have a strong opinion one way or the other, but I just wanted to be sure that -- because what it sounds like here, you've got to have 200 hours plus three years of supervised experience. That is what I am interpreting that to mean right now, and I don't know if that was the intent.

DR. DIAMOND: Other thoughts on that?

DR. VETTER: This is Richard Vetter.

I agree with Ralph's interpretation. I didn't catch that either, but normally the lectures, and so forth, that the residents receive, they would receive during that three years of residency, wouldn't they?

DR. DIAMOND: Okay, so we could go and change that to (b)(1) alone --

DR. VETTER: Right.

DR. DIAMOND: -- and delete that small Roman numeral (ii).

MS. McBURNEY: This is Ruth McBurney.

With the "this experience may be obtained concurrently with the" --

DR. DIAMOND: Training?

MS. McBURNEY: -- "training and supervised

work experience required by paragraph (b)(1)."

DR. DIAMOND: Yes.

MS. McBURNEY: Or (b) --

DR. DIAMOND: (b)(1).

MS. McBURNEY: (b)(1), right.

DR. WILLIAMSON: Jeff Williamson. I support this, too.

MS. SCHWARTZ: Sally Schwartz. I agree that sentence is to clarify.

DR. MALMUD: Malmud. Agree.

CHAIRMAN CERQUEIRA: So I think there is pretty much agreement.

There's been a couple of comments that have been made if perhaps under this .490 we should also include a paragraph similar to what we have on the .690, which is the last (d), which basically tries to -- will give training in a specific modality for which authorized use is being sought,

DR. DIAMOND: I thought about that when I was working on this, and I didn't think that there was enough -- this is such a specific section. This is Manual Brachytherapy Sources and so specific that I can't imagine that there is enough differences in modality, or whatnot, to justify a paragraph (b). It is already such a narrow field, if you will.

CHAIRMAN CERQUEIRA: Okay, how does the rest of the Committee feel about --

DR. WILLIAMSON: Well, this is Jeff Williamson.

I do believe that the Accreditation Committee for Radiation Oncology requires minimum caseload in general brachytherapy as a condition of being an approved program. Is that not true, David?

DR. DIAMOND: Yes, that is correct. This is one of the areas where you must go and enumerate the number of cases that you have done to meet basic -- to become board-certified.

DR. WILLIAMSON: So I guess I would submit the proposition that I think the residency, even minimal residency in radiation oncology, includes adequate clinical experience and hands-on training with forms of manual brachytherapy. I agree with Dr. Diamond that a special modality-specific competence really isn't meaningful.

CHAIRMAN CERQUEIRA: For manual brachytherapy. Richard, do you have any comments, Richard Vetter?

DR. VETTER: No, I agree with David and Jeff's interpretation that we do not need that specific paragraph or paragraph on specific modalities

for this section.

CHAIRMAN CERQUEIRA: Okay, other comments from the Committee?

(No response.)

Now we had one comment from the audience here at NRC headquarters in Rockville. Bill Uffelman? Okay, no, we have answered it.

Okay, so how does the Committee feel? They're happy with .490 as modified?

DR. VETTER: This is Richard Vetter. I'm happy with it.

MS. SCHWARTZ: Sally Schwartz. I'm happy with the modification.

CHAIRMAN CERQUEIRA: Okay.

DR. MALMUD: Malmud. Content.

MS. McBURNEY: This is Ruth. Sounds good to me.

DR. BRINKER: Brinker. It's fine with me.

MR. LIETO: Ralph Lieto. It's okay with me.

DR. EGGLI: Eggli. Okay.

CHAIRMAN CERQUEIRA: All right, so then I think we are finished with .490.

DR. DIAMOND: Okay, why don't we go to 35.491?

CHAIRMAN CERQUEIRA: Okay.

DR. DIAMOND: This is, again, an example of just simply removing a competency statement, to be parallel with what we were doing earlier. This is for the ophthalmic use of strontium-90 for, for example, the prevention of traechia, and so forth.

Simply, if you look at a competency statement, again, we could go and change the wording from "certification" or "attestation," or whatever we would like.

CHAIRMAN CERQUEIRA: Yes, I think, again, we will make that uniform across all of these different modalities.

DR. DIAMOND: Okay, then we will go and skip to 35.690, which is Training for Use of Remote After-Loader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

Once again, Colleagues, format is small paragraph (a), boards pathway; small paragraph (b), which is alternative pathway; small paragraph (c), which is the currently-recognized boards, and small paragraph (d), which is a modality-specific training.

Let's see, paragraph (a) will really be exactly the same as what we just did for the manual brachytherapy sources. So if there is any sense, once

again, that we should go and clarify paragraph (a) in .490, we should do the same in this section, whatever language Dick or Jeff wanted to recommend.

Paragraph (b)(1) is exactly the same.

Paragraph (b)(2) is the preceptor statement. We can discuss, for example, on paragraph (b)(2), just as we discussed a few moments ago, the concurrent experience, should it apply both to Roman numeral (i) and (ii) or just to Roman numeral (ii).

DR. WILLIAMSON: Yes, I would recommend making the changes we discussed for 35.490 --

DR. DIAMOND: Okay.

DR. WILLIAMSON: -- to both paragraph (a) and paragraph (b) to this section.

DR. DIAMOND: That's fine with me. So what we would do is, again, change that last sentence on paragraph (b)(2) to read, "This experience may be obtained concurrently with the training and supervised work experience required by paragraph (b)(1) of this section."

DR. VETTER: This is Richard Vetter. I support that change.

MS. SCHWARTZ: Sally Schwartz. I agree.

DR. DIAMOND: We spent a lot of time in our June meeting on paragraph (d), thanks to Jeff's

help, which basically says that, for whatever specific modality which you're choosing to seek authorization, you must also have specific training in that particular area. So that's a very important change that we made.

CHAIRMAN CERQUEIRA: Any additional comments or changes, disagreement with what has been proposed?

MR. LIETO: This is Ralph Lieto. I have a question for NRC staff in relation to this Section (d).

The very last sentence says, "training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality." The NRC, are the licenses going to list the modalities that the physicist is authorized for?

MR. HICKEY: This is John Hickey.

Yes, it will be either in the license or it will be clear from the application what activity the medical physicist or authorized user is authorized for.

MR. LIETO: Okay, thank you.

DR. WILLIAMSON: This is Jeff.

In redrafting 35.51 for the authorized medical physicist, I tried to eliminate the ambiguity

in the wording that led to NRC staff's initial conclusion that there could not be modality-specific AMP.

CHAIRMAN CERQUEIRA: Okay, any further discussions on this then or does the Committee agree that this is acceptable as written with the changes that have been proposed? Any disagreement on this, rather than running around and getting people's concurrence on it?

DR. WILLIAMSON: Well, this is Jeff Williamson.

I think that at some point we will have to -- maybe it won't be us; maybe it will be the staff -- will have to decide which language to use for hard-wiring the boards, because now the diagnostic 35.190 and .290 have (a) "is certified in nuclear medicine by American Board of Nuclear Medicine," et cetera, et cetera. So the AMP is written in a similar way.

Dr. Diamond has proposed an alternative way of seeding this which lists which boards are currently recognized. So there is an asymmetry in the language that at some point has to be straightened out. All of the sections should be written one way or the other.

CHAIRMAN CERQUEIRA: Okay, I would agree

with that. I think the staff will do so.

It has also been pointed out to me, if we look at the last page in (d), in addition to meeting the requirements of paragraphs (a) or (b), it should also say, "or (c) of this section." I think that is sort of implied.

All right, I think for 35.690, I think there is general agreement on this.

DR. DIAMOND: Dr. Cerqueira, unfortunately, I have to get going. I have some patients waiting. I appreciate you allowing me to go ahead with this therapy section.

CHAIRMAN CERQUEIRA: David, the one section we didn't cover was 35.590.

DR. DIAMOND: Would that be diagnosis?

MS. McBURNEY: I had that one. This is Ruth.

CHAIRMAN CERQUEIRA: Ruth has it, okay. Okay, thank you, David.

DR. DIAMOND: My pleasure. Thank you very much.

CHAIRMAN CERQUEIRA: All right. So we have covered the therapy. I guess we can then go back to 35.51, which is Training for Authorized Medical Physicists, and Dr. Williamson.

DR. WILLIAMSON: Okay, this one is written in a parallel fashion to the RSO and the authorized user for full-time emitting devices. It says, "(a) an authorized medical licensee shall require authorized medical physicists to be an individual who is (a) certified by one of the following specialty boards in radiation oncology physics," and it lists them all, "(b) is certified by a specialty board in radiation oncology physics whose certification has been recognized by the Commission and requires all diplomates" -- it runs through a graduate degree from an accredited institution to two years of full-time practical training in radiation oncology physics, and specifies that it actually has to be done in a clinical facility providing external beam therapy and some form of brachytherapy service.

"Obtains written certification," or I guess maybe now "statement," "of physicists who are certified by one of the recognized specialty boards as to candidates satisfactorily completing the training experience, and (4) passes an examination administered by a diplomate."

Then (4) leads to Part (c), which is the alternative pathway. This is very similar to what is in the current regulation. I have tried to soften it

a little bit because I am afraid there may be some people who want to use the alternative pathway, and so few institutions have cobalt-60 teletherapy and not that many have gamma stereotactic, that I tried to liberalize it a little bit, so that there would be more training facilities that would be eligible.

Then (d) is the modality-specific section. In addition to meeting the requirements of (a), (b), or (c) in this section, "an authorized medical physicist must have training in the modality for which authorization is sought." It lists the features there.

The intent is to basically have the mechanisms that are already used within the community for training new physicists for these modalities, would be able to comply with this sentence.

Okay, so that finishes my summary.

CHAIRMAN CERQUEIRA: All right, any comments or suggestions? There's been a lot of work on this.

MR. LIETO: Jeff, this is Ralph Lieto.

Just on part (c) there, where you have the services in a task listed in those sections, do you think that might be too prescriptive as opposed -- in other words, do you want to list the subject matter as

opposed to the sections, or sections change in content, and so forth? And just a thought, do you think that would be a concern for future changes?

DR. WILLIAMSON: Yes, I thought about this some, and the way I think it is written now is these different sections, 35.643, and so forth, they make reference to spotchecks and full calibrations of stereotactic radiosurgery, high-dose-rate brachytherapy, and cobalt-60 teletherapy. The intent was to actually have experience with LINAC-based external beam to qualify an applicant for doing calibrations on a cobalt unit, since the basic methodology is identical.

The only modality I thought was reasonable to expect a facility to have is high-dose-rate brachytherapy, which is now pretty pervasively available in the community. It's certainly large market penetration compared to the other two devices.

But we certainly could take out 35.67 and put whatever it refers to, which is external beam full calibrations and periodic spotchecks.

MR. LIETO: That would be my recommendation simply because down the pike it may be that people will, or it may be interpreted that they have to be the task on that specific device. Do you

see what I'm saying?

DR. WILLIAMSON: Yes.

MR. LIETO: I don't think that was your intent.

DR. WILLIAMSON: That's correct. I am trying to get away from that.

MR. LIETO: I was thinking that maybe you might want to list, just like you specified full calibrations and periodic spotchecks, and the tasks that are involved as opposed to the section, because I think it is going to be interpreted that they have to have the experience that satisfies that section, which may be to the cobalt or whatever -- that's my concern.

DR. WILLIAMSON: Well, I think that is a reasonable change to make. I support that.

CHAIRMAN CERQUEIRA: Any other comments for Dr. Williamson?

MS. McBURNEY: This is Ruth. I agree with those changes, to list the tasks rather than specific to Part 35, and make it a little plainer.

DR. WILLIAMSON: Yes, just so it is clear to the staff and everyone, too, who is examining this, the concept underlying this is that calibration and quality assurance experience for LINACs is applicable

to cobalt-60 teletherapy. All of the operational procedures that are used for LINAC-based stereotactic radiosurgery I think give one very good general qualifications for carrying out the same tasks for cobalt-60 -- no, for gamma knife stereotactic radiosurgery.

There is, in addition, Part (d) would essentially require alternative pathway candidates as well as board-certified candidates to have gone through some kind of a training experience for the specific device, which would redress any of the small deficiencies or differences between their training experience and what their current clinical duties will be. That's the assumption.

MS. SCHWARTZ: I agree with what you are saying, Jeff, also. This is Sally Schwartz.

CHAIRMAN CERQUEIRA: All right, I think there is pretty good consensus that this is well-written, Jeff.

Does anyone feel strongly that we should have further discussion on this or are people in general happy with the new language?

DR. VETTER: Vetter is happy.

DR. MALMUD: Malmud's content.

CHAIRMAN CERQUEIRA: Okay, good, then

excellent job, Jeff. You've persevered with this.

The next section is 35.55, Training for an Authorized Nuclear Pharmacist. Sally, you were on the Subcommittee, but who was responsible for this?

MS. SCHWARTZ: I was, the Authorized Nuclear Pharmacist.

CHAIRMAN CERQUEIRA: Oh, you were? Okay.

MS. SCHWARTZ: Yes. Actually, I was contacted by Dr. Vetter --

CHAIRMAN CERQUEIRA: Good.

MS. SCHWARTZ: -- actually followed through with this section.

CHAIRMAN CERQUEIRA: Good, okay.

MS. SCHWARTZ: Essentially, there weren't changes majorly in the new Part 35, but there were comments that came up, I guess, in the workshop open session. What I was asked to do is essentially define an alternate pathway for another board, if there would become one. Currently, for the board of pharmacy, there is one national board, the American Pharmaceutical Association, which board certifies nuclear pharmacists.

So what I was asked to do is essentially define what those qualities were, so that if in the future another board would become available, that they

would have to meet the same requirements that are already defined by the Board of Pharmaceutical Specialties, which is what I did.

So, essentially, the (a) is that a pharmacist be board-certified by the Board of Pharmaceutical Specialties or (b) board-certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by the Commission, and then requires all diplomates to essentially fulfill all the currently listed requirements for board certification.

Something that comment-wise has come up since I wrote this from Joel Hung, and I wanted to raise this, rather than being as prescriptive as listing all of these items, as I have done in (b), he did provide a thought that maybe just a general statement to the effect that says, "if certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b)," which define the requirements for licensure -- I guess it would be now (c) -- "of this section, whose certification program should be equivalent to that offered by the Board of Pharmaceutical Specialties in Nuclear Pharmacy, including the recertification process, or have been

recognized by the Commission or an Agreement State."

So I wanted to at least state that to this group, and for myself either is acceptable, the listing of what is currently required or the less prescriptive statement that essentially any board, if it would become available, that it would have to comply.

MS. McBURNEY: This is Ruth McBurney.

I would prefer the way you have it here with setting out the criteria for the Commission to follow --

MS. SCHWARTZ: Right.

MS. McBURNEY: -- on approving any board.

I just had a quick question. Do the Canadians have board certification? Do you know?

MS. SCHWARTZ: I am not aware that they do or not, but there is an omission from this that actually has a reflection on what your question is in the Board Candidate's Guide for the current Board of Pharmaceutical Specialties.

In No. 1 they actually state that, "has graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education or an alternative educational program accepted by EST." So there are other programs available outside the United

States that are acceptable pathways for licensure, board certification. So I would like that written into this No. 1.

DR. VETTER: This is Richard Vetter.

Sally, is there a way to make that more generic? Rather than an alternative program acceptable to the Board of Pharmaceutical Specialties --

MS. SCHWARTZ: Yes, okay, so we could not list that, but --

DR. VETTER: No.

MS. McBURNEY: Okay.

MR. HICKEY: Please speak up.

MS. McBURNEY: Oh, I was kind of mumbling to myself. All right, this is Ruth. I am trying to think of some alternate language.

DR. VETTER: This is in (b)(1)?

MS. McBURNEY: (b)(1).

DR. VETTER: And the intent of the language is just to recognize --

MS. SCHWARTZ: Alternative educational programs, and these are outside of the United States.

DR. VETTER: Okay.

MS. SCHWARTZ: Because there are those candidates that come in with acceptable educational

programs; they still, then, apply with that training --

DR. VETTER: To the Board?

MS. SCHWARTZ: Yes, correct.

DR. VETTER: Well, yes, somehow it seems -- so what is the criterion that the Board uses for eligibility?

MS. SCHWARTZ: Now what board?

DR. VETTER: Well, when the Board -- when applicants come before the Board --

MS. SCHWARTZ: From another country?

DR. VETTER: -- of Nuclear Pharmacy, Board of Pharmaceutical Specialties and Nuclear Pharmacy --

MS. SCHWARTZ: Correct.

DR. VETTER: -- and they have some applicant from a foreign pharmacy school, what is their criterion for accepting it?

MS. SCHWARTZ: All of the listed items, essentially. So that it could be an alternate educational program including all the listed requirements.

CHAIRMAN CERQUEIRA: Under (c).

MS. SCHWARTZ: Of (b) in this section.

DR. VETTER: Well, there aren't any, I don't see any requirements for the educational program

here, other than it is accredited by the American Council on Pharmaceutical Education.

MS. SCHWARTZ: Well, essentially, the 2,000 hours academic, the 4,000 hours of training/experience in nuclear pharmacy practice, and essentially then the passing grade on a board certification exam, those types of requirements.

MS. McBURNEY: This is Ruth again.

DR. VETTER: I'm confused now.

MS. McBURNEY: I was wondering if we could use parallel language to some of these others, that board certification includes diplomates who graduated from -- for example, a medical physicist is from an institution accredited by a regional accrediting body.

MS. SCHWARTZ: Yes, that would be acceptable.

DR. WILLIAMSON: Yes, I think the qualification needs to be put into (b)(1). It is a qualification for the degree, and you have 2, 3, and 4 as separate requirements. So I think the person obviously has to show evidence that he has the 4,000 hours of training experience or additional education.

I understood your question, Sally, to be one of, how do you identify appropriate educational degree-granting programs are acceptable for No. 1, for

No. (b)(1) only?

MS. SCHWARTZ: That is correct. That is correct.

DR. WILLIAMSON: So you have to find a statement for that that probably doesn't make reference to 2, 3, and 4 --

MS. SCHWARTZ: Correct.

DR. WILLIAMSON: -- which are other components.

MS. SCHWARTZ: Those are additional components required.

DR. WILLIAMSON: Yes.

MS. SCHWARTZ: Right. The alternative educational program accepted, rather than by the Board of Pharmaceutical Specialties, accepted --

DR. WILLIAMSON: Yes, so the question is, when the Board looks at candidates who comes from these different programs and looks just at the academic program component of their credentials, what is their criterion for accepting it as a good program versus the bad program?

MS. SCHWARTZ: Well, that's review, I'm assuming, of the educational requirement for the pharmaceutical program at the universities in the alternate country, similar academic, essential six-

year training program, not that necessarily they list that six-year requirement, but it is a six-year degree-granting program in the United States.

So I am not certain how they have evaluated those criterion. I could get a hold of them.

DR. WILLIAMSON: Maybe it would be worth looking into it.

MS. SCHWARTZ: Yes. All right, I will do that.

DR. WILLIAMSON: Because I don't think we want to exclude a pool of qualified candidates from abroad --

MS. SCHWARTZ: Right.

DR. WILLIAMSON: -- if the whole industry depends on them; it would be a bad mistake.

MS. SCHWARTZ: What I could essentially do is get this information and then report back to -- who would be the appropriate individual in this group that I would report back to as far as finalizing this section?

MR. HICKEY: This is John Hickey.

First of all, I wanted to mention that Dr. Cerqueira was paged, so he had to step away from a moment, and he asked that we continue.

Dr. Vetter, I think that they should get back to you with the changes.

MS. SCHWARTZ: Okay.

MR. HICKEY: Does Dr. Vetter agree with that?

DR. VETTER: Dr. Vetter agrees with that.

MR. HICKEY: Okay.

MS. SCHWARTZ: All right. Dr. Vetter, I will get the information back to you then. I will not be back to St. Louis for a week. Is that acceptable?

DR. VETTER: That is acceptable to me. Is it acceptable to the NRC relative to their timeline?

MR. HICKEY: Well, we want to wrap this up as soon as we can, but you could go ahead and submit that. If there's still a piece that is missing, we could handle that later.

DR. VETTER: Okay.

MR. HICKEY: But I wouldn't want the whole thing to be held up because of that.

DR. VETTER: Right.

MS. SCHWARTZ: Right. I will still send it to you in a week.

DR. VETTER: Okay.

MS. SCHWARTZ: All right?

Additionally, for this section,

essentially, this Part (c) is completion of the 700 hours; (b) structured educational program, essentially defining the alternate pathway consisting of didactic training. It provides practical training.

And, No. 3, then, having obtained "written attestation signed by a board-certified nuclear pharmacist or a preceptor authorizing that an individual has completed the required training listed in (b)(2) of this section." So certifying just the training, not the educational material.

DR. MALMUD: Malmud. May I ask a question? How many authorized nuclear pharmacists are there in the United States?

MS. SCHWARTZ: About 490.

DR. MALMUD: Do you regard that number as being adequate to further certify other individuals?

MS. SCHWARTZ: This can also be -- it doesn't require that the training be authorized by an authorized nuclear pharmacist; they can be by an AMP or board-certified, yes, nuclear pharmacist.

DR. MALMUD: So there would be more than ample ways of individuals becoming --

MS. SCHWARTZ: Correct.

DR. MALMUD: Okay. Thank you.

DR. WILLIAMSON: This is Jeff. I have

another question.

Where did the 700 hours come from, and what was the intent behind that? There seems to be a rather large disparity between the training and experience requirements of the Board versus its alternative pathway.

MS. SCHWARTZ: That was written prior. I did not change that. That was what was listed as the alternate training hours, and I was not involved in the writing of that section. I assumed that what my task was essentially was to define what a board, if there were to be another board defined in the United States, what those qualifications should be for essentially a new board.

But now the alternate pathway was defined. I did not define that.

DR. VETTER: This is Richard Vetter.

The scope of our charge did not include addressing the alternate pathway except for the issue of preceptor statement.

MS. SCHWARTZ: And in that case the preceptor statement is just that the preceptors sign or attest to the training, but not the didactic training.

CHAIRMAN CERQUEIRA: This is Manuel

Cerqueira. I think that 700 hours is very similar to what we have in the therapies sections as well as in the diagnostic studies as well.

You know, we had some discussions when Dennis Swanson sat on the Committee. I think people felt comfortable with the hourly requirements in the didactic and the supervised training. I would be in favor of keeping that in.

MS. SCHWARTZ: I agree with that. It was Dennis Swanson who was involved in that portion of the regulation, and I am in favor of maintaining that as 700 hours.

CHAIRMAN CERQUEIRA: Are there other comments?

MR. LIETO: This is Ralph Lieto.

Sally, I have a question on the Section (b) there. I am a little confused by the 1,500 credit hours. It talks about undergraduate and post-graduate.

MS. SCHWARTZ: Correct.

MR. LIETO: Are those supposed to be hours of -- I'm trying to think, God, these people are going to be in there forever.

MS. SCHWARTZ: Fifteen hundred hours, and it should probably not say "of credit," but just of

hours.

MR. LIETO: Okay.

MS. SCHWARTZ: As it is written above, it is a maximum of 2,000 hours can be obtained academically by undergraduate courses. Up to a maximum of 1,500 hours credit can be obtained under certain undergraduate courses.

MR. LIETO: So then that is not supposed to be "credit hours," --

MS. SCHWARTZ: No.

MR. LIETO: -- but they go towards that 2,000 total?

MS. SCHWARTZ: Correct. That is correct. So those words could be removed.

MR. LIETO: Okay. It is also in (c) and (d), too.

Now in (d) it says 220 hours of credit. Is that correct?

MS. SCHWARTZ: That's right, and the way that the current Board of Pharmaceutical Specialties -- actually, I semi-modified this (b). They actually have two programs. Dr. Vetter directed me to -- I had listed them previously. One is the University of New Mexico program, and the other is Purdue University. I think Purdue -- I'm sorry, Purdue and Oklahoma have

two programs, and they allow one 210 and the other, I think it's 217, and we can just take it to 200, if you want, but I just kind of rounded it up to 220 hours. That has been defined by the Board for these individual programs. So I left it as a maximum of 220.

MR. LIETO: Okay.

MS. SCHWARTZ: It seems like an odd number, but that is written in the Guide for the Board of Pharmaceutical Specialties. I can read you their actual language. I will get it.

CHAIRMAN CERQUEIRA: Other comments for Sally?

MS. SCHWARTZ: I can just reiterate the actual statement in there. They are listing it as "successful completion of the nuclear pharmacy certificate program offered by Purdue University, which is 217 hours, or the Ohio State University, 214 hours. Credit for all other courses will be assessed on a case-by-case basis. So I just left it as a more generic 220 hours.

Should I add possibly that, of course, it would be accreditation on a case-by-case basis?

DR. EGGLI: Well, would you reject the board that refused to look at these other programs on

a case-by-case basis?

MS. SCHWARTZ: Well, I mean, it should be looked at on a case-by-case basis.

DR. EGGLI: Well, I'm not arguing what the current Board has decided to do, whether it is wise or not, but these are supposed to be criteria for --

MS. SCHWARTZ: Right, for new --

DR. EGGLI: -- for new programs. So it seems to me you wouldn't be giving up very much to simply delete that, if it is confusing or difficult to enforce.

MS. SCHWARTZ: Right.

DR. EGGLI: So what if a program comes along that has 4,000 hours but doesn't look at those ones? Does it really matter? It seems that it is such a small thing that --

MS. SCHWARTZ: That's true. That's true.

DR. EGGLI: You know, rather than exactly put down the precise board requirements, you really want to capture the essence --

MS. SCHWARTZ: Yes.

DR. EGGLI: -- of what makes your board the way it is.

MS. SCHWARTZ: I agree. For that purpose, (b) could actually be omitted, if that would make

it --

DR. EGGLI: Less confusing.

MS. SCHWARTZ: -- less confusing.

CHAIRMAN CERQUEIRA: Yes, I think that would help.

MS. SCHWARTZ: All right.

CHAIRMAN CERQUEIRA: So it would eliminate 1 actually through (d)?

MS. SCHWARTZ: Yes.

CHAIRMAN CERQUEIRA: Okay. Are there other comments? I guess we could probably send another draft of this portion on because I have to admit I didn't look at it that closely. I think some of the suggestions would sort of simplify it and give us the intended results without making it too restrictive.

Richard, any other changes?

DR. VETTER: This is Richard Vetter.

No, I think these suggestions are excellent. When Sally revises the section, including adding those words under (b)(1), I will make sure that the new section in its entirety gets referred to the Committee, the entire Committee, for an additional look.

CHAIRMAN CERQUEIRA: Okay, great. Shall

we go on to 35.190, Training for Uptake Dilution and Exclusion Studies?

MS. McBURNEY: This is Ruth McBurney. I had that one.

This is the first of the series of authorized user requirement. What I did on this was the hard-wiring and back in the boards that had been accepted by the Commission in the past, and for parallel structure changed what the preceptor signed as just attesting to the satisfactory completion of the training requirement, training experience of 60 hours.

We also added in that, if that training is received in conjunction with a residency program, that written -- I guess we're changing it to "attestation," or whatever -- could be signed by the residency program director.

So those are the basic changes that were made from the new Part 35.

CHAIRMAN CERQUEIRA: I think there was fairly good agreement at the Subcommittee meeting on these changes.

Any other comments?

DR. WILLIAMSON: This is Jeff Williamson.

I think in Section (b)(2), someone

commented on my section that instead of having written and oral exams, one should just have an examination, because some of the boards are talking about going to computer-administered exams and such, and that it seems unnecessarily detailed and prescriptive to specify both written and oral components.

DR. VETTER: This is Richard Vetter.

I think that the comment is an accurate reflection of a discussion that occurred during Committee. Somehow we have overlooked that. But I agree, we did intend to make that a little bit more generic.

MS. McBURNEY: So we would be taking out "written and oral" and it would just be "required successful completion with a passing grade of exam" --

DR. WILLIAMSON: Of an examination, yes.

MS. McBURNEY: -- "examination."

DR. VETTER: Yes, an examination.

MR. LIETO: Ralph Lieto. Are "successful completion" and "with a passing grade" redundant?

DR. VETTER: Yes, yes, take off "successful." That also was a comment that we had earlier.

MS. McBURNEY: Okay.

DR. WILLIAMSON: And then the next

question is on (b)(3). Some of the sections say, "board recognized by a Commission" and some say, this one says, yours, Ruth, says, "by the Commission or an Agreement State."

MS. McBURNEY: Right, I had just forgotten to take that out.

DR. WILLIAMSON: Okay, so "by the Commission" then --

MS. McBURNEY: By the Commission.

DR. WILLIAMSON: -- is what you intend? The idea was several people commented on my strawman T&E that they thought that the recognition process should somehow be centralized.

MS. McBURNEY: Right, at the Board.

DR. WILLIAMSON: Yes, the board recognition process.

MS. McBURNEY: But for (c), if they are already on an Agreement State license --

DR. WILLIAMSON: No, that's okay, I think.

MS. McBURNEY: .290 or .390, yes; then they can do the .190 stuff.

DR. WILLIAMSON: Yes, I think so.

MS. McBURNEY: All right.

DR. WILLIAMSON: It was only (b)(3) I was talking about.

MS. McBURNEY: Yes, I had just failed to take that out, and the same way on .290 as well.

DR. WILLIAMSON: Exactly.

MS. McBURNEY: Right. Corrections there, too. Okay.

Is that it for .190?

CHAIRMAN CERQUEIRA: Other comments for this?

DR. MALMUD: Not from Malmud.

CHAIRMAN CERQUEIRA: Okay, then let's go on to .290.

MS. McBURNEY: Okay. For .290, this is for Energy and Localization Studies. We hard-wired in the boards that have been accepted, including the one that the Commission has recently accepted, and that is the Certification Board of Nuclear Cardiology.

Then, likewise, on (b) we will make the same changes in (2) about the examination, and in (3) correcting the "or an Agreement State."

We also did the same thing for parallel structure on the (d)(2) to obtain a written certification of whatever we are changing that to. The preceptor, that's just attesting to their training.

Or, if it was received in conjunction with

a residency program, then that written attestation can be signed by the residency program director attesting to the fact that they had successfully completed the requirements of (c)(1), the 700 hours of training.

CHAIRMAN CERQUEIRA: Again, the question of "certification" as opposed to some other word will --

MS. McBURNEY: Right.

CHAIRMAN CERQUEIRA: -- be worked with.

MS. McBURNEY: I'm sure NRC staff can come up with some word.

CHAIRMAN CERQUEIRA: A magic word.

Any other questions or discussions for Ruth on .290?

MR. LIETO: This is Ralph. I have two questions.

One, just clarification under (a) that has the certification --

MS. McBURNEY: Uh-hum.

MR. LIETO: So does this mean that they are certified in nuclear cardiology by the new Certification Board of Nuclear Cardiology; they are authorized for all imaging modalities, imaging -- is that correct?

MS. McBURNEY: They can be, but --

MR. LIETO: So if they want to do --

MS. McBURNEY: -- we had a discussion of that. At one time I had pulled out "nuclear cardiology" as a separate specialty, but really as far as the radiation safety aspects of it, it is the same.

CHAIRMAN CERQUEIRA: We had some discussion, I think, during the meeting. We felt that a lot of this would be done at the facility with credentialing committees. We thought about putting language in there that would try to sort of make certain that cardiologists weren't doing brain scans, but I think the general discussion was that was sort of an issue of medical practice rather than a radiation safety issue.

DR. WILLIAMSON: This is Jeff Williamson.

The ACMUI had a very long discussion that ran about two years on this issue. The background was that at some point it was decided to distinguish between low-risk and high-risk modality.

In high-risk modalities the central feature is that purely safety, especially radiation safety, considerations could not be distinguished from clinical experience or clinical competence, whereas for low-risks they could.

So this was the result of a long

deliberation whereby it was decided that the nuclear medicine imaging application should emphasize safety and technical skills rather than clinical competence. So it seemed unwise to reargue this whole large philosophical issue since it was part of the initial SRM from which the new Part 35 regulation was derived.

MS. McBURNEY: This is Ruth again.

Another aspect of that was that, as Dr. Cerqueira mentioned or somebody, that the credible practice for those individuals would probably limit what they could do. A cardiologist would limit, probably limit their practice to cardiology.

MR. LIETO: I just wanted to be sure that that was the intent.

My other comment had to do, under the Section (d) -- was that the alternative pathway with the 700 hours? Under "work experience," (b), and this occurs, I think, in other areas of training/experience, it is a word -- it says, "calibrating instruments used to determine activity." I had a real problem with this calibration.

If I could make the recommendation of using what Sally has under the Authorized Nuclear Pharmacist, where they say, "use and perform checks for proper operation," because they really don't

calibrate it. I think that is saying that the dose is calibrating. They really don't calibrate dose calibrations.

MS. McBURNEY: Right.

MR. LIETO: I imagine if you did, if you got a special setting or something like that, but I think the intent was really to have experience in using and performing the checks for proper operation, if I could just make that recommendation.

DR. EGGLI: This is Eggli.

I think that is correct, and you might use a term such as "quality control procedures" because the actual calibrations are done by the manufacturer.

CHAIRMAN CERQUEIRA: This is verbiage from the old regs., and I think we can certainly make those changes.

I just have one other comment, too, on Part (2), I guess it is (d)(2), where it says, "signed by the residency," again, a lot of the cardiology programs, they are fellows. So it should be "residency/fellowship program." It is a minor change, but it would sort of make it a little bit clearer for some of our constituencies.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: All right, other

questions or issues in this part then?

MS. McBURNEY: Question. This is Ruth again. Would that be true on the Uptake and Dilution as well, that that would be a fellowship, could be a fellowship?

CHAIRMAN CERQUEIRA: Well, I guess there is probably a generic training program.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: Yes, I don't think in that situation it would necessarily be a fellowship.

MS. McBURNEY: I didn't think so.

CHAIRMAN CERQUEIRA: No.

DR. EGGLI: This is Eggli again.

For people like endocrinology fellows, it could be a fellowship.

MS. McBURNEY: Yes.

CHAIRMAN CERQUEIRA: Yes.

DR. EGGLI: If you, again, would say, "training program director" rather than "residency program director," do you not cover both?

CHAIRMAN CERQUEIRA: You do. I guess we could do it that way as well.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: All right, so that should take us through pretty much all of these

sections. I guess the one that we didn't cover that Ruth said she was responsible for was 35.590, for Use of Sealed Sources for Diagnosis.

MS. McBURNEY: Yes, this was a really simple one. All I did was put back in the words that had previously been accepted. In this one, in the current rule there is no requirement for an attestation of that training, for the eight hours of classroom and laboratory training that are required. So I just left it at that without having "attestation." I didn't bring that up for discussion.

CHAIRMAN CERQUEIRA: John, did you have a comment?

MR. HICKEY: Yes. this is John Hickey.

I agree this is a simple section, but I would point out the last line about training on the use of the device, it raises the issue that really we focused on in .690 about the modality. So it seems to me that that should be separated out as a separate paragraph, so that the board certification process does not have to include training in the use of the devices, unless that is the case.

MS. McBURNEY: It doesn't

DR. WILLIAMSON: Yes. This is Jeff Williamson, and I support that change, too: Make a

Section (d) which says, "in addition to satisfying Parts (a), (b), or (c) above" --

MS. McBURNEY: What would the criteria for another specialty board then be?

DR. WILLIAMSON: Well, you see, the concern is that the American Board of Radiology, say therapeutic radiology, would not meet the criterion (b), which says, all diplomates have to have training in the use of this particular device.

MS. McBURNEY: Oh, I see.

DR. WILLIAMSON: So the suggestion is to create a Section (d) which is parallel to the device-specific or modality-specific training that we have had with some of the others.

MS. McBURNEY: Okay. So if I --

DR. WILLIAMSON: Just take No. (c)(5) away --

MS. McBURNEY: Right.

DR. WILLIAMSON: -- and make a Section (d) which says, in addition to complying with the requirements of (a), (b), and (c), an authorized user for such-and-such shall have training in the use of the specific device for the uses requested.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: Ruth, are gadolinium

sources covered under this?

MS. McBURNEY: Are what?

CHAIRMAN CERQUEIRA: Gadolinium sources for attenuation correction, I mean, is that covered under this or --

MS. McBURNEY: No. That is covered with the diagnostics.

CHAIRMAN CERQUEIRA: It is? Okay.

MS. McBURNEY: But the gadolinium sources here are not used for diagnostics. These are like bone densities.

CHAIRMAN CERQUEIRA: Okay. All right

MS. McBURNEY: Yes.

DR. WILLIAMSON: So these would probably be americium.

CHAIRMAN CERQUEIRA: Right, okay.

Do people agree in Jeff's suggested changes to sort of keep it in parallel with some of the other areas?

DR. VETTER: Vetter agrees.

MS. McBURNEY: That makes sense.

CHAIRMAN CERQUEIRA: Yes, okay. All right, well, that takes us through this portion of the document. We were supposed to take a break at 2:45, but is the Committee in favor of continuing, pushing

on to get done?

DR. EGGLI: I favor pushing on.

CHAIRMAN CERQUEIRA: Okay. Because the remaining items aren't really -- we just have to review a couple of other areas.

So, John, do you have any other comments that you would like to make at this point? Because we seem to have gotten fairly good consensus on all of these. At this point should the Committee take a vote formally now or would it be better for the Committee to have some time to think about this and then make comments?

MR. HICKEY: This is John Hickey.

I mean, ideally, the earlier vote, the better, but it seems to me that, even if we take a vote now, that should be subject to review of the edited version that we would send out to the Committee to see if they wanted to add any comments or point out any errors that they notice.

CHAIRMAN CERQUEIRA: What are the wishes of the Committee on how to proceed on this? Approve it, pending review of the revisions?

DR. VETTER: This is Richard Vetter.

I think the suggestions for editing, improvement, et cetera, have been very

straightforward. I would vote for voting for approval now, contingent on seeing the revision, so that we don't have to take a formal vote later.

DR. MALMUD: If that's the motion, I will second it.

CHAIRMAN CERQUEIRA: Okay, we have a motion and a second. Any discussion? Anyone have disagreements on doing that? Dr. Malmud?

DR. MALMUD: Malmud seconding it.

DR. BRINKER: This is Brinker.

Just as a sort of point of order, does that mean that there will be no second vote on the final product?

CHAIRMAN CERQUEIRA: Well, I guess people could give us written comments. But I guess if we approve it, then technically it has been approved.

DR. EGGLI: I think it means that if you see the draft or the revised draft and you don't like it, I think you can retract your vote.

DR. BRINKER: Well, I don't think that's good.

MR. LIETO: No. This is Ralph Lieto.

I tend to echo Dr. Brinker's concerns that voting on something before we have seen the final written version I think I have some great concern

with. So I would oppose taking a formal vote on approving it without having a written document in front of me.

DR. NAG: This is Subir Nag.

I think what we can do, we can vote online. I mean we can say we approve online. That way we won't have to have a separate meeting.

CHAIRMAN CERQUEIRA: Right. I think, John, would that be acceptable for the --

MR. HICKEY: Yes, yes, and I would suggest that people could vote "approve with comments." We can append the comments to the report. If a Committee member feels they have a comment but they don't want to vote "disapprove," they could still vote approved and add their comment.

CHAIRMAN CERQUEIRA: So we do have a motion. Does the Committee -- it sounds like basically get the final text revised, sending it out to the Committee members, and then getting their vote, either a fax or an email vote on the final motion, giving people the opportunity to make specific comments, and if there's significant disagreement, I guess we could convene another conference call. Does that sound acceptable to the Committee?

(Multiple members respond "yes" at the

same time.)

CHAIRMAN CERQUEIRA: Okay, let's go ahead and do that then.

All right, so the other two items on the agenda, then, are basically the Agreement State Implementation of the 10 CFR Part 35 Training and Experience Requirements. I asked John to put this on the Committee agenda because I think we've got a new rule which has been published and goes into effect on October 24th, and then we have like a two-year period during which you can either apply by the old or the new Part 35, and the Agreement States have three years upon which to either become compliant with the NRC or make some statement as to whether they would like to have alternative rules.

So it is going to be quite -- it is going to be very chaotic out there. When the Commissioners approved this, the agreement Level, the Agreement State was Level C, John, is that --

MR. HICKEY: No, B. I'm going to ask Mr. Lloyd Bolling to join us at the table at a microphone, from our Office of State and Tribal Programs, and we can go through this.

CHAIRMAN CERQUEIRA: Okay.

MR. HICKEY: But the compatibility level

is what is called B, which is essentially identical.

CHAIRMAN CERQUEIRA: Right.

MR. HICKEY: So the only issue is timing. It is not whether they are required to implement compatible rules.

Lloyd Bolling has now joined us.

MR. BOLLING: That is correct, John. The Agreement States have been given three years from the October '02 date. So that means that on October of 2005 the Agreement States will have to have a compatible rule, all parts of the rule, including the T&E requirements. The two-year transition period within which the old and the new may be accepted is within the three-year compatibility period.

Now during the promulgation of Part 35, which will go into effect this year, the Agreement States, some organizations I believe petitioned the Commission to have the implementation be sooner than three years, but the Commission has clearly indicated that they want the Agreement States to have the full three years. So that's where we are at this point.

CHAIRMAN CERQUEIRA: That would be ideal. I just sort of recall that in the early nineties the Glenn Commission sort of looked at the NSC and the Agreement States, and one of their conclusions was

that there is no enforcement mechanism at the federal level if the states are not in compliance. So I am just not sure that if the states decide not to necessarily enforce things the way the federal regs. have been written, does the NRC have the ability to enforce it?

MR. BOLLING: I am not sure enforcement is the right word to use, but when it comes to compatibility, those regulations or program elements, and regulations are among the program elements, that are deemed to be high matters of compatibility are reviewed by us on a regular basis when the rules are being promulgated as well as just before one of our routine, periodic audits of the state programs. So that when we go out and audit a program, if we find that a certain portion of a rule has not been adopted or the whole rule itself has not been adopted, the state will not get an adequate review for that period.

As you know, the agreement is between the governor and the Chairman of the Commission. So if, in fact, some health and safety issue has not been addressed, we can go directly to the governor and discuss with the governor what we consider to be a lapse in the regulation. Usually, that is enough to get the regulation passed.

CHAIRMAN CERQUEIRA: Okay, again, maybe I am just being too concerned about something that will work out, but, again, it can be very chaotic out there unless we get very good agreements. So I just kind of wanted to bring that up as an issue.

Ruth, do you think the Agreement States, which are clearly the majority of states now, will pretty much go along with the revised Part 35 and then the revision of the Training and Experience Requirements?

MS. McBURNEY: Yes, I'm pretty sure that they will. For some states the process takes a little longer than it does with others. Some states have to take their rules to a legislative committee; others just to their rulemaking body, which for a health department could be a board of health or a commission, if it is an environmental agency. So the time that it takes to get those rules adopted is going to vary.

I know that the Nuclear Regulatory Commission is training this summer for implementing Part 35, and a lot of the Agreement State personnel are participating in that regional training. It is going to be put on at, I guess, the regional offices, is that right, Lloyd?

MR. BOLLING: That is correct, yes.

MS. McBURNEY: And we have had it brought up at national meetings. So everybody is really aware of the rules and the changes. So it is just a matter of getting it done. It is going to vary from state to state for a while, but I think within that two-to-three-year timeframe you will see them getting them adopted.

CHAIRMAN CERQUEIRA: Well, good, that is reassuring.

Any other comments from the Committee?

(No response.)

Okay, the last thing on the agenda then is the Status of the New ACMUI Appointments and Future Vacancies. John, do you have an update on that?

MR. HICKEY: Yes, I am going to ask Angela Williamson to join us at a microphone just for a moment. I am going to ask Angela to correct me if I'm wrong.

In 2003 the only appointments are people that are eligible for reappointment. There are five of those: Dr. Diamond, Dr. Nag, Ms. Schwartz, Dr. Williamson, and Dr. Vetter. I am not sure, Angela, whether all of them have indicated an interest in reappointment or have we not heard back from some of the people yet?

MS. WILLIAMSON: This is Angela Williamson.

The people that I have a definite commitment to another term from are Dr. Diamond, Dr. Williamson, and Dr. Vetter.

MR. HICKEY: I should point out people are not obligated at this point to indicate whether they are willing to be reappointed, but they will need to indicate that in the future, so that we can arrange the followup by 2003.

CHAIRMAN CERQUEIRA: I think in 2004 I rotate off, and Ruth McBurney will be rotating off.

So I think one of the discussion that we had at the full Committee meeting was to try to do the appointments in a more timely fashion, so we avoid the vacancies. I think we should formally contact all the people that are up for reappointment in 2003 and see if they are interested in being reappointed. If they are not, then we should basically request new appointees for those positions. I guess sometime next year we should sort of do the same for the two people that will be rotating off the following year.

MR. HICKEY: Yes, we agree, and our Directors have indicated their agreement that we need to make sure these things are done with adequate lead

time, so that there is no standing vacancies.

CHAIRMAN CERQUEIRA: Good. Well, I think that pretty much concludes the formal agenda of the Committee. I did say that we would have the opportunity for the public, and there is actually only four people sitting out there in the public here at the NRC headquarters, to make comments.

So, Mr. Uffelman, Bill Uffelman, legal counsel for SNM, wishes to --

MR. UFFELMAN: Never letting a moment to comment on something pass me by, I am Bill Uffelman. I am the General Counsel and Director of Public Affairs for the Society of Nuclear Medicine. Just a couple of nitpicking comments, I suppose, but it is what I get paid for.

Section 35.55, under the Nuclear Pharmacist, the language at the new or what is now (c)(3) I think is inappropriate. The reference to (b)(2) of this section doesn't make any sense anymore. That went back to 35.55 as printed in The Federal Register.

I think what we are trying to say, or what you really want to say because of the rewrite that became (c)(1) and (2) is that (3) needs to say, "listed in (c)(1) and (2) of this section," But

having only spent a few minutes looking at it, I think that is correct.

MS. SCHWARTZ: I think that I understand the comment, and I think it should be (b)(3). I think the issue is the certification or the attestation, which is now in (b) -- or, excuse me, (c)(2). The Supervised Practical Training needs to be attested to by the board-certified nuclear pharmacist. But they are not certifying the didactic training. So it should be just --

MR. UFFELMAN: It should be "Charlie" 2, not "Bravo" 2.

MS. SCHWARTZ: Excuse me?

MR. UFFELMAN: It should be, at least what was handed out here locally, it should be then (c)(2), not (b)(2) because you changed your -- you're in "Charlie," not "Bravo." Okay. I will buy that. I have no problem with that.

MS. SCHWARTZ: That is correct.

MR. UFFELMAN: Okay. Then, I'm sorry, I'm standing up holding all this stuff, and I've got to find the right page before I dump everything.

The training in 35.390, and numerically I think it is 4(g)(1), (2), (3). It was the area where you were talking about the sodium iodide, I-131. I

think that should be "of" rather than "or" in (g)(1) and (g)(2). Otherwise, grammatically, it makes no sense.

MS. SCHWARTZ: Yes.

MR. UFFELMAN: In the beginning, when you were talking about 35.390, I believe it was Dr. Malmud who asked a question about the -- or the question came up as to the three-year residency programs, and the comment was made, "Well, those are grandfathered or the existing ones are grandfathered."

But, in fact, this is the prospective section, so that in fact the ABR program, (b) residency in radiology, or something else with a two-year fellowship, would that, in fact, be covered in (a)(1)? The comment was made, "Well, this was just grandfathered."

I am looking forward prospectively. Are you, in fact, covering all the programs you intend to cover? I know you want to cover them, but did you, in fact, capture that in that language?

DR. WILLIAMSON: This is Jeff Williamson.

I believe that Dr. Uffelman is correct that we should change this to be a minimum three-year residency, including -- "that includes 700 hours of nuclear medicine training," something like that.

DR. MALMUD: But may I suggest that it be a "minimum of three years of residency" rather than a "three-year residency"?

DR. WILLIAMSON: Yes, and then indicate a duration of nuclear medicine training that fits with what was negotiated in previous years, it seems to me would be reasonable.

MR. HICKEY: This is John Hickey.

Could I clarify, are we looking at .390(a)(1)?

MR. UFFELMAN: Correct.

DR. MALMUD: Yes.

MR. UFFELMAN: I think what they want to capture -- ABR's staff representative is here, too. We try and huddle on some of this stuff. They want to capture that a person who has been in a radiology training program which encompasses nuclear medicine is qualified, as is a nuclear medicine physician, or somebody who has done a nuclear medicine residency. Am I correct that's what you are trying to capture?

DR. WILLIAMSON: That was my understanding. This is Jeff Williamson.

DR. VETTER: This is Richard Vetter. That was my understanding as well.

MR. UFFELMAN: So, yes, you do need to fix

the language, whatever the fix is that you want to do.

Other than that, I think we've got everything. We were huddling back here when you were talking about -- and it was a carryforward of the language, but when you look at .590, it says, look at 35.590 in (a) "is certified in radiology" under (a)(1), and then in (a)(2) it says "nuclear medicine by the American Board of Nuclear Medicine." There is no specific reference to nuclear medicine. You know, it is a presumption that nuclear medicine is encompassed in the radiology certification, is that correct?

In an ABR radiology certification, that encompasses nuclear medicine because there is a point back here in one of the other sections where you, in fact, break out and say, "in nuclear medicine by ABR."

MR. LIETO: You mean a special competency -- this is Ralph Lieto -- you mean a special competency in nuclear medicine?

MR. UFFELMAN: Right. Yes, I've got to find the language. I'd better have all the pages flagged here, like I should have.

DR. VETTER: This is Richard Vetter.

My understanding of radiology, it would be old radiology. It is not current diagnostic

radiology. But the old radiology included therapeutic radiology.

MS. FAIROBENT: This is Lynne Fairobent with the American College of Radiology.

Ralph, the question, and I guess Dr. Eggli, the question is, does ABR have a separate certification in nuclear medicine from diagnostic radiology? What's been brought forward is the current language that's in the existing Subpart (j), but my question is, does ABR actually have a separate nuclear medicine certification in addition to the diagnostic radiology certification?

DR. VETTER: No, the diagnostic radiology was special competency, I think is what they have in ABR.

DR. EGGLI: This is Eggli.

It is actually these days called a Certificate of Added Qualification.

MS. FAIROBENT: Okay, and then I guess my question is, do we have to do anything to change to reflect the words that are being proposed in these sections? Because on unnumbered page, but it would be -- Section 35.390(c)(1) states that, "Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section include

the American Board of Nuclear Medicine and the Nuclear Medicine sections of the American Board of Radiology."

So that wording in that particular section on .390 is different than the wording in .190 and .290 and .590.

MR. HICKEY: This is John Hickey.

What is the significance of that difference? What's the concern?

MS. FAIROBENT: My concern is that we don't drop out radiologists who are practicing nuclear medicine.

MR. HICKEY: Okay.

MS. FAIROBENT: Or it is being nuclear medicine physicians certified by the American Board of Nuclear Medicine.

MR. HICKEY: The understanding was that all of these existing board certifications were going to be re-reviewed and determined whether they met certain criteria before they were listed. So at that time a determination would be made whether they are titled correctly. Is that your concern?

MS. FAIROBENT: Well, that and, also, consistent language from one section to the other as you are referring to the board --

MR. HICKEY: Well, it was discussed

earlier that the language needs to be consistent from section to section.

DR. WILLIAMSON: Well, Jeff Williamson, and I think this whole section needs to be rewritten fairly carefully. You know, it seems it would help, first of all, if we put the listing of the boards maybe at the beginning to get that straightened out and then came up with some wordsmithing that gets across the point, which was I think the emphasis, the Subcommittee's consensus was that there should be a three-year residency in something, some field. It just shouldn't be 700 hours of training alone because this is a high-risk modality.

The idea, I think, was the three-year residency in radiology, with the minimum 700 hours of practice in nuclear medicine or certification in radiation oncology, and I guess we would have to maybe break out what the other options would be to make sure we don't leave anyone out. Because the intent was to cover all of the other groups that were allowed to practice this indication, not excluding.

DR. MALMUD: My suggestion -- this is Malmud again -- my suggestion was that we use the term "three years of residency" so that we would not exclude either radiologists who took one year of

training in nuclear beyond their radiology program or nuclear physicians who only had two years of nuclear medicine residency above their basic training in either radiology or medicine or some other field.

DR. WILLIAMSON: Yes.

DR. MALMUD: And that is why I thought the term "three years of residency," rather than a "three-year resident" would rather be prescriptive.

DR. WILLIAMSON: How would you capture the -- or how would you exclude somebody who has a three-year residency in dermatology or something and zero experience or zero significant experience with ionizing radiation medicine?

DR. MALMUD: Don't the requirements for the components of the training program remain, even though they have had as requirements of the three years of training? In other words, are we not requiring that there be some experience within those three years?

DR. NAG: The problem, I think, of the acceptability at three years of residency is that almost every physician has three years of residency. They may be in something closely associated to either radiology and nuclear medicine or radiation oncology. So unless you have those words either "radiotherapy or

nuclear medicine," standards become essentially irrelevant.

DR. WILLIAMSON: All right. Dr. Nag would suggest maybe we put three years of residency in radiation oncology or three years of residency in radiology or a related field that includes at least blah, blah, blah hours of nuclear medicine, imaging experience.

DR. MALMUD: That sounds like an improvement.

CHAIRMAN CERQUEIRA: Well, I think Jeffrey should make these changes and then sort of get them out for comment, so we get full clarification on this, and I guess sort of get all the involved parties to make comment.

DR. WILLIAMSON: Okay, hearing that I am now assigned the task of rewriting of 35.390 --

(Laughter.)

MR. HICKEY: Well, this is John Hickey. Unfortunately, Dr. Diamond had to leave early, but I am sure he would be willing to assist when he's available.

On that point, Dr. Cerqueira, Dr. Vetter, I would ask, do you feel you, with the Subcommittee, are in a position to develop the revised draft?

DR. VETTER: This is Richard Vetter. Yes, I do.

MR. HICKEY: Okay.

CHAIRMAN CERQUEIRA: And we should come up with a timeline on this as well, because this is the 8th, and we really -- Dick, realistically, how long do you think it is going to take your Subcommittee to turn this around?

DR. VETTER: This is Richard Vetter. Well, up until a few minutes ago, I thought we could do it in a couple of days.

(Laughter.)

But now with the potential rewrite of .390 here --

CHAIRMAN CERQUEIRA: Well, what's the Committee's feeling? I mean, I think the issues that have been brought up are -- we don't have David on the line, unfortunately. Jeffrey, what do you think?

DR. WILLIAMSON: I can try to turn it around in a couple of days because later this week the AAPM Annual Meeting starts that I'm going to be unavailable for the next week.

CHAIRMAN CERQUEIRA: I think if we made it a week from today, the 15th, that would be ideal.

DR. VETTER: Sally, are you able to get

your -- this is Richard Vetter -- are you able to get your section to me a week from today?

MS. SCHWARTZ: Yes, I will do that. Actually, I am on vacation this week, but I have my computer with me, so I will contact people I need and I am sure I can have it to you in a week.

DR. VETTER: Okay.

CHAIRMAN CERQUEIRA: So we will aim for the 15th.

Ruth, do you think you could -- you don't have too many revisions on yours.

MS. McBURNEY: This will be pretty simple. I can do that in a couple of days then.

CHAIRMAN CERQUEIRA: So if we did it by the 15th, and then the staff has some verbiage to come up with for some of these things, and --

MS. McBURNEY: So we send them all to Rich again?

DR. VETTER: Yes.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: Yes, and then he would send it around to the staff. When does the staff, if they get everything by the -- Dick, I think your job should basically just be to coordinate and then pass it on.

DR. VETTER: I agree, yes. This is Richard Vetter. If everyone could send me their revisions, I will make sure it all gets incorporated into a single draft, and I will forward that to NRC staff for distribution to the Committee.

DR. NAG: By the way, if when you are doing that you can do it on the edit mode, where you have exact changes on, it is a lot easier to see what was changed, rather than having to go through the entire document.

DR. VETTER: Okay. This is Richard Vetter. Would the Committee like to see it in edit mode?

MR. HICKEY: That means there would be redlines and strikeouts marked on it, correct?

DR. VETTER: That's correct, yes.

DR. NAG: And if you don't like it, you can always turn it off. As you go through the top, you can turn it off.

DR. VETTER: Right.

CHAIRMAN CERQUEIRA: But does the staff, if you get it on the 17th from Dr. Vetter, do you think you could get it out to the people by the 19th of July?

MR. HICKEY: Yes, we would intend to get

it back out the same week. We would like to know from the Committee how long they would like to review it. Again, I suggested that if you want to approve with comments, that could be a type of vote, as opposed to just a straightforward approval or disapproval. Hopefully, there wouldn't be any disapprovals.

CHAIRMAN CERQUEIRA: So if we get everybody to send it over two weeks, or three weekends and two weeks in between, if we go for August the 5th, would that give everyone enough time?

MS. SCHWARTZ: Yes, it would.

DR. VETTER: Yes.

CHAIRMAN CERQUEIRA: Okay, then we could basically, once we have gotten that, we could take the comments and see the level of disagreement, and I guess we could make a decision at that point whether we should send it out for -- if there are substantive disagreements, then we could basically convene another conference call.

Does that sound like a reasonable timeline and game plan on this?

DR. VETTER: Yes, that sounds reasonable.

MS. SCHWARTZ: Yes, it does.

CHAIRMAN CERQUEIRA: Okay. I appreciate Sally's giving up part of her vacation to do this.

(Laughter.)

MS. SCHWARTZ: Thank you.

CHAIRMAN CERQUEIRA: Okay, I have no other -- any new business or any other items that people would like to discuss?

MS. SCHWARTZ: And we will be editing the June 27th, 2002 version in edit mode? Is that correct?

DR. VETTER: That is correct.

CHAIRMAN CERQUEIRA: Right.

DR. WILLIAMSON: Jeff Williamson here.

CHAIRMAN CERQUEIRA: I knew Jeff would have something.

DR. WILLIAMSON: Briefly, for John Hickey, what is the overall process that this document is going to undergo or this effort is going to undergo after the preparation and approval of this document by the ACMUI?

MR. HICKEY: This is John Hickey.

The Commission has asked the staff to provide options prior to the effective date of the rule, prior to October 24th, for their review. That would include the recommendations of the Committee as well as other options identified by the staff, which could include no change. It could include adopt the

ACMUI recommendations, and it could include other options.

So the recommendations of the Committee will be incorporated into that transmittal to the Commission prior to October 24th, but then the Commission will have to review that. It is too early now to try to predict how long it would take for the Commission to decide what they are going to do about this issue.

DR. WILLIAMSON: Is there any opportunity for the ACMUI to have some input or express its opinions about the other option?

MR. HICKEY: We haven't determined that yet, but we can talk more with the Committee and look into that.

DR. WILLIAMSON: I mean, it just would seem to me to be, given how difficult this issue has been, if the Committee could have some kind of a briefing or some opportunity to express its view about the overall white paper that you are going to present to the Commission, including, you know, the other option --

MR. HICKEY: We will look into that. I can't speak for the Commission as to what they want to do, but that is certainly a reasonable request.

DR. WILLIAMSON: This is before it gets to the Commission.

MR. HICKEY: Well, but the Commission has to agree on what the arrangements are.

DR. WILLIAMSON: Well, yes, I understand they have to make a decision and they will or will not consult us, depending on what they want to do, but it sounds like our document is going to be a subset of a larger document that your staff is going to prepare.

MR. HICKEY: That is correct.

DR. WILLIAMSON: So what I'm asking is, do we have any opportunity to express our opinion or views on the other components of the document that are contributed by your staff?

MR. HICKEY: I understand that. I say we have not specifically arranged for that, but we will look into that. But since it is a communication with the Commission, we also have to coordinate that with the Commission, both with respect to the timing and the substance, but we certainly will look into that.

CHAIRMAN CERQUEIRA: And, John, when you tentatively set up a meeting for the ACMUI Committee with the Commissioners on October 28th and 29th, which are a Monday and Tuesday, would we have a time then to discuss this with them?

MR. HICKEY: Well, I don't think that that is a meeting with the Commission. I don't recall -- I think that is the ACMUI meeting, but did we agree that that was going to be a meeting with the Commission? Because you met with the Commission earlier this year. But, again, we could ask if the Commission can meet with the Committee, not just make the written communications.

CHAIRMAN CERQUEIRA: Well, I think what Jeff and some of the other Committee members are suggesting is that it would be appropriate. We have spent a lot of time on this, and we certainly would like to get some feedback as well as have some interaction with these --

MR. HICKEY: But Dr. Williamson is also asking about having prior review and comment, even before this goes to the Commission, but both of those could be arranged, the prior interaction and also a face-to-face meeting with the Commission.

DR. WILLIAMSON: Well, in view of the importance of this to the regulated community, and the conduct of radiation medicine, I think it wouldn't be a bad idea to have -- the more views, I should think the better your report would be, that it would be ultimately to the Commission's advantage to have

additional feedback on the other alternatives that the staff comes up with.

CHAIRMAN CERQUEIRA: So I guess it is the feeling of the Committee and the view from the other people is to basically try to get more feedback to the Commissioners as well as try to meet with them on this specific issue? Is that what people are saying?

DR. WILLIAMSON: I guess I would put it as a form of a motion, if you would like. So that is a motion, that we should have an opportunity to discuss the final report with the Commission and have an opportunity to give some feedback on the report prepared by the staff prior to submission to the Commission.

DR. MALMUD: I'll second that motion.

CHAIRMAN CERQUEIRA: Okay, any further discussion?

(No response.)

All those in favor of the proposal?

Any opposed?

I think it is pretty unanimous, John. It's easy for John to say; he's not going to be here.

Okay, well, I think that ends our business.

MS. SCHWARTZ: Could I ask one thing?

CHAIRMAN CERQUEIRA: Yes.

MS. SCHWARTZ: Could you paginate the document when you send it back?

DR. WILLIAMSON: I will do that.

MS. SCHWARTZ: Thank you.

DR. WILLIAMSON: Sure.

CHAIRMAN CERQUEIRA: I would like to thank the committee for excellent work, and our minimalist audience out here. Thank you.

(Whereupon, the foregoing matter went off the record at 3:36 p.m.)