Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes: OPEN SESSION

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Thursday, October 14, 2004

Work Order No.: NRC-024 Pages 1-287

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

MEETING

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

+ + + + +

OPEN SESSION

+ + + + +

THURSDAY

OCTOBER 14, 2004

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The meeting came to order at 8:00 a.m. in Room T-2B3 of Two White Flint North, Leon S. Malmud, M.D., Chair, presiding.

COMMITTEE MEMBERS:

LEON S. MALMUD	Chairman
EDGAR D. BAILEY	Member
DAVID DIAMOND, M.D.	Member
DOUGLAS F. EGGLI, M.D.	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member
SALLY W. SCHWARZ, RPh	Member

COMMITTEE MEMBERS: (CONT.)

ORHAN H. SULEIMAN, Ph.D.	Member
WILLIAM VAN DECKER, M.D.	Member
RICHARD J. VETTER, Ph.D.	Member
JEFFREY WILLIAMSON, Ph.D.	Member

NRC STAFF PRESENT:

THOMAS H. ESSIG	Designated Federal Official
Linda M. Gersey	NMSS/IMNS
Patricia K. Holahan, Ph.D.	NMSS/IMNS
Merri Horn	NMSS/IMNS
John Jankovich	NMSS/IMNS
Charles L. Miller Ph.D.	NMSS/IMNS
John Szabo, Esq.	OGC
Sami Sherbini, Ph.D.	NMSS/IMNS
Sandra Wastler	NMSS/IMNS
Angela R. McIntosh	NMSS/IMNS
Ronald E. Zelac, Ph.D.	NMSS/IMNS

I-N-D-E-X

P R O C E E D I N G S

(8:05 a.m.)

CHAIRMAN MALMUD: Good morning, ladies and gentlemen. We would like to get started so that we complete today's full agenda on time. There'll be a slight change in the program, and Mr. Essig will begin first with some administrative issues. Tom.

MR. ESSIG: Just a couple of follow-up items from yesterday. One is, there was a question asked on the ACMUI Member Handbook, and I believe it was Ralph Lieto that had asked the question about special government employees. We touched base with John Szabo from our Office of General Counsel, and his response is as follows; as to the member's question, ACMUI members are considered special government employees throughout their tenure and are subject to federal laws and regulations for special government employees. And then he goes on to say, which is, I believe, what you thought was the answer anyway, so we should clarify the handbook so that it just doesn't read only when you're attending meetings and that sort of thing. It's during the term of your appointment to the committee.

And then he goes on to say what is relevant is that when they are not performing services

for the ACMUI, the member should not use their ACMUI title or membership for any non-NRC purpose, unless authorized; such as, using your ACMUI position to benefit others. That was his response, and hopefully that clarifies that matter. But I believe -- my thought was we kind of suspected that was going to be his response anyway, but this clarifies the issue.

A second administrative matter was yesterday when we were talking about the nuclear materials events database, and I believe Mr. Lieto asked the broader question about searching of the database and looking at these -- event information that wouldn't strictly be a medical event, but it would be something that had a clear connection to a medical event; such as, a leaking radiopharmaceutical package and that sort of thing.

My response would be yes, that would be worthy of also looking at those events. I would remind the members that they all have access to NMED, and I sensed from the discussion yesterday that if Mr. Lieto, and perhaps others, would be interested in doing some systematic searches of NMED to ferret out information of that type - namely, maybe a transportation event or a leaking package and what might be the trends there, I think that information

would be certainly valuable.

I have two of my staff here in the audience, Michelle Burgess - if Michelle would wave her hand. She is in the blue over there on the left. She is the NMED Project Manager, and any questions that any of the members would have about either access or how do I navigate once I get in NMED, she would be happy to sit down with you on the telephone and walk you through NMED. Her extension is 5868, so that would be (301) 415-5868. And also, another member of my staff who is knowledgeable in NMED is Ivelisse Cabrera. Ivelisse, if you'd raise your hand. She's sitting next to Michelle, and her extension is 8152. And so either one would be available to help any of the members navigate through NMED.

I think we might even consider, Mr. Chairman, if you're agreeable, that since Mr. Lieto expressed an interest in NMED, if he might want to do some sort of pilot searches, if you will, and use that as maybe feedback to the committee, and it might help structure some of the committee's review of the medical events to looking at some of these related events, and then maybe even looking at the medical events that were included in your package. So with your okay, I would suggest Mr. Lieto being --

CHAIRMAN MALMUD: If he has some time --

MR. ESSIG: I sensed the okay was already given yesterday when he broached the subject, but I didn't want to be too presumptuous.

And it seemed like there was a third matter, but it will occur to me later, so I think that takes care of the administrative items that I wanted. I'm sorry. Charlie has one.

MR. MILLER: Yes. I had the occasion to talk to Szabo this morning also. I ran into him, and I specifically focused on the question that was raised by you, Dave, concerning the travel. I think Tom's answer with regard to the periods, during your whole appointment period you're governed by that 24/7. He said he doesn't necessarily agree with the law, but we're bound to uphold it. So again, if you have any questions, feel free at any time to give any of us a call, or John Szabo directly. He's more than willing always to answer any kinds of calls of that nature.

CHAIRMAN MALMUD: Thank you. And the next item on the agenda is the presentation of the final draft 10 CFR 35 T&E by Dr. Broseus.

DR. BROSEUS: Thank you all for having me. I want to lead off very quickly, have as short as possible presentation so you all will have plenty of

time to discuss any issues that you might want to bring to our attention with regard to rule making. Let me just briefly go through the status of where we're at.

The proposed rule, as you know, was published on December 9th for a 75-day comment period, which ended on February 23rd. Since that time, the staff has been in the process to resolving comments from the public, including the advisory committee, the agreement states, and so on.

The draft final rule is now out for 30-day comment by agreement states, and by the ACMUI. We're doing this in parallel to keep things moving as quickly as possible. The formal ending of the 30-day comment period is October 18th.

As I go through my presentation, I'd like to emphasize that I'm discussing the staff's approach to the rule making. The issues before us are staff discussion, and approval of our final recommendation with the Nuclear Regulatory Commission's commissioners.

Very quickly, as most of you know, I just want to remind you that Subpart J, which was due to expire this October, the staff published on September 16th an extension of the effective date for Subpart J

to October 24th, 2005. The reference to the *Federal Register* announcement is in your slides, if you need it. This is going to allow time for a board to apply for recognition of board certifications under the forthcoming revisions to Part 35.

Let me briefly go through some of the examples of key comments that we have on the proposed rule. This is not meant to be an exhaustive listing of the comments, by the way, but to pull out some examples. The handout materials that were provided in advance, including the rule making package, has a detailed summary of the comments.

The first one that I'd like to mention is a preceptor's comment that they should not be required to attest to a candidate passing a board administered exam, and on the use of the word "attest" versus "certify" in preceptor statements. The staff believes that the second comment is a good one. I meant to say to the first one, and we'll go back to that in a moment. That our final draft rule substitutes attest or attestation for certify and certification in the requirements for preceptor statements.

We feel that the comments that we received from ACMUI and the public are valid in that regard. And also, removes a little bit of ambiguity about what

is certified versus attest. We have board certifications and attestations as preceptors.

The next slide --

MEMBER NAG: I have a question about the first part.

DR. BROSEUS: Sure. Yes, I'm coming back to that right now.

MEMBER NAG: Okay.

DR. BROSEUS: Okay. An example of the first one was flagged by commentors in proposed rule 35.390C, in which it appeared to apply - in fact, the words did say that a preceptor would be attesting to all of the requirements for board certification, including the examination. And the staff agrees that it's inappropriate to ask a preceptor to attest to a passing of an exam. That's part of what a certification is about, and so our draft final rule, which you all had distributed to you, had that requirement removed and reworded that. We also sought comments on that, not just from ACMUI, but other members of the public.

There also was a comment by ACMUI and members of the public to allow for the authorization of radiation oncologists who complete residency programs under 390. One of the big issues here, I

believe, for ACMUI and others was to make sure that oncologists who are now able to perform therapies for which a written directive is required, using material for which a written directive is required, continue to have that ability. They qualify under Subpart J, but many of them do not qualify under what we have in the proposed rule.

We took this into account and developed a new Section 396, which provides for well-trained oncologists to have an avenue to be approved for uses under 390. A key requirement that we have in there is to make sure that there's training and experience for use of unsealed sources, unsealed byproduct material.

MEMBER NAG: May I?

DR. BROSEUS: Sure.

MEMBER NAG: You're saying the preceptor should not be required to attest to candidate passing board exam would be fine; however, this will contradict your 396 because you are going to have someone who became board certified, but may not have had the 80 hours or may not have had a preceptor for the unsealed source, and may require a separate unsealed source preceptor.

DR. BROSEUS: That's okay.

MEMBER NAG: But then you're saying

preceptor should not be allowed to attest candidate passing board exam. Isn't that contradictory then?

DR. BROSEUS: The requirements -- there's several conditions of 396, and I'd urge you to look through them. But one of the key ones is that if an individual is certified by a board for the other sections where therapy has been done, the sealed sources, brachytherapy or the high dose rate units - if they are board certified and have the T&E for unsealed sources, then they may be approved.

We can go back and look and make sure that we haven't built in something that isn't appropriate. If you have a particular observation, I'll make a little note and get back to you.

MEMBER NAG: No. If you go back to your previous slide, and if you look at that, in 396 you really need the preceptor to certify that three unsealed source, but here you are saying you are not required to attest for a candidate passing board exam. So if someone would pass board exam but needs an additional attestation --

DR. BROSEUS: I understand.

MEMBER NAG: So you need to be careful how you word that sentence, because otherwise you are going to contradict yourself.

DR. BROSEUS: So your comment is to make sure that we're not requiring unnecessary attestation, and just attestation to the training and experience for unsealed sources. Is that correct?

MEMBER NAG: No. I think I'm trying to say that the wording should be such that you don't contradict yourself. I mean, your meaning is -- they are well-meant, but the wording can be contradictory. That's all I'm saying.

DR. BROSEUS: Okay. Thank you. We'll note that.

CHAIRMAN MALMUD: WE also have a comment from the public.

MS. FAIROBENT: Thank you, Dr. Malmud. My name is Lynne Fairobent with the American Association of Physicists. Dr. Nag, the origin of the comment that generated I'm sure this first bullet on Roger's behalf had to do with the fact that when a preceptor is going to sign the preceptor statement, the individual may actually have not completed the board exam process. And, therefore, asking the preceptor to attest that the individual has passed the exam was premature, so that was the origin of that.

MEMBER NAG: I know the origin, but the way it is put, it can become contradictory, and I'm

trying to say before it becomes contradictory, you need a preventative measure. I know what the objective is and what it is meant to say, but the wording may not be what is really meant to say.

DR. BROSEUS: Okay. Thanks for the observation. We'll go back and look at that again.

CHAIRMAN MALMUD: Roger.

DR. BROSEUS: Dr. Malmud, there's somebody --

CHAIRMAN MALMUD: Oh, Dr. Zelac.

DR. ZELAC: I'd just like to comment that if my understanding of what 396 preceptor is attesting to is simply the additional number of hours of unsealed material training that the individual has undergone, period. The individual who would be applying for authorization would, in addition to that preceptor statement, submit either a copy of their board certification, for which no additional attestation would be required. Is that correct, Roger?

DR. BROSEUS: Yes. I'm re-reading our draft right now, and I believe that the concern that Dr. Nag expressed is not there. However, I would encourage you that if you see something there that we haven't seen, to annotate it and call it to our

attention because we want to have a rule that's out there that's clear and understandable, and is not internally contradictory. Okay. So thank you for looking at this very closely.

CHAIRMAN MALMUD: Roger, may I ask for a concrete example. Let's say that there is a radiation oncologist, board certified, who now wishes to use unsealed sources, but did not have experience in unsealed sources during his or her residency training. How many hours of training does that individual require be attested to?

DR. BROSEUS: Under 396, it's 80 hours.

CHAIRMAN MALMUD: Eighty hours.

DR. BROSEUS: Yes.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: Yes, I have some questions too about the meaning of 396. This is meant to apply for any radionuclide and form of administration other than oral. Is that the correct --

DR. BROSEUS: It's written for parenteral administration.

MEMBER WILLIAMSON: Which means what in the NRC?

DR. BROSEUS: I'd go back and look at the dictionary, but I believe it means administration by injection. It's not oral.

MEMBER WILLIAMSON: So it would cover, for example, installation of P-32 radiochromic --

(Simultaneous speech.)

DR. BROSEUS: We didn't say intravascularly. We didn't say venous or anything like that. We used parenteral. My understanding parenteral would include like --

CHAIRMAN MALMUD: I believe parenteral is anything except oral.

DR. BROSEUS: That's how I would interpret it, yes.

MEMBER WILLIAMSON: And so if the -- is this to be done on a radionuclide by radionuclide basis, or if, for example, a radiation oncologist qualifies for say P-32 intra abdominal installation, and then subsequently wants to do Zevelin or something else - is there a need for the individual to do anything else, or is this actually --

DR. BROSEUS: The rule doesn't say that. The rule says -- it doesn't name a radionuclide, and the intent in Part 35 now is to have more general rules that cover broader aspects. You shouldn't have

to come in for a license amendment if somebody -- you know, I could conceive of circumstances where that might be, but that's not the intent of the rule. The intent of the rule doesn't say for P-32 or abdominal sitees or whatever. It isn't narrow, it's broad, for which a written directive is required for parenteral administration, period.

MEMBER WILLIAMSON: And I guess then that a radiation oncologist then by complying with 396 and getting 80 hours of training and experience, and then doing what is it - 392 for thyroid radioiodine treatment? Is it 392 or 394?

MEMBER EGGLI: Depending on whether you're doing a benign or malignant -- 394 is malignant.

MEMBER WILLIAMSON: So then by -- or if they wanted to do 392, as well, then three times 80 hours and they would be able to have the equivalent authorization, authorized user privileges as --

MEMBER EGGLI: It would be three times 80 hours.

MEMBER WILLIAMSON: Okay. That was going to be my follow-up question, is that for multiple -- how would you handle the case where a physician wanted to do both radio Iodine and more general radionuclide therapy - would you want just one 80-hour training?

DR. BROSEUS: It sounds like it's coming under --

MEMBER WILLIAMSON: Yes.

DR. BROSEUS: -- now if it's really broad. It depends upon what the particular application is. I could foresee using material that would fall under the requirements for 396, and if they wanted to do a certain level of activity with I-131, they'd have to meet 392 or 394.

MEMBER WILLIAMSON: Yes. So that would be another 80 hours, or could the same 80 hours be used, and effectively the additional requirement for the radiation oncologist would be to have three supervised radio Iodine treatments for thyroid carcinoma?

DR. BROSEUS: Well, the requirements for case experience are in there, and so if a person didn't have the case experience required for 392, they would have to pick that up.

MEMBER WILLIAMSON: But they wouldn't need an additional 80 hours of training and experience.

DR. BROSEUS: That's not the intent of the working group.

MEMBER WILLIAMSON: What is the intent of the -- in terms of trying to qualify for multiple authorized user privileges.

DR. BROSEUS: Well, I think the intent is for an individual who is using byproduct material for which a written directive is required, to have experience with unsealed sources for which a written directive is required. So they're aware of the safety requirements, the hazards, the cautions associated with these higher levels of activity, so if they have a spill or whatever, that they could take care of it. Think about this for a moment. Sometimes a physician is his own radiation safety officer, or her own radiation safety officer. It isn't to require 240 hours. It's to have an appropriate amount of training and experience for the type of use you're going for. And it doesn't say P-32 and 396. Okay.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: To qualify under 396, I don't remember -- I don't have it in front of me. Do you have to be a 400 or higher authorized user to qualify for unsealed sources?

DR. BROSEUS: You don't have to be authorized in the other types of uses.

MEMBER EGGLI: Okay. Because --

DR. BROSEUS: What it does do is admit, if a person is board certified for those types of uses, they may use that board certification as evidence of

their T&E.

MEMBER EGGLI: But one of the issues though is, there are only two kinds of administration, basically. There's oral administration and parenteral administration, and if I can come in under 394 and 396, I can do 80 hours of training, and I can bag the 700 hours in Part 300, so why the heck would I ever want to worry about Part 300, because I can circumvent Part 300 all together by doing 392, 394, and 396. I've got everything available under Part 390.

MEMBER WILLIAMSON: May we should multiply the 80 times --

MEMBER EGGLI: No, I'm not trying to suggest that. But I think there's a potential inconsistency there. And if you limited 396 to those who are certified at 400 or higher, then I have no problem with 396.

DR. BROSEUS: I'm sorry. Would you repeat what you just said.

MEMBER EGGLI: To qualify to use unsealed sources under 396, if you have to be an authorized user of 400 or 600, then I have no problem with 396. But if anybody can go an 80-hour pathway and get into 396 without being an authorized user in 400 or 600, then I have a problem.

CHAIRMAN MALMUD: But you have to be board certified.

MS. CHIDAKEL: If I could clarify; now this is a technical discussion. I know this is a technical discussion.

CHAIRMAN MALMUD: Would you please introduce yourself.

MS. CHIDAKEL: I'm Susan Chidakel. I'm the Office of General Counsel Senior Attorney. I don't know if you all have the draft final rule in front of you or not, but if you will look at the draft final rule, it says that the licensee shall require an authorized user for the administration requiring a written directive to be a physician who is an authorized user under 490, 690, or before October 24th, 2005, 940 or 960, or certified by a medical specialty board whose certification process has been recognized under 490, 690, or before October 24th, 940 or 960. So I don't know if this answers your question. And then in addition, has completed these 80 hours and so forth. I don't know if this resolves your question or not.

MEMBER EGGLI: It does. Thank you.

DR. BROSEUS: I think we're covered here, because there is not an alternate pathway also.

MEMBER EGGLI: Okay. I'm happy with that.

DR. BROSEUS: Okay. Great. But thank you for attending to that, because that's something I don't believe we necessarily thought about in the working group.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I think it's an excellent idea doing this 396, and resolves a lot of the complexity and arguments that we've had over the 390. The only suggestion I would make to you to consider is to fold into this a parallel definition of acceptable board certification, on the assumption that the American Board of Radiology will eventually adapt and require the 80-hours and three cases as part of the certification process in the future, so that then the additional requirements --

DR. BROSEUS: Well, if ABR has certification recognized for the other uses and a person comes in with 80 hours, they would meet the requirements of 396, so I think there's sufficient there now. Now they could add 80 hours and create a new certification, but 396 does not need a new certification. There's not a new certification.

MEMBER WILLIAMSON: Yes, I understand that. I'm suggesting you could potentially structure

396 to be the same as the other rules, which would have both an alternate pathway and a board certification pathway, which would then, at that point if and when American Board of Radiology adapts and makes it clear that --

MEMBER EGGLI: I think the American Board of Radiology intends that it's diplomats should be certifiable for all 390 uses.

MEMBER WILLIAMSON: That's my understanding, as well.

CHAIRMAN MALMUD: May I suggest, in listening to all these questions, that it might be most useful if there were a spreadsheet which had matrices in it, including certification by the American Board of Radiology, the American Board of Physicists in Medicine, the American Board of Nuclear Medicine, the American Board of Radiation Oncology, and the American Boards of other specialties in one column, indicating what the requirements are for those individuals to achieve satisfactory compliance with NRC regulations for the performance of tests involving unsealed sources, so that it would be very clear to any user what his or her requirements are, because if this committee, which has worked on it with you for months, if not years, remains confused, the public-at-

large, particularly the users, are going to be extraordinarily confused. And it doesn't seem to be clear yet to us as a group, as to what the requirements are going to be for individuals who will have completed training by October, who will complete training after October, and what the additive numbers are, though you've clarified an issue certainly for us this morning.

I think a spreadsheet would be most useful, and that would be something that anyone could look at and say well, this individual qualifies. I'm not speaking about the credentialing process in the hospital. That's separate. I'm talking about NRC, satisfying NRC regulations.

DR. BROSEUS: I think I would refer that to our Material Safety and Inspection Branch for consideration in developing guidance with the rule. I think at the point we're at, to develop something at this point, we're trying to get this rule out so these things will be in place, but I think a potentially good suggestion for explaining things and how the rule works, and so I would expect the MSIB to take this under advisement as a suggestion. There's been a hand back here for quite some time.

CHAIRMAN MALMUD: Yes, I'm sorry. Could

you introduce yourself, please.

MR. MOORE: Yes, sir. Dr. Malmud, I'm Scott Moore. I'm the Chief of the Rulemaking and Guidance Branch. I'm Tom's counterpart. We can certainly work towards getting such a spreadsheet, but as Roger just noted, I don't think we would be able to provide that within the time period that we're asking for comments back from the ACMUI.

We put this item on the agenda primarily so that the ACMUI can prepare comments back to us within the time period that we need them, and have asked you for them, which is October 18th.

I just heard Dr. Williamson make a suggestion to us with regard, I believe, to 396. What we really need for the ACMUI to do is to make those suggestions to us as a body in writing, and we have another hour and a half for you all on the agenda to prepare such comments in writing to us to work together as a group, to decide what you want to make in comments back to us, the agency, if you want to make any such comments on the draft final rule.

Within our time frame, we're asking for the agreement state comments back by the 18th, and for us to stay on schedule, we need the advisory committee comments back also by the 18th. We can continue to

provide comments throughout the next hour and a half and discuss the rule, but I do need to let you all know that we need the ACMUI's comments to go forward, and that's the time schedule that we're working against.

CHAIRMAN MALMUD: So you need comments by the end of today.

MR. MOORE: We need them back by the 18th, sir.

CHAIRMAN MALMUD: Dr. Diamond, I think you were next, and then Mr. Lieto.

MEMBER DIAMOND: Ladies and gentlemen, obviously what we have here are some very substantive changes in the regulations, and in this pre-decisional material, as you can clearly see, even we as very experienced members who have been working with those regulations, I've been involved for six years myself. I think Dr. Williamson for nine years. There are very important questions related to how the regulations are being interpreted. There's absolutely now way it is appropriate for us to come to a consensus opinion for you by October the 18th, absolutely no way whatsoever.

What ought to be done is that these pre-decisional regulations ought to be released to the stakeholders, to the public, at this time, so that

everyone can take a look at them. Good guidance is not to supplant bad rulemaking, and I think we need to get this out to the stakeholders. These are very substantive changes.

My understanding, for example, is that a radiation oncologist in practice who's currently not licensed to, for example, use some of these materials, will not be grandfathered if he or she wishes to use, let's say Zevelin radio immuno therapy in the future without going through a fairly proscriptive set of tasks. And I think that in the grand scheme of things, we have lost our main focus.

When this process started several years ago, one of the key elements was that we all agreed that board certification would be the default pathway to authorized user status. Now we're learning that because of the way the hours are enumerated, that board certification in radiation oncology, for example, by the American Board of Radiology would not necessarily accomplish that task because of how the 700 hours are accomplished.

We had Donna-Beth yesterday tell us that we needed 700 hours of classroom laboratory experience - to paraphrase - exclusively and specifically related to unsealed radio isotope material. My question to

her is what are you going to talk about for 700 hours in classroom laboratory exclusively related to that. It makes no sense at all to me. And the point related to that is it's a different interpretation of how you're counting hours that now leads some members of the staff to say that the ABR Boards in Radiation Oncology or not satisfying the requirements and, therefore, we need to create this new 396. So as you see, gentlemen and ladies, I have some serious issues with the substantive and interpretive changes that we see before us. And I believe the correct approach is to release this pre-decisional material to the public for public comment. And after discussion, I'd be happy to make a motion to that effect.

CHAIRMAN MALMUD: Thank you, Dr. Diamond. Mr. Bailey. Excuse me. Mr. Lieto was waiting in line.

MEMBER LIETO: I have two comments, one a general question. At the teleconference, I believe that one of the committee members had requested that we have before us a version of the proposed rules redlined, strikeout, underlined edition-type document so that we could see where the changes were in relationship to what had been proposed from last year. Has that been made available, or is that available?

MR. MOORE: I could address that. The request at the teleconference was wherein the draft rule was issued in final that a redlined strikeout be prepared at that time.

MEMBER LIETO: No, that was not the understanding I think at the teleconference. I'd be glad if board members here --

MR. MOORE: I disagree with you.

MEMBER LIETO: Well, I guess I'd like to ask the committee members, because that's been one of the biggest problems in coming before this group, is that we get this document which is what's supposed to go to the *Federal Register*, and we have repeatedly said that it's very difficult to look at things out of context with a specific rule, and that in order to understand all the nuances that go into the changes that the working group is recommending, especially with these changes of 396 and some of these other things regarding grandfathering and so forth, it's very important for us to understand what the working group is intending to put in there, and be sure that our understanding is correct. It's just plain difficult to look at it through this part, and just like happened a little bit earlier. There was a misunderstanding about what the working group was

intending or has put in there versus what the committee members have.

I've been on here through this T&E, and this has been a request repeatedly from committee members. And if I'm wrong, I'd like one of the committee members to let me know, but that's one of the things that I think really would aid. I would heartily support Dr. Diamond's statement about the realization that we're going to go through all these changes in an hour and a half, come to a consensus for the NRC working group, I think is really unrealistic. And I think a lot of committee members that I've talked to didn't even recognize the October 18th deadline. Okay. That that was going to be the expectation, that we're going to spend less than two hours, come out with a consensus document over all these changes, and then walk out of here with this is what the ACMUI wants to do, I think is a little unrealistic; especially not having a good working document to work from.

CHAIRMAN MALMUD: Thank you, Mr. Lieto. The next was Mr. Bailey.

MEMBER BAILEY: Yes. I'm not sure that ACMUI is aware that the Organization of Agreement States has petitioned the NRC on this very item, and

this petition has now been accepted. And it seems that assuming that NRC will take the petition with some seriousness, that were going to end up in another rulemaking process almost immediately.

The agreement states, all of them signed off that they wanted this petition, that they're not happy with the way the current rule is written with regard to T&E. It may not be -- the agreement states may not agree with the physician members on T&E, but at least we think it needs to be clear, and it needs to be based on some sort of information, some value judgments on really how many hours. It was asked, how do you spend 700 hours? I personally do not know.

We have begun to look at what is the rationale for the number of hours being required, and for which groups? And I think maybe it's totally premature to go forward with this rule at this time until we have had more comment.

MS. CHIDAKEL: Excuse me, if I may interject here.

CHAIRMAN MALMUD: This is Susan Chidakel.

MS. CHIDAKEL: Yes. I wanted to sort of clarify and sort of focus on what we're doing here, if I may, from my perspective.

The rule did go out for comment to the

public, the proposed rule, with major changes went out for comment and was published in the *Federal Register*, and we have received the comments back, so the public did have an initial comment period to review the major changes of the T&E.

The main thing that is changing now with our draft final rule is in response to the comment that we should have a breakdown of the hours, a specification of division up of the, say for example, 700 hours between on the one hand classroom and laboratory, on the other hand work experience. So this is the main thing, and I do believe this is the main thing that we need ACMUI's input on right now, because the other changes, while there have been changes made in this draft final rule, I think the majority of the basis of the rule as it was, the proposed rule basically was essentially very similar to what we are coming out with now with the draft final rule, with the exception of this hour issue.

Now with regard to the hour issue, bear in mind that we not affecting the board certification pathway. We are not breaking down the hours between classroom and laboratory and work experience with regard to board certification. The proposal for the breakdown of the hours goes only to the alternate

pathway. And I think is what we - excuse me, I see someone shaking his head. Do you disagree with what I've said?

MEMBER NAG: Yes.

MS. CHIDAKEL: Please.

CHAIRMAN MALMUD: This is Dr. Nag.

MS. CHIDAKEL: Well, basically that was the emphasis that I wanted to put on this, and we do need ACMUI's input on that particular issue, in particular. That is the whole point and the whole focus, as I see it, of our discussion this morning, so that I want to make sure that we're not going to go into all other directions and not resolve this issue, because the rest of the rule did go out, like I said, for public comment with the exception of the 396. This is true, that was added, and other changes that I consider were relatively minor, but the main change, and the main thing we need ACMUI to look at is the division over the hours. And again, bear in mind the division of the hours only goes to the alternate pathway, does not go to the board certification.

CHAIRMAN MALMUD: If you'd remain at the microphone.

MS. CHIDAKEL: Sure.

CHAIRMAN MALMUD: The issue that both Dr.

Nag and Dr. Eggli are going to raise, I believe, is this; the board certification pathway is not independent of the alternate pathway since if an individual does not pass his boards at first taking, that individual will have to have documented that the individual received a certain number of hours of training in the course of preparation for the board certification; that is, during the residency program. Therefore, the residency program must include the requirements of the alternate pathway, or the individual physician will not be able to meet NRC standards.

MS. CHIDAKEL: The individual always, of course, has the option to do the alternate pathway. Let me just -- I don't want to be facetious.

CHAIRMAN MALMUD: Excuse me. You are incorrect, if I may say so. The individual does not have the option of the alternate pathway when in the course of his residency training, where he fully expects to become certified within a year or so of completing the residency, those requirements were not met by the residency because though the current regulations indicate that only the alternate pathway must have the numerical requirements, the residency will not have prepared the individual unless the

residency meets the alternate pathway requirements.

MS. CHIDAKEL: I understand. I understand what you're saying. I did hear the same argument during the telecon.

CHAIRMAN MALMUD: It's not argument, it's a fact.

MS. CHIDAKEL: And I understand -- well, forgive me, I'm sorry. We're talking about semantics here. I understand the discussion. I understand the point that you are making.

If I may, and I'm not trying to be facetious or anything else on this issue - while I understand the problem, this is not a problem that's unique to the medical profession, frankly speaking. I'm an attorney. I went all through law school. I took four years, or 3-1/2 years, or three years of whatever it was to go through law school and meet all of these tough requirements and pass my law school exam. If I don't pass my bar, I have the same problem, so that this is - you're shaking your head, but it's true. I cannot practice law really before a court if I'm not bar certified, which is essentially the same thing as being board certified.

MEMBER EGGLI: That's wrong. There are boards who don't allow their candidates to take the

exam until they've been in practice for more than a year.

MEMBER DIAMOND: Under the new requirements for radiation oncology, radiation oncology residents who graduate their programs, they will take their written boards in the fall after they finish training. And if they pass that, they will take in the spring, following completion of training, the oral boards; thus, for a person who has completed training on schedule, has completed the examinations and passed them sequentially, one will not be board certified for essentially four years, so every single resident coming out of training will not be board certified for a minimum of one year, and during the first year of practice by default would have to fall under the alternate pathway.

MS. CHIDAKEL: I understand. I see what you're saying.

MEMBER DIAMOND: And because of the way we are enumerating these hours with the 700 being specifically and exclusively devoted to the unsealed radioisotopes which makes no sense to me, there's going to be --

MS. CHIDAKEL: This problem -- this was never -- I never heard this problem explained before.

What I heard in the telecon was the idea that people would be failing their boards and, therefore, would be out of luck. I never heard this discussion --

MEMBER DIAMOND: The other issue, just for your information again - this is not the world in which you function - is the boards set failure rates that unfortunately are probably artificially high, and they do that for a number of reasons. The failure rate for the Part 1 Written Boards is somewhere around 30 percent, so you have some very, very highly educated well-trained people that are failing simply to meet the criteria of the curves. The fail rates for the orals - Subir, what do you think - they are probably around the same?

MEMBER NAG: Thirty percent.

MEMBER DIAMOND: So you're talking about large numbers of extremely qualified people who are not passing on their first go-around. There's really no stigma associated with it. It's kind of the way the game is played.

MS. CHIDAKEL: Let me see if I can understand your position then. Are you saying that you don't feel there should be any change as far as specification of hours, either in the alternate pathway or the board certification path?

MEMBER DIAMOND: I think the main issues, if I may, are that -- my sense is that the NRC staff is interpreting the enumeration of hours differently. And based upon that different interpretation, the American Board of Radiology for Radiation Oncology certification would not meet all the requirements that are being enumerated and, therefore, we're falling into this alternate pathway problem. That's number one.

Number two, all of the residents coming out of training now will not be board certified for at least a year and, therefore, will all fall into the alternate pathway matrix.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Okay. I do have a few comments. Although this was out for public comments a couple of weeks ago, this was not conveyed to the ACMUI, so the ACMUI has not had a chance to look at it in detail. One thing would have helped would have been an email that this is being out and have that sent to us. But one of the things is that next month, I am giving on how do you get certified. And because of that specific reason, I had to talk with NRC officials to gain some of the insight and, therefore, I do have a little insight because of that. But the

ACMUI members have not had that chance for the interaction, so I do support Dr. Diamond's proposal that we be given more time to be able to analyze and understand this. We could do it, perhaps, as a subcommittee or any other way you need a two week notice, because otherwise you will not have a chance to discuss this among ourselves.

With this alternate pathway of 396, a board certified radiation oncologist can become an authorized user of the 390 requirement, but will require 80 hours of unsealed sources extra. Now the board at the moment is not requiring that 80 hours, but once it does, it will solve the problem. I think one of the problems you are seeing right now of making a spreadsheet is that the board requirements are changing, and they have not finalized what the exact requirements are, because of this situation. The NRC is making some of these requirements, and then the board has now to see whether it can meet these requirements. For, for example, right now the American Board of Radiology does not require a separate 80-hour as noted, although it may be incorporated as part of the program in many of the programs. Now the board has to make a separate decision whether they are going to make that 80-hours

incorporated within that training program. So at the moment, we can't even make a spreadsheet. So I think with all of the confusion going on, I do support Dr. Diamond's proposal.

MR. MOORE: Dr. Malmud.

CHAIRMAN MALMUD: Who just said Dr. Malmud?

MR. MOORE: I did.

CHAIRMAN MALMUD: Okay.

MR. MOORE: This is Scott Moore. Dr. Nag just recommended that an email would have helped. I'd like to point out that Sandy Wastler did send an email. We have a 30-day comment period for agreement states and ACMUI built into the rulemaking process to comment on rules. We have a very tight deadline for complex rules, and this is certainly one of them.

Sandy sent out an email to all members of the ACMUI at the start of the 30-day comment period. The 30-day comment period ends on October 18th, and it was sent to agreement states at the same time. Each of you received an email from Sandy at the start of the 30-day comment period, and we asked for comments back from the ACMUI at the end of the 30-days, which is October 18th. So in response to what Dr. Nag just brought up, we did send the email.

CHAIRMAN MALMUD: I think Dr. Broseus was next.

DR. BROSEUS: I have a couple of observations. One of them is sort of parallel to Scott's, but not quite the same. The working group feels a tug both ways, but we feel it's very important to get this rule out as soon as possible. And if the rule were reopened for public comments, that would cause quite a lengthy delay in getting this rule on the books, and getting stability into the regulation in this particular area.

The second observation is that I believe if we come back and focus on some of the key elements here, that it is possible to move forward productively. 396, if it were in redline, in a redline strikeout, will all be redlined because it's new. And I have a copy here which I can circulate to people - in fact, I'll pass it around. Dr. Nag asked for this yesterday, but if you could bring questions you have to me about these particular areas, I think we could focus on them.

One of the comments that Dr. Diamond made related to the interpretation of the 700 hours, and differing messages that you received from the staff. I've tousled with those very issues when we were

developing guidance in 2002 before the current rule was issued, and so my own personal opinion is that a comment coming back from ACMUI that recognizes that and calls that to our attention, we can go back and look at it in the supplementary information how to address these differing views and clarify them because the steady message has been from the NRC, and the people developing the rule and the guidance that are guiding this forward is to have reasonable rule, have it clear, and not have different interpretations that cause problems.

So once again, I would just say anything that we can come out of this meeting with about October 18th that would move this forward is important because it may be the Commission would not grant us the privilege of extending the rule if that were a recommendation in order to go forward. Thank you.

CHAIRMAN MALMUD: I think Dr. Williamson was next.

MEMBER WILLIAMSON: I think maybe with regard to Dr. Diamond's suggestion, we need to think through the different parts of the rule, 100, 200, 300, 400, and 600, and ask the question for radiation oncology and other boards potentially, too, if the number of hours of training and experience in the

alternate pathway is a problem. So if one looks at the 490, the alternate pathway for brachytherapy, manual brachytherapy requires 200 hours of classroom and laboratory, and 500 hours of supervised experience which I think the word is involves, it doesn't say exclusively devoted to, but involves the handling and preparation of sources.

Do Dr. Diamond and Dr. Nag think that the current four year residency complies would allow an applicant to satisfy that requirement for the alternate pathway for manual brachytherapy?

MEMBER DIAMOND: This is Dr. Diamond. To answer your question, Jeff, I believe that many of the programs currently satisfy all of those requirements, and for those programs that do not, relatively minor additive changes would satisfy that requirement.

MEMBER WILLIAMSON: Okay. Let's go to 600 now. Do Dr. Diamond and Dr. Nag think that the rule as written, which again the alternative pathway requires 200 hours of classroom and laboratory, plus 500 hours involving, and then again a slightly modified laundry list of technical tasks associated with high dose rate and teletherapy. Do you think an individual that has successfully completed a four year residency to date in radiation oncology could comply

with the requirements of the alternative pathway?

MEMBER DIAMOND: This is Dr. Diamond. Once again, by the way I account for hours, the answer would be yes.

MEMBER WILLIAMSON: The third question - 396.

MEMBER NAG: You haven't asked me.

MEMBER WILLIAMSON: Oh, I've asked both of you.

MEMBER NAG: You haven't given me the chance to answer.

MEMBER WILLIAMSON: I'm sorry. You're right.

MEMBER NAG: It will depend on how the hours are interpreted. That's what I'm trying to tell you; that if you are saying that the 500 hours include your experience in handling of radioisotope, that includes the 600, but also includes the 400 - yes, then you will meet it. But if someone says yes, you have the experience in manual brachytherapy on the 400, that was the 500 hours. Now you have to show me a separate 500 hours for the use in 600. That will be very difficult in some of the training programs that don't have their own HDR. But if it did comprise a part of the overall training, yes, there is no problem

meeting it. So that was my reason for asking the NRC how are you affecting these hours.

MEMBER WILLIAMSON: And let me finish with my third question, and then I'll shut up. The 300 now requires 700 hours, and I think it is not -- in the alternate pathway it is distinguished between, of course, classroom and laboratory, and supervised work experience. I think it is by NRC's own admission that radiation oncologists today would not satisfy that, but the 396 pathway does seem to provide a solution for practicing radiation oncologists that have either in their residency or in subsequent practice acquired that experience to be able to easily comply and do what they're doing, and someone who has never had that - well, two weeks of training and three cases is some barrier, but it doesn't seem to be a completely unreasonable one for someone who hasn't had that experience. So do you think that, does it matter whether 300 requires 700 hours now? That's my question.

MEMBER NAG: Yes. I think the -- I mean, I did discuss this with the NRC officials because I am going to be talking about this in a meeting, so I had to clarify for my own understanding before I say it to the general radiation oncology community. The general

radiation oncologists will not be able to meet the 300 requirement of 700 hours, but because they can qualify under the 400 and the 600, then they can add the 396 and qualify by that log, so that is not a problem. The one problem would be that until the board -- until the American board of radiology requires an 80-hours of unsealed sources built into that program, they will have to somehow show that they have the 80-hours of separate unsealed source somewhere, so that may be slightly difficult, but not impossible.

MEMBER WILLIAMSON: So I guess the question is, is whether the issue raised by Dr. Diamond, which is certainly a frightening prospect, is valid.

CHAIRMAN MALMUD: Thank you. Dr. Zelac, I believe, had his hand next.

DR. ZELAC: Thank you, Dr. Malmud. I'd like to point out several things that I think are pertinent to the discussion. First, in terms of the total number of hours required in the different modalities there have been no adjustments from the current rule. And there was clearly extensive discussion involving the advisory committee, the various boards, the public when the current rule was adopted, so if we're talking about, for example, the

700 hours, that has been on the books for two years now, and apparently is not providing an impediment to people achieving authorized user status.

Secondly, I'll wait until Dr. Diamond is finished, because this I think is -- Dr. Diamond, I wanted you to --

MEMBER DIAMOND: I'm listening.

DR. ZELAC: Okay. Particularly hear this. Since we are talking about now unchanged requirements from the current rule, it's appropriate to take a look at the statements of consideration that went along with the publication of the current rule with regard to things like the 700 hours, and where one acquires it, and what qualifies for requiring it. And there are two places in the statements of consideration for the current rule that are applicable. One was to the 290 requirements, for which there are 700 hours, and the second was for therapeutic utilization.

Quoting from the *Federal Register*, "We recognize that physicians in training will not dedicate all of their time specifically to the subject areas in 35.290" - not talking about 700 hours there - "and will be attending to other clinical matters involving the diagnostic use of material under the supervision of an authorized user; example, reviewing

case histories or interpreting scans. Even though these clinical matters are not specifically required by the NRC, this type of supervised work experience may be counted toward the supervised work experience to obtain the required 700 hours." That's one area.

The second has to do with training and experience requirements for sealed byproduct material, and the quote here from the Statements of Consideration, "The NRC agrees that concurrent training should be allowed for the clinical and work practical experience requirements in 35.490 and 35.690. Therefore, we revise the regulatory text to allow for concurrent work and clinical experience."

MEMBER DIAMOND: This is very helpful information, Ron, because listening to you, that Statement of Consideration is much closer to how in my mind I enumerate for these hours, the same way I would believe our Chairman does, and perhaps the entirety of the committee. And also, sounds to me different than what I heard yesterday. And I would go back to Jeff's series of questions when he was asking do the training programs satisfy these hours. And based upon those Statement of Considerations with respect to 300 level uses, I would say that many of the training programs already do satisfy those hours, and the ones who do

not probably could meet them with very minor changes.

DR. ZELAC: The other last point that I would make with respect to -- in response to what Dr. Williamson had brought up is, if you look at what the board requirements are versus the alternate pathway requirements for 190 and 290, it was built into the board requirement meeting the requirement in the alternate pathway, except for again in terms of the numbers of hours have to be met. We have been careful, however, in the rewrite in the working group to try to not put additional requirements - and this is the issue that's been raised by Dr. Malmud - additional requirements that would apply specifically to the board certification pathway. So the dilemma is there, and I think it's perhaps somewhat unavoidable from the way we're approaching this if, in fact, we are going to go down the pathway of specifying training -- excuse me, classroom and laboratory subgroup of the total experience required.

DR. BROSEUS: Excuse me for interrupting, but I want to supplement what Ron said by noting that in the supplementary information for the draft final rule, we have brought forward this discussion he just quoted into the supplementary information, and added a bit to it just to clarify that the NRC's intent is

to make sure that radiation safety training is adequately addressed, because we're also dealing with the didactic hours issue, and so that discussion is in the supplementary information.

MEMBER WILLIAMSON: A point of clarification. What is supplementary material?

DR. BROSEUS: Okay. I'm talking jargon - excuse me. The Statements of Consideration - it's the front part --

MEMBER WILLIAMSON: Is this the thing that we heard --

DR. BROSEUS: Yes. It's the first part of that. At the end of that is the rule text, but the supplementary information has a discussion for rational rule change and comments and responses.

MEMBER WILLIAMSON: Do the stars refer to the current Part 35 published in --

DR. BROSEUS: Pardon me?

MEMBER WILLIAMSON: Do the stars refer to the *Federal Register* version of the rule published April 24th, 2002, or some other version of the rule?

DR. BROSEUS: Let me give you a specific answer, a correct answer to that. Okay? The stars refer to text which is in the current rule which is not up here. The only thing that we put in there is

where rule text is changed. Current rule text includes what was published in 2000, some minor corrections put in to correct typographical errors in the draft final rules published since then, and the extension of Subpart J. That is current rule language now, and so what you see here is changes from current rule language. Current rule language on the books legally.

MEMBER WILLIAMSON: My question is if I'm looking at this *Federal Register*, April 24th, 2002 - am I accurately reading these stars.

DR. BROSEUS: No.

MEMBER WILLIAMSON: No.

DR. BROSEUS: No. What I just said - April, 2002 does not take into account the most current rules on the website here, and in January of this year the *Federal Register* published Title 10, which includes the typographical error updates and so on.

DR. HOLAHAN: But those are minor changes, so basically what you see in the rule text before you is the current rule with some modifications, like minor corrections.

MEMBER NAG: You very well clarified the 390, 490, 690. Could you do similarly for the 390,

that is, are you going to allow overlap in that 700 hours of training for the 390? The 390, 490 - you were very clear. I thought I knew what 390 was, but the 700 would be separate for unsealed source, but if you're having -- if you're allowing overlapping 490 and 690, and ultimately 290, why are you not allowing overlap in that 390?

DR. BROSEUS: I have a note for myself to go back to the working group that says clarify in the supplementary information the meaning of these hours and look at this overlap, and we'll discuss that in the working group, and make sure we have an appropriate statement there.

CHAIRMAN MALMUD: Okay. So Dr. Nag will get that information clarified by you, Dr. Broseus, or Dr. Zelac?

DR. BROSEUS: We'll take it as a comment on the draft final rule in our development of the final supplementary information.

MEMBER NAG: If that 390 can be clarified that there is overlap, then you don't even need 396 because the --

CHAIRMAN MALMUD: Let see, I'm trying to see who was next. Mr. Bailey.

MEMBER BAILEY: We have a real problem,

and when I say "we", I think most of the states do. When we go to adopt these NRC rules, we have to meet a standard of clarity. These regulations fail miserably on clarity, and I hope -- I mean, it's obvious that if we're having this much trouble, it's going to be very difficult for lawyers in the Office of Administrative Law in the 33 states to accept these regulations as being clear.

The second thing that we have to do is we can't have interpretations in the regulations and standards that you're going to apply an interpretation of the regulations and Statements of Consideration. Those are called underground regulations in most states.

Thirdly, when you add a provision such as you've done with 396, that is a - and I never can say this word - substantive change in the regulations, and we would have to go back out for public consideration of those brand new requirements. So these regulations as they're being proposed now will be extremely difficult for many, many states to adopt. And because they're not clear, we're just making a machine for misunderstanding of requirements from state to state.

CHAIRMAN MALMUD: Thank you, Mr. Bailey. That was the concern that I was raising earlier. I

think that from the Office of Counsel, Ms. Chidakel, pointed out the process has been adhered to, and I accept that personally. I can't speak for the whole committee. However, clarity is not there. It is simply not there. Here we are, months of discussion - we don't understand it. How is someone in another state going to understand it? How is anyone in a position of authority who doesn't deal with this regularly going to understand it? There is no clear guideline that is able to be looked at in one or two pages and a conclusion drawn. That's my concern; that we will bring embarrassment upon ourselves and the NRC in passing regulations that are so cloudy that no intelligent educated Ph.D. who hasn't been involved - or M.D. - who hasn't been involved in these issues for months can understand them. That's my concern. But I'm speaking for myself here, and next, Dr. Diamond.

MEMBER DIAMOND: Let me give you an example of that. I've just been reading the 396 language, if I could ask everyone here to take a look at this, please. The construction - this is the alternate pathway for the unsealed byproduct material requiring a written directive. The construction, as I'm reading it, is A, or B, plus C. Okay. A, or B, plus C is the construction. A is essentially the

grandfather clause for A use, who became A use prior to October, 2005. B is individuals who are certified by the boards prior to October, 2005, and C.

As I understand this, for a resident, for example, who finishes his or her radiation oncology training in the spring of 2006 or 2007, 2008 it is not humanly possible for that person to ever give parenteral administration of unsealed byproduct material unless there's a typographic error.

MEMBER WILLIAMSON: I think if I could clarify, it's really A or A Prime, or B, or B Prime, and C, so within the A clause and B clause it distinguishes between satisfying Subpart J versus the current regulation, so I think on a technical point, I don't think the concern is warranted.

MR. MOORE: Dr. Malmud, Scott Moore. If the advisory committee's comment is that the additions with regard to didactic hours in 396 or any changes since the proposed rule are not clear, those types of comments would be helpful to us, because they give us some direction as a group, as a writing group on what we can do with respect to the draft final rule. And if you can in particular point out the areas that aren't clear or give us directions on how to clarify them, those would be helpful.

I would note that with regard to the public comments on the proposed rule, and also on the agreement state comments, Mr. Bailey, on the proposed rule, I don't recall that we got comments that the rule itself wasn't clear, so with regard to what went out and was commented on in the proposed rule stage, I don't recall that we got comments back saying it wasn't clear.

MEMBER DIAMOND: This is Dr. Diamond. But again, getting back to my question which was premised on clarity - let's take the hypothetical example of a radiation oncology resident graduating from a program in 2006. That individual will not be able to sit for his or her boards until 2007, so obviously not board certified at that point. This individual will not satisfy Paragraph A, nor will they satisfy Paragraph B. And because the construction -- Jeff, if I'm wrong, please explain how I'm wrong.

MEMBER WILLIAMSON: Okay. A resident who graduates and is not board certified would be able to become an authorized user of 490 or 690 under the alternate pathway, and therefore, they would satisfy the first part of Clause A. It is an authorized user under 490 or 690, and then the "or before October 25th" this is for the previous people - but if they

become by whatever pathway a 400 or 600 AU, they satisfy A.

MEMBER DIAMOND: So you're saying that the commas before and after "or", that that should be October 24, 2005 - I see, that's how you're interpreting the --

MEMBER WILLIAMSON: Yes. That's --

MEMBER NAG: For 940 and 960.

DR. BROSEUS: Let me expand. October, 2005 is capturing people. You can come in under Subpart J. Subpart J disappears October, 2005, and so everything that comes after the "or" disappears in 2005. But a person could use either pathway up to that point.

MEMBER DIAMOND: So again - so, Jeff, that hypothetical individual, the day he or she finishes his training will already have AU status obviously under 490 and 690.

MEMBER WILLIAMSON: Even before they --

MEMBER DIAMOND: If they're in training, right.

MEMBER WILLIAMSON: After three years if they have the 700 hours mixture of didactic and supervised training, just as fellows in current training programs can become AUs through the action of

the Radiation Safety Committee. I don't think that -- it's not going to be a big problem.

CHAIRMAN MALMUD: Who is next? Mr. Lieto.

MEMBER LIETO: Yes. I have a point, just to be sure I understand, a couple of questions for clarification for Roger. The intent as to what is going to be published would be the final rule. Is that correct? There's not really going to be any more public comment. Is that correct?

CHAIRMAN MALMUD: That's correct.

MEMBER LIETO: Okay. A specific question related to 396. A physician, ABR certified under 290 wants to come in and be approved for parenteral applications, therapy applications - he would not be able to be qualified under the board certification route. I mean, he would not be able to be qualified, period. Right?

DR. BROSEUS: If I recall correctly from previous discussions in this advisory committee, many times the training that a person has under 290 is going to get them close to or qualify them for 300 use, and so you don't have to worry about 396. Ron, we talked about this before. Do you want to expand upon that?

CHAIRMAN MALMUD: Dr. Zelac.

DR. ZELAC: I think the point to be made is that 396 was intended very specifically for radiation oncologists to be able to use unsealed material that required a written directive. For those who have been trained specifically not for radiation oncology, essentially for nuclear medicine, it would be expected that those individuals would satisfy the requirements for 390 if they intended to use materials for which a written directive was required.

The last point to be made is that some of the training that such individuals, and a large part of it, actually, that individuals would receive under the 290 would be applicable to the requirements under 390, a lot of the basic information would cross over. Specific information relating to, if you will, therapeutic use, use of unsealed materials in therapeutic quantities would have to be added to the training such individuals would receive before they would qualify for 390 use.

MEMBER LIETO: Mr. Chair, a follow-up point. I guess the reason I was asking is that there may be a number of areas where nuclear medicine physicians don't want to deal with Iodine, nor have that authorization or those restrictions on their license. Okay? I shouldn't say restrictions, but

that latitude on their license, and want to only deal with the non-Iodine therapy applications.

DR. BROSEUS: Well, they could apply for just whatever they need. They don't have to apply for --

MEMBER LIETO: Well, that's kind of my --

DR. BROSEUS: That's not an issue.

MEMBER LIETO: Well, that's my point, is that if a physician comes in who's board certified and is approved under 290, what you're saying is that he has to come under 390 or that's it, because if you look at A and B, it doesn't allow anybody who's board certified and approved under 290 to come in and get 396.

MEMBER NAG: Well, I think the confusion is 396 was meant only for people for radiation oncologists, basically only for people who qualified under 400 and 600 who solved the problem that the radiation oncologists may not handle the unsealed sources. The 396 has nothing to do with nuclear medicine physician, so when you're talking about 396, only refer to radiation oncology training.

CHAIRMAN MALMUD: That is my understanding, as well, Dr. Nag.

DR. BROSEUS: That's it.

CHAIRMAN MALMUD: And Dr. Broseus confirms that. Does that answer your concern, Mr. Lieto?

MEMBER LIETO: Well, you answered my question. Yes.

CHAIRMAN MALMUD: Thank you. I think that Sally Schwarz, you were next.

MS. SCHWARZ: I just wanted to ask a question.

CHAIRMAN MALMUD: I couldn't hear you. I'm sorry.

MS. SCHWARZ: Sally Schwarz. I'm just concerned about the authorization for nuclear medicine physicians under 390. Actually, that's what I'm concerned about, and I think that's what Dr. Eggli was going to raise, as well.

CHAIRMAN MALMUD: All right. Then we'll pass to Dr. Eggli.

MEMBER EGGLI: Okay. Actually, Jeff asked his questions with respect to 400 and 600 users. Nobody has so far asked the same questions for 100 series users, 200 series users, or 300 series users.

When I look at the -- there are a lot of different boards who qualify people in these areas. When I look at the American Board of Nuclear Medicine, I have no problem assuming that the American Board of

Nuclear Medicine will hit the training mark. My big problem is the vast 70 percent of all nuclear medicine in this country is practiced by diplomats of the American Board of Radiology, and the American Board of Radiology trains people in a wide variety of imaging modalities, and the training allowed is governed largely by the regulations. So as the American Board of Radiology looks at trimming its previously 1,000 hour training for a radiologist in nuclear medicine to 700 hours, it's hard to get everything in.

And the biggest problem that I'm seeing here is the 200 hour requirement for 300 uses. First of all, I have a son who attends a well-known college in the northeast. They spent three hours a week in class, 15 weeks in a semester, so that about 45 hours for a college course. Two hundred hours is 4-1/2 college courses devoted to issue of safe handling of radiopharmaceutical strikes me as a little on the high side for safe handling. No, actually it strikes me as wildly on the high side for safe handling.

The other issue is, now I only get these people - first of all, I think I'm the only person sitting at this table who trains people for 300 uses or 200 uses. I only get these people for 700 hours. If I now lose five weeks, which is 40 hours a week of

their time to didactic training and safe handling, I now have less than three months to teach them clinical nuclear medicine and make them competent.

I think this rule will have the unintended effect of impairing the clinical experience of diplomats of the American Board of Radiology in clinical nuclear medicine, and that may have a limiting effect on how they perform clinically, and maybe a greater hazard to public safety than the hours of training.

I sat down and designed a didactic radiation safety program for my residents, including every conceivable topic, plus supervised what I would call laboratory experiments where we set up experiments on the use of the equipment and safe handling, and we monitor them in a laboratory environment, much like you would have gone to a lab section in a college course. I came up with 50 hours of training, and I think 50 hours actually for Part 200 uses is very appropriate, and I think something closer to 100 hours for Part 300 would be appropriate. Because again, for 300 uses, we talk about the broad uses of so many radiopharmaceuticals.

Now I've got two basically - I have orally administered therapies, and I have parenterally

administered therapies. And for orally administered therapies, those we're only going to do radio Iodine, they have an 80-hour requirement of training right now on the alternate pathway. And again, the argument that I'm not going to have to train the alternate pathway is specious because I'm going to for the reasons that Dr. Diamond described, I'm going to have to train everybody to alternate pathway rules.

Now we're saying that we need another 120 hours of training, of didactic training to handle one other category of administration, which is basically beta emitters administered parenterally. And the safety issues don't change if I put it in a joint, if I inject it into the peritoneal cavity, if I inject it intravenously, whether it's really a coloital beta emitter or in solution - none of the safety issues that I need to train for changed, so I've got two categories of therapy that I need to train for under Part 300, oral administration and parenteral administration.

I think NRC has recognized that there are two broad categories of therapeutics in the way they're now describing Part 396. So I think 200 hours is unnecessarily excessive, and will - since I'm only going to get them for 700 hours, is going to limit my

ability to make them clinically competent. And I think that is going to damage healthcare in the United States.

DR. BROSEUS: Mr. Chairman.

CHAIRMAN MALMUD: Dr. Broseus.

DR. BROSEUS: We're moving into the other topic, which I did want to address, and if I just might present a couple of slides to talk about that, and then we can come back to some of the other issues. And that is, we did have a teleconference on October 5th to talk about the issue of - I'm going to put quotes around - "didactic hours", and we presented recommendations that came forward from our working group, which are appearing on the slide behind me now, which has the subdivision, including the 200 hours of didactic training that Dr. Eggli just mentioned. And one of the objectives of the working group today is to get any recommendations that ACMUI may have about what is the proper number of hours.

Additionally in that meeting, we heard some discussion about definition of what the hours are. And, for example, in those sections in Part 35 dealing with T&E, the term "didactic" isn't used. What we have is classroom and laboratory training, except for individuals to qualify as nuclear

pharmacists. And for that particular category in the current rule, and in the proposed rule which we published, there was a reference to didactic hours requirement for nuclear pharmacists.

Now the working group has been thinking about these issues, especially since the telecon, and it would be also useful if you feel there's a need to look at the definition more to get some feedback, and a basis if you think there's a need to change the definition.

Now the working group was considering eliminating the term "didactic" from pharmacy for the requirements for nuclear pharmacist, and substituting the term classroom and laboratory hours to make it clear. And so what I'm suggesting is that as we move forward, and it's 9:32, that we also would benefit if you have comments about what the proper balance of hours is, a basis for a change, and Dr. Eggli suggested some, as well as is there a need to look at the definition of didactic hours, that is classroom and laboratory hours, which is what most people I think mean by that term, if there is a need to elucidate that, should it be in definitions and rule space, or in supplementary information. You, Dr. Malmud, pointed out that one could get into a slippery

slope if you start defining things, and so on.

I'd also like to - since I got the chair back - just mention, we've already talked about our closing period for comment being October 18th. We plan right now to hopefully have this rule go to the Commission by mid-November, and would anticipate publication in 2005. Thank you for letting move on a little.

CHAIRMAN MALMUD: Certainly. Dr. Williamson is chomping at the bit.

DR. BROSEUS: I'm at your disposal.

MEMBER WILLIAMSON: I wanted to ask a question to Mr. Bailey, who has gone away, so perhaps I should -- I'll just ask. I'll ask, I think, a follow-up question to what Dr. Eggli has presented.

In radiation oncology, which is a 4-year program, I think the 200 hours, while not absolutely required by the ABR, I think is met by virtually most of the diplomats. And this is met not just by courses that deal with sealed sources and brachytherapy. They have a long radiation physics sequence. They have radiation biology. They also have probably formal instruction in statistics and design of clinical trials and interpretation of clinical studies, et cetera; as well as numerous sessions on radiation

safety dealing with more specific devices and programs that they have.

For the 700 hour training program you administer, I assume these are diagnostic radiology residents who also get a similar broad didactic training experience in radiation physics, radiation biology, and what happens if you get inadvertent exposures to fetuses and so forth, teratology which is equally applicable to external sources of radiation and internal in terms of the basic principles. So you really have to give 200 hours of your 700 hour segment.

MEMBER EGGLI: If I look at the diagnostic radiology physics curriculum, I come up with another 50 hours of didactic training in the rest of physics for radiology, so for our radiology residents now have actually planned a roughly 100 hour course; 50 of those hours, which as we look at it, we felt were relevant to the nuclear medicine requirements, and 50 hours that we thought were probably not relevant to nuclear medicine requirements because they deal with devices and don't fall under what we thought was the spirit of the regulation.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Dr. Broseus, you had in your

previous slide, you had the requirement for 35 up to 35 390, could you enumerate now for 490 and 690 in one slide. That way we can show the whole thing. I mean, that again - 700 and 200, but my question is that someone who has this 200 has -- included in that body of knowledge is the requirement partly of the 390, so in the 396 you are asking for additional 80-hours specifically for unsealed sources. And that is the specific requirement. It's not part of your overlapping requirement.

For someone who has spent 200 hours in didactic to then have another 80-hours that is separately for unsealed which is partly covered in the radiation oncology training, but hard to dissect out that there was 80-hours built within that 200 hours - is going to be an excessive requirement for a board certified radiation oncologist, because when you are trying -- I give my course in brachytherapy, and my course is probably one of the more extensive in brachytherapy in the country. And I can accomplish that within a period of two to three years in about 80 hours that is all about the specific brachytherapy things. So that includes some of the requirements in handling liquid or unsealed source also. So if you ask me how many hours did I give last year on

specifically unsealed source out of my 200 hours, that's very difficult to dissect out, so I think that 80 hours additional for 396 is very, very -- it's probably an over-burden.

DR. BROSEUS: Would you like me to address the first question, which is how many hours for 490 and 690 it's 200 hours.

MEMBER NAG: I know, 200 and 700.

DR. BROSEUS: Okay.

MEMBER NAG: What I meant was having it on that so someone can look at it and automatically see it. I mean, I know how many hours it takes.

CHAIRMAN MALMUD: Excuse me. May I interrupt. I just want to clarify Dr. Broseus' answer; that the total hours for 490 and 690 is 700, of which 200 would be didactic in each case. Is that what you said?

DR. BROSEUS: Classroom and laboratory training.

CHAIRMAN MALMUD: Thank you. Now the second question - Dr. Nag's question. Well, actually it's a point. You're making a point that you believe the 80 hours of additional training for the handling of unsealed sources for radiation oncologists who are otherwise fully trained and will have had already

completed physics training, which includes some hours that overlap into unsealed sources, that the 80-hour requirement may be excessive.

MEMBER NAG: Yes. I mean, basically at that point the only extra thing you need to know is what do you do in terms of a liquid spill that we generally do not handle in a sealed source, although we partially do, so there is really very little extra knowledge required to then be able to handle unsealed source.

CHAIRMAN MALMUD: Dr. Diamond.

MEMBER DIAMOND: Just to clarify something; so you're asking about grandfathering of board certified radiation oncologists who are not licensed for 300 level uses.

MEMBER NAG: Right.

MEMBER DIAMOND: And you feel that a radiation oncologist who's been in practice 10 or 20 years, who has never been licensed to give Strontium or Iodine, or P-32, that that individual can start giving these agents, or Zevelin, or whatever - going from zero to that level in less than 80 hours.

MEMBER NAG: In less than 80 hours, because you have already the body of knowledge on what to do for therapy. Now you have to get the additional

requirement on what to do if you have a spill. In 80 hours, what are you going to teach someone, a curriculum that will cover 80 hours.

MEMBER DIAMOND: If I may respond to focus this discussion just towards the radiation oncology community for a minute. My feeling is, is that I would be satisfied if the following exists. I'll be satisfied if it is either in the Statements of Consideration or in other manners that the spirit that Ron Zelac mentioned for 490 and 690, and which was mentioned elsewhere today regarding the enumeration of hours, if that is in that same spirit, I would be happy, because what that means is that an individual going through the board pathway, which we intended all along to be the AU pathway, if that individual, once he or she becomes board certified, can satisfy all the 300 level uses. So if that spirit is interpreted in that manner, I'm very happy in that regard, number one.

Number two, recognizing that every single radiation oncology resident coming out will have to fall under 396 until he or she becomes board certified at a minimum, I think that that is okay, as well, because during the course of his or her training, he or she will easily have satisfied the 80-hour

requirement, and you need to, of course, have the three cases which is not a big deal. And they've already satisfied Paragraph A by virtue of their other training, so that's good.

The third scenario is what Dr. Nag is mentioning - what about those radiation oncologists who are Aus, have been in practice for many years, but are not licensed for 300 level uses. In that particular case, I do think that individual needs additional training. Is the number 80 hours? I don't know. Is the number 5 hours? No.

Quite honestly, my opinion, for that physician who has not been doing any of these uses and may have been out of practice for 10 or 20 years, I really don't have a big problem with the 80 hours, Subir. I really don't. So anyway, to bring this to focus, I think if we can come to consensus on the spirit of enumeration, that will satisfy a major issue. We now have clarification for the 396 alternate pathway use that these residents coming out of training or folks who have not yet passed their boards because they failed the first time or two, will be taken care of.

And as far as the grandfathering issue for folks that have never been licensed for 300 level

uses, I personally believe they do need additional training. And I think we can discuss what the number is - is it 80, is it maybe a little less than 80, but certainly not, in my opinion, going to be 5 or 10.

MEMBER NAG: No, I think, David, you are somewhat mistaken. A person who had finished their residency, just finished their residency and became an authorized user in 490 and 690, will still require 80 hours to be able to do the 390. And that will require that you have to demonstrate an additional 80 hours, and that is excessive because that person has recently finished training, and many of those 80 hours were already included in that 490 training.

MEMBER DIAMOND: By my understanding, Subir, and please, staff, correct me if I'm wrong - by my understanding, those 80 hours should easily have been satisfied during the residency program. In other words, that person, the day he finishes training, does not need to then go and take an additional 80-hour course. All you need to do is have attestation that those 80 hours were satisfied during your 4-year residency. Am I correct on that?

MS. SCHWARZ: That's correct.

MEMBER DIAMOND: Okay.

CHAIRMAN MALMUD: Thank you. Sally.

MS. SCHWARZ: I still have concerns about the 200 hours for the nuclear medicine physicians. That's a concern of mine that I believe that that 200 hours is too high in terms of nuclear medicine physicians in additional training.

MEMBER EGGLI: I would like to speak to the logic of that. This is Dr. Eggli. My understanding of the way the regulation is written, as the subparts get higher numbers, those are both greater complexity and higher risk for the patient. But yet, as we look at Part 300 T&E requirements, Part 400 T&E requirements, and Part 600 T&E requirements, they are identical.

If, in fact, there is an escalation in risk and complexity of therapy as we go from Part 300 therapies to Part 400 therapies, to Part 600 therapies, then again it seems that the requirement for 200 didactic hours in Part 300 is excessive because it, in fact, matches the didactic requirement for what are acknowledged to be higher risk and more complex therapies that a Part 300 user could not do.

DR. BROSEUS: I'd like to just interject, that when you get to the 300 level, the split starts to become the form. The 300 is unsealed, 400 and 600 is sealed. And so you may have equal level of

complexity doing Zevelin, and dealing with some of the things that Dr. Nag was talking about --

MEMBER EGGLI: I would, in fact, argue that there is a different level of complexity. And, in fact, you argue that - "you" being NRC staff - argued that when you put the spheres into brachytherapy, because you considered them more complex than could be covered. And again, it looks to me for all practical purpose, like a 300 material, so that again, I think your own logic system says that there is greater complexity and higher risk in manual brachytherapy.

CHAIRMAN MALMUD: Excuse me. Did you want to respond to that, Dr. Broseus?

DR. BROSEUS: One thing I want to say is that the major split at that level is the physical form.

CHAIRMAN MALMUD: Dr. Zelac, did you want to respond to that?

DR. ZELAC: Yes, I'd like to make a point. For 490 use and for 690 use, in addition to the classroom and laboratory, plus work experience which are common among 390, 490, and 690, the additional risk levels that you speak of are dealt with by the additional requirements for 490 and 390 in the

alternate pathways to have three years of supervised clinical experience. That doesn't appear for the 390, so the higher risk levels that are associated with 490 and 690 are covered in the requirements by the additional clinical experience of three years.

CHAIRMAN MALMUD: Thank you. Does that clarify it? Does that satisfy your concern?

MEMBER EGGLI: No. My concern that 200 hours in Part 300 uses is excessive is not satisfied.

CHAIRMAN MALMUD: So your point is that the 200 hours for 490 and 690 may be valid, but if that's the case, your argument is that the 200 hours for the 390 is excessive by comparison.

MEMBER EGGLI: Yes.

CHAIRMAN MALMUD: All right. Your argument has been heard. Yes. Is it Mr. Moore or Dr. Moore? I'm sorry.

MR. MOORE: Mr. Moore.

CHAIRMAN MALMUD: Mr. Moore.

MR. MOORE: I guess an other thing to consider is that there is a very large group of stakeholders that recommended something in the range of 200, and that's the agreement states for the 300 series. And that's something we have to consider. The working group certainly looked at that, and they

looked at numbers less than 200, or slightly less than 200, but arrived at the recommendation of 200 to the agency, which segues into the comment that Mr. Bailey made regarding to the petition.

I do want to let the ACMUI know that there is a petition. It has been docketed. It's from the Organization of Agreement States, many, many agreement states signed onto it. It has been accepted by the agency as a petition. I think it's premature to say that it will result in a separate rulemaking. There are a number of options that the agency has in how to deal with petitions. They range from addressing it as a comment, to handling it as an absolute separate formal rulemaking in parallel to this rulemaking. It certainly deals directly with these issues of didactic hours, both for the alternate pathway and for boards, so it overlaps entirely with the issues that are here. But it's a very formal mechanism in the rulemaking process, and we will treat is very formally as an agency, so the committee needs to know about that.

I guess I'd like to also go into something that will maybe take this above the technical discussion that we're having. The rule is due to the Commission by the staff in mid-November. That due date is non-violable unless the Commission gives us

relaxation in the date. We would need a strong basis for an extension to that date, and so we're looking at a due date to the Commission about a month from now.

If the ACMUI believes that additional time is needed for the ACMUI to review and comment back to us, or for the public to look at again for that matter, then we would need you to provide us a comment to that effect. One option you have is to make that comment to us as a body, but beyond just telling us that you need additional time to do that, I think you would be well served in telling us the basis for needing that additional time, because we would certainly need to tell the Commission why we would need the additional time. And then it's up to the Commission to decide whether they're going to give the staff additional time before we present the rule to the Commission.

In addition, we've certainly heard you, the body, saying today that public comment - certainly, Dr. Diamond raised this - is needed on some of the more significant areas, like 396. We checked with our Office of General Counsel. The comments that came in during the public comment period and the changes that were made by the staff subsequent to the public comment period, namely, the addition of 396 and

this addition of didactic hours, don't pass the threshold for going out for public comment again in terms of significance, so we're not legally required to go out for public comment again.

That said, if the ACMUI believes that we should go out for public comment again, that's certainly a comment that you can give us, and you can make a recommendation that we should do so. Again, I would recommend that you give us a reason for going out for public comment again, and the staff would certainly take that into consideration, and inform the Commission that you recommended that, and the Commission would take that under advisement.

CHAIRMAN MALMUD: Thank you, Mr. Moore. Perhaps I --

MR. MOORE: Charlie may have additional comments about that.

MR. MILLER: I want to make some comments, but Ralph has had his hand up, and if he has a point he wants to make --

CHAIRMAN MALMUD: Well, rather than doing that at the moment, may we get back to Mr. Moore's observation, because there are two issues that have arisen, Mr. Moore - one came from Mr. Bailey, and that is his view, meaning the view of the states that Part

396 is, in fact, from their view a substantive change. That's the term that he used.

Counsel for the NRC, you tell us, feels that it's not a substantive change, so there seems to be a disagreement between the states and Counsel for the NRC as to what constitutes a substantive change. But NRC has the final say, and I will defer to you in a moment, then there is no substantive change because NRC has the final say. But Mr. Bailey did say, and I was taking down notes as he was talking, that the states regard 396 as a substantive change and want it to go public. That comment will come forward from the ACMUI, namely, a protest that the states regard 396 as a substantive change which has not had adequate opportunity for public comment. That's one point.

The second point is that Dr. Zelac agrees with us, though it was not his presentation, that there is a dilemma in the board versus alternate pathway in the fact that the alternate pathway does dictate to the boards that which they should teach in order for a graduate of the boards to qualify for practicing, even though that individual may not have had the opportunity to, or may have failed taking the board certification exam the first time. And I would point out to you, which is a matter of concern to me,

that if we graduate a number of physicians after four years of college, four years of medical school, four years of residency training in radiation oncology to enter a field that is nationally under-supplied and create a roadblock to that individual practicing in a small town in a rural state, as represented by the states, we will have created a great embarrassment for us, the NRC, and I am sure it will reverberate in Congress, because this is a field which is terribly short of individuals. The number of training programs in radiation oncology is not enormous to begin with, the number of graduates is not enormous, the shortage is great. These individuals are not incompetent because they didn't pass the boards. They simply haven't passed the boards. There's a cut-off point, so I believe that we have to look at this very carefully, both for the public good - mainly the patients, as well as for those individuals who have spent so many years in training. And with all due respect, it's not quite analogous to passing the bar exam. There are differences, though there are similarities. Now I defer to distinguished Counsel.

MS. CHIDAKEL: Thank you. I just want to clarify a couple of things. First of all, please note I did not say that 396 was not a substantive change.

Actually, I specifically mentioned that 396 was one of the only changes, the only real changes that I saw to the rule from the time that the rule was proposed. I specifically said that.

I didn't pass on the issue of whether it was a substantive change. In that connection, let me raise - since we were talking about the Office of General Counsel's view on republication in the *Federal Register*. The test is whether the change is such that it is so far from what was proposed that the person who read the rule would not have been given proper notice that they could comment on that issue. I know that's kind of complicated, but what I'm trying to say is the decision was made that this was not outside the whole area of T&E, of training and experience, which was the focus of the rulemaking, so that is why I'm talking about the hours now - the hours issue now, 396. That is why the decision was made by OGC management that this was not necessary, legally necessary to be republished. As I believe Scott pointed out, certainly that doesn't mean we can't republish it if there are policy issues, if the ACMUI wants to come out and make that argument and have a basis, and give us reasons why they feel that this is not -- while it isn't legally necessary, you know,

certainly you can make an argument as to why you think it's a good idea. But that is the issue. And the issue is that we didn't see anything in the changing in the hours issue that was totally, completely outside of the scope of the proposed rule. Does your answer your question?

You made another point. I'm sorry that it has escaped me now.

CHAIRMAN MALMUD: There were two issues. One was with respect to 396, and the other was with respect to the dilemma created by establishing criteria for the alternate pathway which would be applicable to all residency training programs because a certain number of people who complete their residency successfully do not pass their board certification within a year. By the time they've graduated from the residency, completed the residency, if you will; and, therefore, they would be limited in their employment opportunities to very large institutions where they'd be under the umbrella of someone else, leaving the smaller facilities, particularly those represented by the states which are very often in smaller cities, uncovered by graduating fellows.

DR. BROSEUS: I put on my health physicist

hat for a minute.

CHAIRMAN MALMUD: Please do.

DR. BROSEUS: And those are exactly the people that sometimes the health physicist is concerned about. Many serve as their own RSO, and that's in the rule. So the concern is to make sure they have sufficient training. Now if they could get it with less hours and it applies to unsealed sources, I'm assuming that these individuals, even though they're not board certified, can go out and practice medicine, and that's not our concern. Okay. They're a licensed physician. That's all it takes in the rules. So the real question then is what is a sufficient number of hours - and if we can focus on that today and by the 18th, and satisfy both needs, we've gotten home.

CHAIRMAN MALMUD: Dr. Diamond.

MEMBER DIAMOND: To answer Dr. Malmud's question regarding do we think this needs to be published for comment - based upon the discussions we had earlier, my personal feeling, and this is not represented by necessarily the radiation oncology community. This is my personal feeling. My personal feeling is that if the Statements of Consideration do reflect what I believe is a logical enumeration of

hours, given all of the potential algorithm pathways that we talked about, that with respect to the radiation oncologists and 300 level uses, I can live with this.

CHAIRMAN MALMUD: Thank you. Dr. Miller.

MR. MILLER: If you will indulge me - as a layman, I've listened to this discussion for about an hour and a half now, and I think it's been a lot of discussion, debate, whatever you might want to call it. At the risk of sounding obnoxious, I hope I don't, but what we have to understand is the Commission has given the staff a challenge of stabilizing the medical regulations. I think we all agree - Dr. Diamond made a statement early, bad regulation - if I remember the quote - with good guidance is not the way to go. So no one wants to put out - the staff certainly does not want to put out bad regulations.

That said, Dr. Broseus and the working group and members of my staff have been working extremely hard over the last couple of years to try to come up with regulations that will meet what NRC feels needs to be done with regard to regulating the community. However, taking in all stakeholder's comments, I'm drawn to the conclusion that there is no

regulation that we can promulgate in this area that is going to satisfy everyone.

The agreement states have expressed some serious concerns with regard to the regulations. Part of what the agreement states dilemma is, they are co-regulators with us, and in talking to many members of the agreement states, I think their preference would be to have something that's more prescriptive, that would allow them to regulate.

In talking to members of the medical community, I think people want flexibility so that it's not so prescriptive, that people are limited in what they can do, so that creates somewhat of a dilemma to satisfy our stakeholders.

With regard to the dates, the schedules for the promulgation of the rule, I don't want the staff to come across as being bureaucratic, and we have to meet this date come hell or high water. We're going to meet it regardless of what people's views are. However, my concern is for those of us in the room who are old enough to have taken FORTRAN in college and used it as a computer language, I don't want to get stuck in an infinite do-loop in trying to get this rule out, and that's what I feel that we're getting to. We can't continue to have bring me a

rock, comment on it. Bring me a rock, comment on it. We have to be able to reach a point that we can get a rule that's meaningful, that puts people in place that we are satisfied are qualified to do this job, but not put such a burden on the industry, if I may call it that for this aspect of it, that they can't practice.

So if we were to go to the Commission, and I don't know the Commission's view of that, because the Commission gets very anxious to not to want to delay rulemakings. If I were to go to the Commission and ask them for more time, I'd have to be able to articulate why that time is needed, what's going to come out of it for the general good, and give them some rigid answers as to why at the end of that time we're going to come up with a product that's better.

The product that's better in my view would need to have a consensus, at least by the staff, the committee - I don't know if we can get a consensus with the agreement states - that what we've come up with is workable. And if we were to go out and ask for more time, make further changes to the language as Roger and the working group have crafted it, I would ask the committee to have the involvement to the extent that whatever is recrafted is liveable with the committee, so that we don't have to come back here in

six more months and continue to debate the issue as we have for the last couple of years.

That said, as time marches on, part of the reason we had to extend Subpart J was we were unable to draw a conclusion over the past year, and promulgate a rule that would give boards enough time to do what they need to do with regard to certification. My fear is we're going to end up in that same dilemma again this year. That's a dilemma, and what do we do about it? So that's the world that I see that we, the regulator, live in. How can we get through it?

CHAIRMAN MALMUD: Thank you. Are you going to address the comments that Dr. Miller made, Dr. Lieto?

MEMBER LIETO: Yes, and then some. I guess what I see as a problem is the sort of like almost less than a week deadline that we have, where we are -- with what Mr. Moore said, we're kind of really, from my perspective, being put into a corner. All right. And we don't have an alternative.

I think if we could maybe have a few more weeks to address these changes, because I'd like - again, this is my opinion - what I see are three major areas of what looks to me as changes in this piece

here. One has to do with the radiation safety officer, which appears to have met the intent of the ACMUI, but again I'm going to come back to this - I want to see this in the context of the whole Part 35. The training and experience, which probably is the number one issue that is before this group, and the grandfathering aspect, especially with respect to authorized medical physicists.

I think if we - again my opinion is that if we could have all these changes, including the proposed by the working group, before us and maybe in a teleconference in the next week or so with the committee, or maybe even a subcommittee if the Chair deems appropriate, to look at all these changes, and then get back to the committee as a whole, we might be able to address these within a matter of two, three, four weeks at most.

Now I don't know if that's unreasonable. I mean, if that's too long, then I guess we're painted into a corner, and I don't have a suggestion. So that's a suggestion. I do still have some points to make on the hours, and Dr. Eggli's issue about 390 hours. So I don't know if we want to address that comment that I --

CHAIRMAN MALMUD: Well, why don't you

finish your comments, and then we'll move on to the next one.

MEMBER LIETO: I tried to -- I think there's some -- trying to understand where the working group came from in terms of the number of hours that are proposed in here. I think what have been also -- the 392s, and 94, and 96 in here also, but if you look at Subpart J, which is the current where we're at right now, if I am interpreting 930 right now correctly, it requires 80 hours of training and experience, plus 13 thyroid cases, is the way currently is the 390 requirement. And that the 80 hours would be the didactic portion of training and experience.

If we look at the proposed 390, we've now gone up from 80 hours to 700 hours, and 200 of those 700 hours, which were 80 before; in other words, we've gone from 80 to 200 hours of didactic training, laboratory and classroom experience. If we look at the 392 and 4, which are the thyroid in the parenteral requirements requiring 80 hours for thyroid, 80 hours for the other - which comes out to 160 hours if you wanted to sort of go back the route of I want to get parenteral, and then I want to get thyroid without going the 390 route. Basically, I'm trying to get to

some type of an equivalency.

The 200 hours still is almost a factor of one-third higher, just even using that relationship. So it gets, I think if we're even trying to keep things at even scale, the 200 hours is probably a factor of maybe two or close to that high. In other words, maybe something like 100 to 120 or 30 hours might be more appropriate for the 390 aspects, and bring it more into line what we're requiring for the other uses. But not having sort of a sense of where these numbers came from originally, other than they were just proposed by, I'm assuming the OAS. Is that correct? Is that where the numbers are - okay. So that might be maybe a starting point to suggest in adjusting the 200 hours, if that's one of the things we wanted to achieve right now.

CHAIRMAN MALMUD: Does that complete your comment?

MEMBER LIETO: Yes, thank you.

CHAIRMAN MALMUD: May I -- oh, Dr. Williamson.

MEMBER WILLIAMSON: I have a comment, too, which I think is relevant. I think I agree with Dr. Diamond that from radiation oncology and medical physics point of view, this seems to me to be a great

improvement, and within the limits of my sort of ability to digest the details of legalistic language, I think it's resolved many of the major concerns that our community has had.

Having said that, I'm a strong believer in the dictum that the devil is in the details, and there are changes of commas and ands, and ors that are very difficult to follow. And I have not been able to descend to that sort of level of detail, and indeed working with others outside of this group is the best way I think to shake down this regulation and determine whether there are small bits.

The second point is, it does seem like a substantive issue of the 200 hours in 390 is a significant concern, and could cause harm to our colleagues' practice in therapeutic nuclear medicine. And I would defer to Dr. Eggli's recommendation that the definition of the additional hours or whatever be better calibrated to the actual teaching practices that are now used in the program, that exist - assuming that we accept the premise that what is being done now is an adequate standard of educational rigor.

And I guess the third point I wanted to make is that I would like to follow-up on a question Mr. Bailey has -- a challenge Mr. Bailey has put

before us. He's made, in addition to the -- he's indicated the agreement states are dissatisfied with the current final regulation on three grounds. I think the issue of substantiveness is clear. Then there's the issue of vagueness, and I guess the charge that the regulation is not clear.

Now I spent three hours reviewing this on my way here, and within my limitations I thought it was reasonably clear. Of course, I have some questions - I am not a lawyer, and I'm not an expert in regulatory affairs. I'm an amateur, but it does seem like the nature of this regulation has a certain level of complexity that is essentially the bottom line. You have to distinguish between Subpart J, which was a temporary regulation, and what happens in the future. That's a sort of a required element of complexity, when you have a two-track system where the boards are not hard-wired into the regulatory language, they need to have complying regulations to define what are appropriate boards that is going to introduce an element of complexity that you simply cannot dispense with, if that's the approach that is going to be taken. You have a set of criteria for the boards, and you have a set of criteria for the alternate pathway. I think that there's a consensus,

maybe the agreement states don't share it, but that the nature of the boards is such that their requirements are not written in the language of the alternate pathway, and that public health, which is an important goal - not just public safety, but public health requires that the system of health care education not be disrupted, unless there's really and overriding concern. So grant that.

So having been through this, I mean I guess I would ask Mr. Bailey to expand on this, and tell us what is wrong with this regulation. And secondly, since the 700 and 200 hours has been put into the alternative pathway, what is the concern of the agreement states?

DR. BROSEUS: Mr. Chairman, I must beg for a short break.

CHAIRMAN MALMUD: Dr. Broseus asked for a short break, and I think that's a reasonable thing to ask for at 10:15. Does Mr. Essig agree?

MR. ESSIG: I want to give Dr. Broseus the relief that he's seeking. However, I have one point with regard to the agenda. We had allocated time for the committee to write a memo, and I realize we obviously aren't at that point. But what I wanted to raise is there are four items remaining on the agenda

for today. One of them, namely, the abnormal cross-criteria, we desperately want to seek feedback from the committee, so I would like to keep that on the agenda.

Another agenda item is on the National Source Tracking System, which was an information brief for the committee. We could do that at another time. We are prepared to do it, we can do it another time, so that would save us some time there. We have two hours allocated for Dr. Vetter to present the ICRP-2005 recommendations. That is something that perhaps we could do in abbreviated form. The purpose of it was for Dr. Vetter to seek the committee's views, because he is representing the committee next week at an ACNW working group which is convening for a day, and he wants to make sure that he carries any concerns that the committee had. Now I realize that some of you maybe have little or no interest in the ICRP-2005 recommendations, and others do have some, and so I just raise that as maybe an item that we could either -- we could shorten or handle it in some other way.

CHAIRMAN MALMUD: Dr. Vetter indicates that he may not require the two hours, and it could be handled in a lesser period of time.

MR. ESSIG: Okay.

CHAIRMAN MALMUD: I just asked him that question while you were speaking.

MR. ESSIG: Okay. Fine. And then the fourth item is the tail-end, sort of the wrap-up to make sure we have agreement on the action items, and that kind of thing. I guess a break is in order, but after we come back then I would like to still keep on the table, if we could, the notion of whether or not some thoughts can come forth in a collective manner from the committee for the rule that we've been talking about.

CHAIRMAN MALMUD: Well, having listened to all of the opinions, I think that we probably can. We'll do that after the break.

(Whereupon, the proceedings in the above-entitled matter went off the record at 10:17 a.m. and went back on the record at 10:35 a.m.)

CHAIRMAN MALMUD: You're all invited to come back to the table for reconvening. Dr. Broseus is ready.

DR. BROSEUS: Thank you for the break.

CHAIRMAN MALMUD: I enjoyed sharing it with you.

(Laughter.)

CHAIRMAN MALMUD: It was not joint. It

was sequential.

May I do a little introduction to the reconvening of the last session?

MR. ESSIG: You may, but I just want to make one point first, which is the adjustment in the agenda.

CHAIRMAN MALMUD: Yes.

MR. ESSIG: The abnormal occurrence, criteria discussion which we want to see the views of the committee, I had talked with Ms. Jones, and she's agreeable to come back at one o'clock.

CHAIRMAN MALMUD: Thank you.

In the latter part of the last session and during the break, I had the opportunity to speak to some of the members of the committee, and if I may, I would like to summarize what might be an appropriate action at this point.

Let's just review for a moment the material on Dr. Broseus' slide. Nuclear pharmacy, 35.55, total hours 700, didactic 200, in vitro 35.190, total hours 60, didactic eight, diagnostic only 35.290, 700 hours including 80 didactic, and then therapeutic and diagnostic 35.390, 700 total hours, 200. That's unsealed.

Then if we had extended, if Dr. Broseus

would give us editorial permission to extend his table, the next line would be 35.396, 80 hours specifically for unsealed sources applying only to Board certified radiation oncologists. Is it Board certified or Board eligible?

DR. BROSEUS: Board certified.

CHAIRMAN MALMUD: Board certified radiation oncologists.

DR. BROSEUS: Or authorized users.

CHAIRMAN MALMUD: Or AUs, plus three cases.

Then we have 35.490 and 25.690, each of which would have 700 hours in the first column, 200 hours in the second column, and that's sealed, more complex, to include classroom laboratory work and three years of clinical experience.

Does that summarize factually what would appear in that table or what does appear in that table?

DR. BROSEUS: Sounds right to me.

CHAIRMAN MALMUD: Thank you.

Now, the real issue that seems to be percolating around the table is the issue of didactic hours, not the issue of total hours, and here we come back to the definition of didactic, which we raised in

an earlier session.

Didactic includes a classroom and laboratory experience. No one has an argument with that as long as laboratory experience includes clinical laboratory experience. When I'm in a clinical laboratory with a resident, I'm instructing the resident. The resident is essentially functioning in a training role.

The proof of that is that I could probably do three to five times as much work without the resident present as I am with the resident --

(Laughter.)

CHAIRMAN MALMUD: -- because I am instructing the resident.

DR. BROSEUS: I thought it was a patient.

CHAIRMAN MALMUD: And Dr. Eggli and Dr. Diamond and Dr. Nag all have the same experience. So that is didactic time. It's a one-to-one didactic time, much better than sitting in the classroom with 600 students in a 101 course in college, which is certainly didactic by anyone's definition.

So I think that the issue arises for the definition of didactic, and the concern, quite frankly, that's coming from various members of the committee is that no one in this room but a lower

level employee of minimal experience becomes overly enthusiastic and decides that the training program at Harvard or at Yale or at Washington University or at Hopkins does not have 200 hours of classroom time. Hence it does not meet the requirements of the NRC, and that that employee's citing of that program can escalate into something which would be embarrassing to everyone involved.

So the question really is not any of the issues that we've reviewed, but the issue, again, of what is didactic. If didactic includes instruction in the classroom, in the laboratory, and clinical laboratory, everything on the table is acceptable, I believe, to everyone who has raised a concern about this, including the states who wanted to have these numbers of hours as they are.

Now, is that acceptable to the staff here of NRC? What do you consider to be didactic?

DR. BROSEUS: Let me discuss some of the issues that have come up. One of them is expressed in a concern from the states that the 700 hours includes the classroom laboratory training in safety related items that are enumerated, for example, 390, under little Roman i. Little Roman ii is supervised clinical experience loosely termed. Okay?

The concern of some states is that that time over there would be used to count when they're not really learning safety. That's the idea, and so if there is a definition or re-definition, they have to be careful about that.

You know, I personally believe from my experience as a health physicist -- and is there something we can do with the ringing on the speaker, please? It's driving me nuts -- that a physician, for example, or a pharmacist working with a physician or a supervisory nuclear pharmacist is learning safety in the clinic lab, you know, but some of the arguments are, well, the use in time reading scans and call that classroom and laboratory training, and so that's the concern, I believe, that people have.

Also, you know -- I'm sorry. That's all.

CHAIRMAN MALMUD: Well, then you and I agree, if I interpreted what you say correctly, that when a physician and/or physicist and/or radiochemist or pharmacist is working with the resident in providing care to a patient while being instructed in safe handling of radioisotopes in, for example, doing lymphocytography in the separating of the dose into its various syringes in gloving, in indicating what the radiation exposure might be to both the worker and

to the patient from this, that that is didactic training on a one-to-one basis, much more valuable than sitting in a classroom with 400 students in a Physics 101 course. This is one-to-one didactic training by a fully qualified professional.

If we accept that as didactic, then a portion of the time that we are spending with the residents is, in fact, didactic. I can't imagine any better training.

MR. MOORE: Dr. Malmud, this is Scott Moore.

I think the intent of the staff is that with regard to classroom and lab, a portion of the time that's spent on rad protection instrumentation, rad physics, chemistry, and rad bio, if it's performed in, say, a nuclear medicine hot lab, if it's performed in a scan room, if it's performed in an I-191 administration room, if it's focused on those issues, radiation protection instrumentation, rad physics, chemistry, or rad bio would count as didactic training.

CHAIRMAN MALMUD: Now, having said that, Mr. Moore, is there any indication to the training program directors that this, in fact, NRC policy that would be accepted so that when perhaps a lower level

employee of a region comes into a department and challenges whether or not this is didactic, there is an NRC statement that what you just said is true?

MR. MOORE: I think it's up to us to make that clear in the final rule. The staff's preference would be to make that in the statements of consideration, which Roger refers to as the supplementary information. The reason the staff would prefer to put that in the statements of consideration is because we're concerned about unintended consequences by putting it into the rule itself.

CHAIRMAN MALMUD: Amen. So am I.

MR. MOORE: The terminology that is used in the current rule is classroom and laboratory. We have taken a broad interpretation of classroom and laboratory, and I think we can put text in the statements of consideration that reiterate what I just said, that we've taken a broad interpretation of classroom and laboratory, and we consider classroom and laboratory to include, you know, the nuclear medicine hot lab, the scanning room, patient rooms, as long they cover the required topics in rad safety and protection, instrumentation, rad physics, chemistry, radiation biology in those locations.

CHAIRMAN MALMUD: Having said that, may I

ask the members of the committee if they are, therefore, with that definition, willing to move forward with approval of the current recommendations?

Would someone wish to make a motion?

MEMBER DIAMOND: I believe there's a question.

MEMBER SULEIMAN: Sorry. I want clarification.

CHAIRMAN MALMUD: Okay.

MEMBER SULEIMAN: You know, the sign is changing where you're doing computer training, remote site training.

DR. HOLAHAN: On-line training.

MEMBER SULEIMAN: That's right. On-line training. Would that be considered part of the didactic classroom?

CHAIRMAN MALMUD: If it's related to radiation safety training, if it is radiation safety training. If it's simply transmitting images which has nothing whatsoever to do with radiation protection and radiation safety, in my mind -- and I speak for myself, not for the group. I haven't polled them on this -- I wouldn't consider that radiation safety training.

On the other hand, if it relates to the

calculation of doses, if it relates to the correct -- to the standardization of instrumentation, if it relates to the correct checking of a dose in a well counter, to the calibration of a well counter, the answer is absolutely.

PARTICIPANT: We would agree with Dr. Malmud's response.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: In the spirit of moving forward, I am inclined to agree with these, but I must say and from personal experience in being involved in the training of residents that on the whole they are very, very smart people, and it simply does not take 200 hours to give them the training in the area of 300 uses. That's simply a lot of time.

What do we do? We give them reading assignments. We'll give them NCRP 116 and some other things and then they come back and we'll discuss that together, but I just want to say they're very smart people, and you can give them this information in much less than 200 hours.

DR. BROSEUS: Does your training program include laboratory time exercises with the geiger counter?

MEMBER VETTER: All of these things, oh,

yes, all of these things.

CHAIRMAN MALMUD: I think that Dr. Eggli was next.

Dr. Eggli.

MEMBER EGGLI: Yeah, and again, I need to stay say that I think 200 is way too long and we need to look at a proportion of time. I had these residents for 1,000 hours. Then 200 hours represented a portion of that total 1,000 hours. It represented 20 percent.

Now that I have these residents for 700 hours, 200 hours on safety represents a significantly larger portion of their time and, again, compromises my ability to make them clinically competent as well as safe.

And I think we need to try to maintain some sort of balance here. I think 200 hours is really way more than it takes to train them in safety, and I need to train a well rounded, clinically competent, safe nuclear medicine physician, and this new regulation -- and, again, I realize this is alternate pathway, but I have to train to alternate pathway -- this new regulation will hamper my ability to make them clinically competent.

DR. BROSEUS: This is draft right now.

Let me emphasize that. So what is your the irreducible minimum?

MEMBER EGGLI: Truthfully, I think for 200 uses 50 hours is adequate, and for 300 uses 100 hours is adequate.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

MEMBER LIETO: I was just going to make a motion to the committee. It seems like the whole stumbling block here is this number of hours for 390. I think we're all in agreement pretty much with everything else. So I'd like to make a motion that the committee propose 80 hours of didactic training and experience for 35.390 authorized uses, plus the already stated 12 varied therapy cases.

CHAIRMAN MALMUD: Is there a second to that motion?

MS. SCHWARZ: I second the motion.

CHAIRMAN MALMUD: Dr. Schwarz seconds the motion.

Is there discussion of that motion? I'm sorry. Sally.

MS. SCHWARZ: From my perspective certainly what we're trying to teach is safe handling of isotopes. With 290, nuclear medicine physicians receive a significant amount of training to handle

unsealed sources.

To move from the unsealed sources in nuclear medicine to the therapeutic radiopharmaceuticals that are also trained in nuclear medicine, I believe that they certainly have within that 80 hours a significant amount of time in terms of the safe handling of unsealed radioactive sources.

They are different types, and there are different considerations, but I think that the total 80 hours is a sufficient amount of time to cover what is required.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. Well, one possible good thing you could do is then you could eliminate now the 396 because 396 requires a -- no, requires a Board certified radiation oncologist to have 80 hours.

MEMBER EGGLI: Specifically for unsealed sources.

MEMBER NAG: Right, and then if they can qualify under 396, they will also now be able to qualify under 35.390 or 35.390 will have --

MEMBER EGGLI: No, No.

MEMBER NAG: Why not?

MEMBER EGGLI: Because the 700 hours.

MEMBER NAG: but the 700 is -- I agree

with what you said before. The 700 can overlap between the different training modalities.

MEMBER WILLIAMSON: The 700 for unsealed radioactive sources. I think you would be making a big mistake to oppose these.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: I would disagree with Dr. Nag because 396 only addresses parenteral applications. Three, ninety includes both that plus the oral. So 390 would be a much larger application of unsealed radiopharmaceuticals.

CHAIRMAN MALMUD: There's a motion on the table.

I beg your pardon?

DR. BROSEUS: You're shooting yourself in the foot if you put 396 up.

CHAIRMAN MALMUD: There is a motion on the table for approval and discussion.

Mr. Moore?

MR. MOORE: With respect to the discussion, I guess an important factor that everybody needs to be aware is that the agreement states in the proposed rule, I believe it was Alabama and Iowa did recommend a specific number, 200 of didactic hours in comments on the proposed rule, and they may have

recommended in the petition itself 200 hours also.

And so if the ACMUI does pass such a motion, then the staff will have to consider the motion relative to the comments on the proposed rule and also the petition itself. So Mr. Bailey may have some comments relative to that.

CHAIRMAN MALMUD: Dr. Diamond.

MEMBER DIAMOND: I would defer to Mr. Bailey.

CHAIRMAN MALMUD: Mr. Bailey is looking for something.

MEMBER BAILEY: Go ahead. Let me find the paper.

MEMBER DIAMOND: Because there's a motion on the table, I'd like to discuss it further.

Ralph, if I may be clear, in your motion it would be 80 hours specifically of didactic for 390 in the context of a total of 700 hours; is that correct?

MEMBER LIETO: That's correct.

MEMBER DIAMOND: Thank you.

MEMBER NAG: Again, on that same thing, now you are having a 390 for 80 hours, 390. This includes both the parenteral and the oral administration for unsealed sources.

MEMBER DIAMOND: That's correct.

MEMBER NAG: In the 396 pathway, you are now having a radiation oncologist who has done oral therapy to now require also the same number of 80 hours only for the parenteral portions. So that does not really match. I mean, I would say in that case that for the 396 you would probably require a letter number than the 80.

CHAIRMAN MALMUD: That doesn't address the motion on the table, which we'd like to move forward first. Are you addressing the motion on the table, Ralph?

MEMBER LIETO: Yes. I would like to also point out that 390 requires 12 cases total. In other words, three cases of each of the four different classes of radiopharmaceutical therapies, whereas in 396 it only addresses three cases of any one form of the parenteral.

So from the standpoint of the clinical case documentation, 390 is, again, more varied and has a wider range of requirements than the 396.

CHAIRMAN MALMUD: Thank you.

The motion on the table is to reduce the 200 didactic under 35.390 to 80. Is everyone happy with the number 80 or -- oh, more discussion. Mr.

Bailey.

MEMBER BAILEY: I was just going to respond. I quickly looked through the petition and whereas 200 is referenced, I only see it specifically in reference to the pharmacist, and that the petition really asks for simply some numbers to be put in.

And I know these numbers have been tossed around, but as late as October 5th, there was no -- it was the first time there was really a poll on whether or not the agreement states agreed with these numbers. So I don't know that the agreement states have agreed on these numbers because the poll has not been tabulated to my knowledge, and I know at least one state, since it was me, did not agree with the numbers and, in fact, suggested that basically the equivalent of what I considered one graduate health physics course, three lecture hours and four hours of lab for one semester or about 120 hours would be an appropriate amount of training in the health physics radiation protection.

Now, people have come back and made arguments for 200, but those arguments are a little, to my way of thinking, a little weird in that they are comparing what an agreement state person who goes to the Oak Ridge five-week course gets.

So I don't think we're talking about an equivalent situation.

I also want to take this opportunity. When I spoke before about clarity and all, I was speaking not for the agreement statements in a poll that had been taken, but as a personal opinion having worked for two agreement states and how we adopted regulations. I wanted the record to be clear.

CHAIRMAN MALMUD: Thank you for clarifying that.

Dr. Diamond, did you have a comment?

MEMBER DIAMOND: Yes. I would just comment that given that 390 does require 700 total hours, given the requirements for three cases for each of the four classes, I think it would be reasonable to keep the 700 total hours and proceed in a favorable fashion with the reduction of 200 hours didactic to 80 hours of didactic, given that I do not believe this would have any negative impact on public safety.

CHAIRMAN MALMUD: Any further discussion of this item on the table?

If not, may we vote? All in favor of this?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: It carries with unanimity except for one abstention. So the recommendation is that the table presented by Dr. Broseus be amended for 35.390 to show 700 hours in Column 1 and 80 hours in Column 2, recognizing that that's plus 12 cases, three of each type of the four, and this is for unsealed sources.

DR. BROSEUS: I might make a small correction. Twelve cases are not required in all situations. It was a footnote which grants us at least three cases in Category G2, also satisfies Category G1. So one can get away with nine cases.

CHAIRMAN MALMUD: I stand corrected because your table didn't specify that. You are correct.

DR. BROSEUS: Yeah. Secondly, we had a motion. I've recorded that to go back to the staff with. It's useful also though to have a strong basis for this. What is the committee saying in terms of a basis of sufficiency of 80 hours?

CHAIRMAN MALMUD: That which I have heard, and please, anyone augment or change my comments if

you wish, is that Category 35.290, which is diagnostic only, includes 700 plus 80 of didactic, and the therapeutic application on top of the diagnostic is generally covered in the 80 hours that are presented in the diagnostic. Since the therapeutic relates primarily to the use of beta emitters, the same radiation safety practices apply, as do for the gamma emitters, though there's recognition that beta and gamma emitters are different and that the radiation burdens from them are different, and that the shielding for them is somewhat different.

And, therefore, 80 hours would represent an adequate number of hours. It is also the number of hours which is used in nuclear radiology training programs currently, as documented by Dr. Eggli, who has a nuclear radiology training program and represents 80 hours of training, which is the rough equivalent of three courses of three hours a week in any college program.

Tricia.

DR. HOLAHAN: Could I ask a question? Two-ninety (35.290) training is 80 hours as well. So would you envision any differences in the 290 training versus the 390 training, Dr. Eggli?

MEMBER EGGLI: I can speak to that

question only in that I think, again, the group we're talking about are diplomats of the American Board of Radiology because the other training programs would probably for 390 encompass easily the 200 hours.

But diagnostic radiologists train in 12 different modalities, and therefore, their time is a little bit more limited.

It is my understanding that it is the intention of the American Board of Radiology to have their training programs train residents in diagnostic radiology for certification or licensure for uses under Subpart 300, and therefore, it may be moot whether the requirements for 200 or 300 are different, given that the Board intends that all of the residents should be trained to the level of Part 300 uses.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

The other comment is, I believe, that 390 does not require the 12 cases of varying types, that 290 doesn't require them and 390 does.

MEMBER EGGLI: Yes, that's correct.

CHAIRMAN MALMUD: So that's a difference.

DR. HOLAHAN: Yes, but the argument that the agreement states made, and correct me if I'm wrong, but they felt that there was a risk with 390 uses that there wasn't associated with the 290 uses.

MEMBER EGGLI: And the only thing I would say is that 80 hours for uses under Subpart 200 is probably excessive, but again, since it's the intent to train everybody to at least the 300 level, it's unimportant.

But if you feel it's important to make the distinction, then I have no problem with reducing the number of hours under Part 290 T&E requirements, which I actually did suggest a few minutes ago, that I thought 50 hours would be more than appropriate at Part 290 T&E, but again, I believe that the American Board of Radiology intends to train all of its diplomats under the rules of Subpart 390, and therefore, the distinction may be more theoretical than real.

CHAIRMAN MALMUD: But there is a distinction in the requirement for the cases between 290 and 390.

MEMBER EGGLI: Yes.

CHAIRMAN MALMUD: Does that answer your question, Dr. Holahan?

DR. HOLAHAN: Yes.

CHAIRMAN MALMUD: Dr. Broseus?

DR. BROSEUS: I missed something. You attributed to Dr. Eggli a comment about 80 hours is

required by ABR, but I didn't really hear a number.

MEMBER EGGLI: No, I don't believe I said a number.

DR. BROSEUS: What is the requirement? Do you know?

MEMBER EGGLI: For ABR?

DR. BROSEUS: Yeah.

MEMBER EGGLI: Right now ABR is waiting for NRC to say something. As a matter of fact, there's a lot of uncertainty in ABR training programs right now waiting for this final regulation. I can tell you that because there are 12 modalities out there that diagnostic radiologists have to train for, that wherever NRC sets the threshold, that will be what the training programs require.

It used to be that we trained our residents to $1,000 because that's what was required for NRC authorized user status under Parts 290 and 390 previously. Now if it's going to be 700 hours, then the ABR requirement will be 700 hours, and it's just a necessity because there are 12 modalities.

And if the training requirement becomes 80 hours for subpart 390 T&E requirements, then that is what the American Board of Radiology will suggest to its training programs that they ought to offer.

DR. BROSEUS: Let me ask one more devil's advocate question, and that is where you're describing a scenario in which medicine becomes more complex and there are more applications and more and more and more, and therefore, being the devil's advocate. This tells me that the physician who's doing that needs more radiation safety, not less, and so maybe somebody should add hours to the total training program to make sure there's enough radiation safety rather than trimming the safety part to make sure there's enough time for clinic.

I emphasize devil's advocate.

MEMBER EGGLI: Keep in mind that we are providing almost as many hours again in physics training that is pertinent to the other modalities in radiology, such as CT, plain film, and all of the other areas where ionizing radiation issues, and again, that is, we have designed our program. We designed 100 hours of classroom lecture. Half of those would fit the description in the regulation for nuclear medicine. The other half we considered to be more limited to other forms of diagnostic radiology and not directly applicable to the handling of unsealed sources.

There was some crossover, but at least 40

percent did not readily cross over. So we're providing far more physics training, health physics training to our resident than will satisfy NRC because we have other modalities where we're training these kinds of issues where we didn't see a direct crossover.

Now, maybe we should have been more generous in our own internal definition and said it all crosses over, but we didn't do that. We separated diagnostic radiology physics from nuclear medicine physics.

CHAIRMAN MALMUD: Dr. Broseus, does that satisfy your devil's advocacy question?

PARTICIPANT: Well, I think what I'm hearing is that you're using the term "physics," which some people may interpret as principles of physics more broadly to include health physics, radiation safety related topics; is that correct?

DR. BROSEUS: Yes.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yeah, I'm worried now that this motion for 80 hours is based on a misunderstanding of what the 200 hours are allowed to be. Okay. The 200 hours, it doesn't say they have to be on radiation safety and only the physics, narrow

physics that's relevant to radiation safety.

If I read what it says, it says radiation physics and instrumentation. It doesn't say that learning to use instrumentation to determine a dose for X-ray computed tomography can't be counted. You know, it says radiation physics. It says radiation biology. This could be any kind of radiation. It doesn't even specify that it has to be ionizing radiation biology. It could be, for example, ultraviolet light biology.

PARTICIPANT: And we do count the radiation biology in the --

MEMBER WILLIAMSON: Now, mathematics pertaining to the use of measurement of radioactivity and then, you know, chemistry of byproduct material for medical use is more specific, but I'm asking, I guess, if in this calculation of hours the sort of broadness of what is allowed to be counted has been considered.

CHAIRMAN MALMUD: I imagine that question is directed to Dr. Eggli.

MEMBER WILLIAMSON: It is.

MEMBER EGGLI: And we tried to consider that, and we did consider that there was an area of overlap. Probably about 30 percent of our lectures

overlapped the two areas where we have obligation to train, and then we had an area where we thought there was clearly not an overlap, and as we are looking at coming up with total hours, that's where we were running into trouble, is coming up with total hours.

And, again, I think we have a fairly comprehensive program, and if you look at the total amount of time we have, it's certainly equivalent to a semester long college course.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Mr. Lieto has a question.

MEMBER LIETO: I wanted to clarify just a question or point. The wording in the original proposal says "has completed 700 hours of training and experience including a minimum of 200 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material."

So the 80 hours that we're referring to or that the motion, the approved motion took place is in that definition. So the more general definition of physics and safety in X-ray and CT would not have been applicable the way that the definition is for that section.

So I would say that we're fine in what we

proposed.

CHAIRMAN MALMUD: Thank you.

Now, the motion was passed with unanimity, one abstention. May we move on to the next item? And does this satisfy the NRC's need to bring this forward to the next step?

DR. BROSEUS: I'd just like to make one clarifying comment. I'm not sure that Dr. Williamson was serious about including ultraviolet, but we're talking about ionizing radiation here. While it's not defined in Part 35, it is defined in Part 20. Radiation means ionizing radiation.

CHAIRMAN MALMUD: Thank you for clarifying that for the record, Dr. Broseus.

May we move on?

Thank you. It has been a most stimulating session, which has come to a resolution.

MR. MILLER: I think we can all agree on that.

MEMBER NAG: Now that we have had no 390, what I'd like to bring up for a brief discussion here is 396. Eighty hours is a submission for unsealed sources (phonetic) both for parenteral and for oral administration. Am I right? Yes, no?

MEMBER EGGLI: Three, ninety or 396?

MEMBER NAG: Three, ninety.

MEMBER EGGLI: Three, ninety.

MEMBER NAG: So 80 hours submission for both the oral and for the parenteral. With 396 we are only going to do parenteral because the 396 under the parenteral for those who are Board certified in radiation oncology who have now already spent quite a lot of time in therapy and now need to know about unsealed sources for the parenteral administration only.

For that group of people, are you going to need the same eight hours that you require for somebody who is learning both about thyroids and about parenteral administration, yttrium (phonetic), and so on, or my proposal is that for somebody who already is an expert on handling radioactive material in the source, but the parenteral only 80 hours is excessive. If you want me to put a number, I would say it has to be less than 80. Whether 60 or 40, I think we can deliberate, but if the APR rate is going to be sufficient for only a limited component of that, by definition it should be somewhat less.

CHAIRMAN MALMUD: Does anyone else wish to address that or do you want to make that as a motion and see what the response is?

MEMBER NAG: If you want me to make a motion, I would make a motion that for 396, the didactic component of that be 60 hours.

CHAIRMAN MALMUD: Is there a second to that motion?

Not hearing a second, we will --

MEMBER EGGLI: I'll give him a second.

CHAIRMAN MALMUD: You're going to give him a second?

MEMBER EGGLI: Sure.

CHAIRMAN MALMUD: Dr. Eggli gives you a second, which now opens it up to discussion. Dr. Broseus.

DR. BROSEUS: It would be helpful to include in the motion if possible, not to make it too complex, a basis for this of sufficiency.

MEMBER NAG: The basis is that for the entire scope of unsealed sources, including the parenteral and the oral administration, we are requiring 80 hours. What percentage of that is oral and what percentage of that is for parenteral is hard to say, but allowing for overlap and so forth, I would say, you know, that is why we bring it down. Instead of half-half, I'm looking at 760 rather than, you know, 40 and 40.

CHAIRMAN MALMUD: The point might be made that in providing the therapeutic application of radionuclides, one often does a diagnostic test first with another isotope or a lesser amount of the same isotope.

In addition, it may come to pass that the oral administration of a therapeutic or diagnostic isotope would be associated with the use of a therapeutic isotope in the future, and for that reason it would be safer to leave a number at 80.

And we recall that under Part 35.396, it specifically says 80 plus three cases. Under 35.390, it's 80 plus 12 cases. So there is a difference, and in the sense that we don't know what will evolve in the future, it might be best to leave it as it is.

However, that is open for discussion.

Dr. Williamson.

MEMBER WILLIAMSON: Well, I think in practice, complying with the 80 hours, you know, given the extensive base of didactic training that radiation oncologists get, you know, much of the physics and instrumentation would be applicable.

I think that in practice the incremental burden would be very small. I think the only case that I can think the 80 hours would affect, you know,

a very direct way in the way you're thinking would be those that fail the recency of training test. I've forgotten which paragraph. It is in Part 35, but it seems to me that someone who is seven years beyond their residency training and has not had experience with radionuclide therapy probably would, in fact, have to have 80 hours' worth of training in order to add this new credential.

MEMBER NAG: Basically that is what I was thinking of.

MEMBER WILLIAMSON: And, you know, I'm not sure that someone who is out away from this for ten years, speaking as a physicist, whether it would be such a bad thing that they repeat, you know, this much training.

CHAIRMAN MALMUD: Mr. Lieto, you had a comment?

MEMBER LIETO: Well, I was going to state that I would oppose reducing the 80 hours because I think there are more radiation safety considerations associated with the administration of parenteral radiopharmaceuticals than oral, and also it would remain consistent with what we have in 392 and 394 as requirements for all administrations. So I would like to just keep it as is.

CHAIRMAN MALMUD: Thank you.

Any other comments?

(No response.)

CHAIRMAN MALMUD: If not, should we call the vote on it?

MEMBER NAG: I withdraw my motion.

CHAIRMAN MALMUD: The motion is withdrawn. Thank you, Dr. Nag.

MR. MOORE: Dr. Malmud, point of clarification. This is Scott Moore.

When you're talking about moving on to the next subject, are you talking about moving on to the National Source Tracking System or are you talking about moving on to the next subject within Part 35 T&E?

CHAIRMAN MALMUD: Is there another subject under 35?

PARTICIPANTS: Yes.

CHAIRMAN MALMUD: Then we'll move on to the next part of 35 T&E. Is that what you wanted to do?

We have a member of the public who wishes to make a comment on Part 35.

DR. WHITE: Thanks.

Jerry White, American Association of

Physicists in Medicine.

I'm impressed with the great attention to detail that you've given to the training requirements for various physicians, but there are some T&E issues, I think, that we made comments on regarding authorized medical physicists, grandfathering of authorized medical physicists, and RSOs for medical physicists, and I'd just like to ask the ACMUI if they have had the opportunity to consider those, and if the changes might be substantive, if there could be some way that -- I know the paper copy of these changes is not available, but if there were some oral discussion that you might want to have or have some way to have other eyeballs look or know about these changes.

CHAIRMAN MALMUD: We have several physicists here who have not commented yet. Dr. Williamson, we haven't heard from you for a while.

(Laughter.)

MEMBER WILLIAMSON: Well, I think that, you know, I have reviewed this, and I think for RSO -- I think. I say this very tentatively because it is a complex regulation. I don't think it is unclearly written, but I know how disastrous the misplacement of a comma and the transposition of an "and" or "or" can be, and I would think that it would serve the

regulated community and the NRC to have a few more eyes look closely and analytically at these various revisions because while they may not be substantive according to the letter of the Administrative Procedures Act, nonetheless, we have had mistakes in the past that have been very embarrassing, and I would think that we should find some way to on a short-term basis make these pre-decisional document public or available to people who wish to look at it.

I think this would help the ACMUI in crafting its final memo to have some additional input from expert reviewers. So I would ask that we figure out some way, if necessary, reading this into the public record or making a motion to append it to the meeting summary which must be posted in ten days or simply taking the common sense step of putting it on the Web so that those people who wish to see it can see it.

CHAIRMAN MALMUD: Thank you.

MEMBER WILLIAMSON: I think it can only help improve the final product to have some unforeseen or unanticipated consequence or, you know, mistake revealed.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter, do you have a comment?

MEMBER VETTER: Yes. I don't have the test in front of me, but when we reviewed this prior to our conference call, it appeared to me that the question that Jerry raised about RSOs has been adequately answered. That is, there was a gap for those physicists who qualified under ABR, and now there is one of the "ors" that says if you have a Master's degree in physics and two years of experience, you will qualify as the RSO, and I think that takes care of ABR's concerns, doesn't it, relative to RSO?

CHAIRMAN MALMUD: Dr. White, you raised the question.

DR. WHITE: Dr. Vetter, I just have to say I don't know because without seeing the actual text, it's just so hard to respond. Sorry.

MEMBER VETTER: Okay. Point well taken, but in my opinion it does take care of it.

CHAIRMAN MALMUD: So Dr. Vetter reassures you, Dr. White, that in his opinion it is taken care of, though you haven't seen the text, Dr. White.

Mr. Lieto.

MEMBER LIETO: I would like to also support Jeff's recommendation that we release this predecisional document for people to look at. I

think, you know, Jerry White's, you know, comment being a point that the medical physics community would like to see that this is addressed.

I do agree with Dick though that I think it does answer the concern. I have an additional question regarding the RSO preceptor issue.

CHAIRMAN MALMUD: Before we go on to your additional question, is there any objection to distributing this document?

Dr. Miller.

MR. MILLER: The committee is certainly within its rights to make such a recommendation if you so choose. We recognize that will be a recommendation if you choose to make it that the staff will have to take to the Commission itself for approval, and if the Commission were to approve it, and I think what I'm hearing is a recommendation.

To put it out for public comment again, to put it out just for the public to look at and as a set of eyes serves no purpose in my view with regard to trying to reach a final product unless there's a view that you would want to seek as a committee the public's views on this before we go forward.

And I go back to my comments this morning of we've got to get to a point where we're not stuck

in an iterative process that we can't get out of. At what point in time do we move forward?

So you know, with that, the question becomes does the committee think at least from the staff's perspective that the rule should be put out for public comment and, if so -- and I need General Counsel's help on this, Susan, if you can listen -- I'm going to ask a question if you'll indulge me of our representative from the Office of General Counsel.

If we were to consider putting the rule out for public comment, could you limit it to some portion of the rule or do you have to put the whole thing out again for public comment?

MS. CHIDAKEL: The reason I was just talking to Sandy when you called my attention to your questions is that I need to take these issues back to the Office of General Counsel. I'm not really prepared at this point to answer those questions, and I raised the issue of Sandy.

I think, you know, these are recommendations you can make, but I think I need to go back to my management and have these issues resolved.

MR. MILLER: Exactly. I mean, before we could act on the recommendation, we would have to get approval.

MS. CHIDAKEL: You would have to get an official opinion from the agency.

MR. MILLER: Scott is trying to get a point in here, I think.

MR. MOORE: Yes. If I may, there are rulemaking mechanisms whereby we can make predecisional rulemaking -- maybe I should call it draft rulemaking -- available for the public to see. The Office of Nuclear Reactor Regulation is using that mechanism, namely, posting it on the Web, for the public to see.

If the ACMUI believes that we should do so, you know, it's certainly within your prerogative to make such a motion and pass it. This has certainly been such a controversial rule and that mechanism has not been used within NMSS very frequently. You know, we would certainly consider it, and may consult with the Commission before we would do so.

MR. MILLER: Well, we would consult with the Commission, yes.

MR. MOORE: Okay. Please recognize that the Commission itself has not seen this language that's before you. So you're seeing a draft final rule that the Commission itself has not seen.

So you know, if you want to pass a motion

that either it be made public so that you can share it and talk to your counterparts and colleagues or that it be made public and it be commented on again, that's certainly all within --

MR. MILLER: Scott, so that they're clear on the motion that they need to make --

MR. MOORE: I think Dr. Suleiman had a comment.

MEMBER SULEIMAN: I have. I need some clarification. What we're talking about that the public hasn't seen that's pre-decisional, will that be published as the final rule to take effect after a certain amount of days or is that going to be published as proposed rulemaking?

MR. MOORE: I can answer that. If it goes out now without any change in process, after we would get your comments, we would -- and the agreement states' comments, we would send it up to the Commission in mid-November. The Commission would eventually vote on it as Roger's last slide showed, and it would go out as a final rule. It would not go out again for public comment.

MEMBER SULEIMAN: Okay, all right. Interesting.

CHAIRMAN MALMUD: Does that answer your

question, Dr. Suleiman?

MEMBER SULEIMAN: At some point NRC will determine whether there have been substantive changes to the document, whether, in fact, you'll reconsider and go back and propose it as a new rule because it's up to your --

MR. MOORE: No, no. I can answer that. I checked with the General Counsel yesterday, and the General Counsel's office yesterday actually, Stu Treby, was of the opinion that it did not need to go out for public comment. I don't think "substantive comments" is the actual phrase. I think Susan gave the correct legal threshold.

MS. CHIDAKEL: And please let me clarify. He's not the General Counsel.

MR. MOORE: Okay. The General Counsel's Office.

MS. CHIDAKEL: For the record, his position is the Assistant General Counsel for Rulemaking and Fuel Cycle. So to make clear that, you know, he's not the General Counsel.

But in any event, Scott Moore is certainly right. That is still our position.

MR. MOORE: It did not pass the legal threshold that it needed to go out for public comment,

again, but that doesn't mean that it can't go out for public comment again.

Now, in response to Charlie's point to clarify, there are a couple of options. One is the ACMUI could recommend to the staff that it should go out for public comment again, and we'd ask that you give us a basis for that if you pass a motion to do so.

Another comment that the ACMUI could give us, you could pass a motion that it be made available to the public not necessarily for comment, but just made available publicly, and there are mechanisms that the staff could do that.

CHAIRMAN MALMUD: Excuse me. By the term "made available," that means it will be made available to the public to see prior to anyone in the NRC seeing it? I mean, does that create an embarrassment for anyone?

MR. MOORE: No, no. It won't be an embarrassment.

CHAIRMAN MALMUD: I just want to make sure.

Dr. Williamson.

MEMBER WILLIAMSON: Well, then, you know, let me state my intention was not to materially try to

delay the process of ultimate approval, but only to aid this committee by sharing this with colleagues or being able to share this, to be able to solicit additional input on the details.

So given that, I would make the motion that we make it available to the public and not request a separate cycle of public commentary.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I was going to second that until he said not make it available and not allow public commentary. I think that's the reason you want to do this, is so that they can get some input from the other parties.

I mean, I don't disagree with that we don't want another around of rulemaking and that whole business, but you know, I think you need to see this --

MEMBER WILLIAMSON: Well, sending it for public commentary is a formal mechanism. It has to be published in the Federal Register again. It would be a substantial delay in their process of several months. I am simply proposing to make it available to the public immediately.

MEMBER LIETO: What's the value of making it available if no one is going to have the ability to

provide input to the staff to see if there are issues that we may have not recognized that create difficulties?

CHAIRMAN MALMUD: I understand your question.

Dr. Suleiman.

MEMBER SULEIMAN: Right. We need to follow some discipline in the process. If we want this to be published and not get any comments, I agree with Charlie Miller. There's no point in it. The decision is made. We've been given the opportunity to see it, but it's the NRC's decision.

That's why I was asking earlier for clarification. If there was, for lack of a better word, significant, substantive, whatever changes where it has changed enough and that's the NRC's call, then they would say, you know, "We have to go back and go through the whole public comment period."

But it sounds like to me that we're beyond that, and this was just a courtesy. Here's what the final rule is going to be.

CHAIRMAN MALMUD: You've raised the question which I was going to ask in a different manner, and that is that we have physicists on our committee. Dr. Vetter has seen it and has no

objection to it. Dr. Williamson has no substantive objection to it, though he says he has not reviewed every last detail of it to his satisfaction, but he has no objection to it. I don't see why the usual process has to be invaded.

MEMBER WILLIAMSON: Can I state my rationale, please?

CHAIRMAN MALMUD: Yes, you may.

MEMBER WILLIAMSON: My rationale would be that there would be individuals I could personally solicit feedback from on the details and be able to give a more informed evaluation of this regulation as a member of the ACMUI. That's maybe a weak rationale, but that's, in fact, what I would do if it were made available --

CHAIRMAN MALMUD: Thank you.

MEMBER WILLIAMSON: -- to those who are interested in reading it.

At least I personally would solicit some additional input from members.

MEMBER LIETO: But then you'd be providing input into the working group.

MEMBER WILLIAMSON: That's correct. I would, you know, attempt to do this. I think the time frame of three, four days from now is very tight to do

this, you know. To try to get a few more days would be helpful.

CHAIRMAN MALMUD: Does anyone wish to make a motion to that effect or shall we just --

MEMBER WILLIAMSON: I have made the motion.

CHAIRMAN MALMUD: Trish?

DR. HOLAHAN: Yes, excuse me.. I'd like to emphasize what Dr. Miller said. First of all, we'd have to go to the Commission and ask if we'd have to put out the draft rule language on the Web, but what I understand is what you're saying is if we put it up on the Web and you would solicit comments from specific stakeholders and get back to us, and so you'd need more time.

MEMBER LIETO: This is Ralph Lieto.

I would agree with what you just said, Trish.

DR. HOLAHAN: Okay.

MEMBER LIETO: Now, how much time? Is two weeks unreasonable or ten days or something like that? I mean, I know we want to try to keep it short, but I think what you're talking about in terms of basically two business days is not really practical.

MEMBER WILLIAMSON: Yeah. So I think my

motion would have to be amended to include enough time to accommodate your process for querying the Commission and then give people a few days to the selected few people that perhaps I and other members of the ACMUI would solicit to get input; we would need a few days to --

DR. HOLAHAN: We would have to make it available to all the public. You can't just go out to a few.

MEMBER WILLIAMSON: Well, it would be available to all the public, but you know, I am not going to personally contact each member of the public who reads this. I would contact a, you know, few knowledgeable people, you know, and Dr. Vetter, could detect errors in this.

MEMBER VETTER: I think what Dr. Williamson has suggested does have value, but I also think there's a huge risk there in going out and soliciting input from a few selected individuals. Someone out there will not be contacted and will be very unhappy with the process.

CHAIRMAN MALMUD: Thank you, and there's a member of the public that wishes to make a statement.

DR. WHITE: Yes, I would just like to, in

answer to Dr. Hiller's (phonetic) question, I think the value is clearly the staff has taken guidance from the ACMUI in this regard, and that if there's some way for the regulated community to have consultation with or voice an opinion to the ACMUI, I think that's an appropriate method for perhaps effecting change in this. I think it's not really a "do" loop issue. I think it's more a limits issue. You know, the epsilon and sigma issue.

We're getting very close to the final product after many years of effort, and these last few details would benefit from just one more look, and it doesn't need to take more than a week or so. I mean, I don't know exactly how much time, but we're really not talking about extending another request for public comments, but just rather one more set of eyeballs for these final things which for physicists are very important.

The grandfathering of AMPs is a vital issue for us, and we don't know what the language looks like.

CHAIRMAN MALMUD: Thank you. We've heard your concern.

There is a motion on the floor. Has it been seconded?

MEMBER LIETO: I will second.

CHAIRMAN MALMUD: Mr. Lieto seconded it. Any further discussion of the motion?

MEMBER SULEIMAN: What is the motion?

CHAIRMAN MALMUD: Would you repeat your motion, Dr. Williamson?

MEMBER WILLIAMSON: The motion is to make the predecisional rule publicly available so that ACMUI members may be able to solicit additional input in formulating written opinions for the staff.

MEMBER NAG: I would suggest that same motion -- just leave out the last part of the sentence. You don't need to hear why it has to be made public.

MEMBER WILLIAMSON: All right. So I'll rephrase. The motion is to make the predecisional material publicly available and extend the deadline for ACMUI input to give us five working days from the date it is made publicly available to finalize individual comments to the staff.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I think this modifies the whole process. I think we should just go -- I would not support.

CHAIRMAN MALMUD: You're not supportive of

it.

MEMBER SULEIMAN: No.

CHAIRMAN MALMUD: Any other comments?

Call the question. All in favor.

(Show of hands.)

CHAIRMAN MALMUD: All opposed?

(Show of hands.)

CHAIRMAN MALMUD: The motion does not pass.

May we move on to the next item if there is another one under Part 35?

DR. BROSEUS: I've completed my presentation.

CHAIRMAN MALMUD: You've completed your presentation, Dr. Broseus?

DR. BROSEUS: Save one item, and that is to thank you all for the extraordinary effort put into this because everybody has put a lot of labor into having the rule that comes out. Yes, pat yourselves on the back. We are, too. This is a difficult rule, and we're doing our best to make it good, and you guys have done a lot in that direction. I really appreciate this.

CHAIRMAN MALMUD: And the committee appreciates your effort and the enormous input that

we've had from you and your staff.

DR. BROSEUS: Well, I am at your disposal if there are anymore questions.

CHAIRMAN MALMUD: We do have a full agenda. Is it something that's urgent, Ralph?

MEMBER LIETO: Well, if we're not going to be putting this out for a predecisional, then I think we need to address these specific points then, and if it takes a while, then I guess that's going to be the case.

MEMBER WILLIAMSON: This is the last moment. We need to take the time.

CHAIRMAN MALMUD: What would you like to take a little time on?

MEMBER LIETO: Well, my next point that I would like to address, I've got actually two. It appears that in this predecisional documentation it states that a person who was an RSO and then is no longer an active listed RSO cannot be a preceptor. So if our esteemed colleague, Dr. Vetter, leaves his institution as an RSO and is no longer the listed RSO on the license, he cannot be the preceptor for anybody else's training and experience.

And so I would like you to address that point first.

DR. BROSEUS: Is that a question?

CHAIRMAN MALMUD: Is that a question to Dr. Vetter?

MEMBER LIETO: No, it's a question to the NRC staff.

DR. BROSEUS: We haven't changed the definition of a preceptor except to add to it as recommended by the ACMUI to say it could be a person who is familiar with the training. In other words, they don't have to direct the training. Okay? That's in 35.2, is the definition.

So we haven't changed the definition except to add to, as per your recommendation. Okay?

And the other areas where we talk about the preceptor rule itself are basically unchanged. So I'm not quite sure what the basis for the question really is.

MEMBER LIETO: Well, it's on actually page 33. It says if an individual status as an RSO, ANP, ANP or AU is dropped, revoked or removed from the license or because of poor compliance with the NRC's regulation, that person can no longer serve as a preceptor. I mean that's what it states.

Now, I don't know if that was the intent, but what it states is that --

DR. BROSEUS: I'm not sure that we have the same page number. Is this -- is there an issue number associated with this? Because the --

MEMBER LIETO: Actually it's issue number two on page 33 on what I have. It's your pagination. So even an authorized user who may have been on a license and maybe the Director of Training; so I think there needs to be a clarification.

And I think this also gets to the issue of authorized medical physicists and who can be a preceptor for an authorized medical physicist. We've got to, you know -- that would basically almost eliminate a first pool of authorized medical physicists.

DR. BROSEUS: I think as I read this, this is in response to a comment from an agreement state about who can and can't serve, and at the end we're talking about if somebody is removed for cause that that would be --

MEMBER LIETO: Well, it says "or" and it doesn't --

DR. BROSEUS: Right, but we would have to go back and, again, look at your comment and insure that we haven't put something into the response that is removing the ability to be a preceptor that's in

conflict with the definition intended for --

MEMBER WILLIAMSON: Well, I guess this is a good question. If the director of one's training program retires and ceases to be an authorized user at some future point in time, can that person serve as the preceptor for a graduate of the program, presuming they were under the assumption that they were an authorized user, you know, at the time, in the time frame that's relevant for documenting the applicant's credentials.

That's the question.

DR. BROSEUS: My first stop is to read the rule. Ron, do you want to add anything?

My first stop would be to read the rule and see what it says.

MEMBER WILLIAMSON: Well, tell us. We are asking you.

DR. BROSEUS: Yes.

MEMBER WILLIAMSON: I mean, that's evading.

MEMBER LIETO: I think, you know, and I know I'm sounding repetitive, it gets back to being able to look at the rules that we're going to be, you know, recommending and submitting changes for. You know, if we're not going to -- I don't know if we need

to go to a formal motion or not, but I think if we've only got a few days to provide comments to the NRC staff, you know, I think we need to be given the tools to make, you know, valid comments and knowledgeable comments to you and to see it in the whole context of the preceptor definition, especially with the RSO and especially with the authorized medical physicist aspects because there has been a number of changes, that I would like to see that, you know, within the next day or so.

I mean, if I've only got basically to the 18th, then I'd like to see that, you know, by the end of the day tomorrow.

MEMBER WILLIAMSON: I just would like to have the answer to my question.

DR. BROSEUS: If I understood the question correctly, could a person who was an authorized user continue to serve as a preceptor.

MEMBER LIETO: Correct.

DR. BROSEUS: And I would have to look and see what the rule says, but on the face of it, I would say, no, they're not an authorized user. If a person isn't named in the rule as a person who can serve as a preceptor, then the answer to the question would be no, but I also have to look at the definition, and if

that person, for example, was in a training program, during that training program, I'm not sure about this.

Ron?

DR. ZELAC: This is Dr. Zelac.

If one looks specifically, Ralph, at the question of the radiation safety officer, the best thing to do is to look back at the definition that appears now in the rule for radiation safety officer, and it reads that an individual who meets the requirements in 3550(a), meaning Board certified, and 3559, recentness of training and experience, or is identified as a radiation safety officer on a license.

So in Dr. Vetter's case, for example, if he were to cease being the radiation safety officer at Mayo Clinic, he would still qualify as radiation safety officer on a quick read under the first provision that I read, that he meets the requirements in 3550(a) and 3559. At least for the next seven years he would.

DR. BROSEUS: This is really not a new question. This is an interpretation of the current rule. So I think that answers the question.

Thank you.

MR. MOORE: And if I may address Dr. Lieto's comment on the timing question, first of all,

with regard to getting, you know, full information by tomorrow, with regard to the red line strikeout version, the staff is preparing a red line strikeout version. One has been developed, but it's not QAed.

Going back to the comments from the telecon, I think we said in response to Lynn's recommendation that we thought it was a good idea and we would certainly consider it.

The staff plans to do so for issuance of the final rule. With regard to getting it out, we want to make sure that we get the right thing out and there are not errors in it before we issue it.

With regard to getting out a full rule, we agree that that would be helpful. If the committee needs additional time, that would be certainly something we could consider, but as I had mentioned, we would need to ask the Commission for that, and to do that, you know, we would need you all to tell us that you need additional time for that and give us a basis for that, and you know, we would tell the Commission that.

But absent that, we would have to work under the schedule that we have now.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: I think the other

issue that was raised on the teleconference is the issue of grandfathering for the authorized medical physicist. Why that is of special concern is that the authorized medical physicist as an entity within the regulations hasn't existed until recently, and so there is a concern about how the details of the grandfathering would work in order to assure that there are enough individuals who are grandfathered into that status that there would be an appropriate supply, an adequate supply of preceptors.

This is a confusing issue to me. As I understand the concern, it's that in many agreement state licenses there is no counterpart to the authorized medical physicist or HDR physicist that's named in the license, and so that there is a pool of potential individuals fully competent HDR, gamma stereotactic and Cobalt 60 teletherapy physicists who are carrying out all of the duties named in the 600, but simply because of the peculiarities, the semantical differences effectively in the way licenses are written in some agreement states versus in NRC directly regulated states, there will be a group of individuals who won't be grandfathered, and so there is some concern, you know, how large this pool of individuals will be, whether this was going to cause

difficulties in the early implementation of the rule to be able to get the individuals named on the licenses, et cetera.

And so I think as I recall from the teleconference this was sort of answered in the negative as being, well, just tough luck. These people won't count as AMPs and can't be preceptors. And I was wondering if you had put some further thought and have any idea on how this might be resolved either in rule language or in the implementation of the rule.

DR. BROSEUS: We in the working group gave considerable attention to this issue, but I'm going to defer to Ron and MSIB to see if he can address this a little later. I might be able to.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: What the working group had recognized was exactly the same issue that you've just raised, and what the working group had hoped could take place was a suggestion to be made available to the general medical physics community as well as their regulators, many of whom are in the agreement states, to move ahead forthright before Subpart J is gone, to in some way become named on a license, to become listed on a license and thereby be eligible to serve

as a preceptor for others seeking similar authorization.

I know that there was reluctance on the part of our Office of State and Tribal Programs to convey this in that fashion, to make such a suggestion through an all agreement states letter or some other mechanism to the agreement states, but I think that issue was probably at least one that I would have expected would have been discussed at the recent OAS meeting in some fashion so that there wouldn't be people in such a gap in the future.

DR. BROSEUS: The reluctance, Ron, was in putting a requirement in here that would be laid on agreement states because we have to be very careful about that.

DR. ZELAC: I wasn't speaking of a requirement. I was speaking specifically of a suggestion to be made, and I think there was --

DR. BROSEUS: -- SPB and others and the state members of the working group are aware of this.

CHAIRMAN MALMUD: Thank you.

Mr. Bailey.

MEMBER BAILEY: I have to address that. I mean, only one-fifth of the medical licensees are in NRC territory. So you're going to have four-fifths of

the facilities not having named medical physicists. Quite frankly, this is the first time I've heard of this potential problem, but I think we've probably got wrapped around the axle on 10(e) for doctors, quite, frankly.

I can tell you right off we in California would object to it because it's an increase in work load to go just to meet a new whim, to go through and evaluate the medical physicists that are presently operating on our licenses.

We do have a list of people that we consider to be qualified as medical physicists, but to go through and name them on a license would be a tremendous work load, I think, on the states to do. So I'm sure we would object to doing it.

DR. BROSEUS: But what I'm hearing though is that the state recognizes that these people are qualified and almost by implication that your state, persons who are well qualified will likely be authorized.

MEMBER BAILEY: I have to respond to that that in most cases I would say we do not know who the medical physicist is at a hospital. We know how the RSO is. We know in most cases who the authorized users are, but in many, many cases, we don't know who

the medical physicist is or whether there is even a resident medical physicist on the staff of that hospital or whether or not they're contracting with someone outside the hospital itself.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: So what will your state do then in this situation? Because a new regulation will come around which says that you have to have authorized medical physicists. One of the criteria for being an authorized medical physicist is that another authorized medical physicist attests to the competence of the individual.

So what would be a solution to this in your state? I'm curious to know.

CHAIRMAN MALMUD: The question is directed to you, Mr. Bailey.

MEMBER BAILEY: Basically, what we are doing right now is if this question comes up, and it came up in the mammography field, is that we look for Board certified people. Absent someone being Board certified, then we have basically an underground regulation that says, hey, you're going to get on the list, and to do that, you have to have your training and experience, your equipment, and your protocols you're going to use.

Now, I will go back and see what, if any, plans we have made to add medical physicists to the license, and I think we need to query all of the agreement states. I'm not sure that all of the agreement states -- in fact, I'm sure not all of the agreement states are really aware of this provision.

MEMBER WILLIAMSON: I guess the other question I would ask to the staff along the same lines is, you know, my understanding of how we function as a broad scope licensee, even as an NRC regulated state is specific physicists and authorized users are not actually mentioned on the license, but the license gives the radiation safety committee the authority to review the training credentials of candidates for authorized user and authorized medical physicist.

And as an act of the radiation safety committee, basically designate these individuals in these roles. So would you consider individuals that have been designated by the radiation safety committee of a broad scope licensee in either an agreement statement or in an NRC state to acceptable preceptors?

CHAIRMAN MALMUD: To whom is that question addressed, Dr. Williamson?

MEMBER WILLIAMSON: This is addressed to, I think, Dr. Broseus and Dr. Zelac, who seem to be

fielding these questions.

DR. BROSEUS: Let me tell you what I'm hearing, and we need to go back with. First, you have identified the potential problem that a person cannot serve as a preceptor who is not an authorized medical physicist, but has never been authorized, and it's a chicken and egg syndrome.

And so we have to look at have we adequately provided for an avenue for people to serve as preceptors to be precepting for an authorized -- attesting for a medical physicist. That's number one.

Number two is an issue that is already there and dealt with routinely on broad licensees, and that is basically the broad licensees have the same responsibilities that license reviewers do. I shouldn't say it that way, but they're bound by the same rules. Okay?

Now, generally speaking, and I'd have to look at this in detail, if an individual is named by a broad licensee or a permittee, like in the VA, they can serve in the same role as an authorized user, authorized medical physicist or whatever. Please correct me if I'm wrong, but I think that that's a non-problem.

The problem we need to go back with to the

working group is to make sure we have provided an avenue appropriate for a person to attest for medical physics.

MR. MOORE: Roger, if I may, in answer to Dr. Williamson's question, I guess first I'd like to say that the question that you raise, it's a problem under the current rule as much as it's a problem under the draft final rule, and so it's not a new problem that you're raising. It's a problem with the rule that's out there right now. The wording itself doesn't change.

That said, you know, it's a valid question. I can't speak for the legal interpretation, but I think we would take a common sense approach, and if a person is identified as a user under a broad scope license or under a master material license and that identification is made in writing somewhere, I would think that we as a regulatory agency would recognize that the same as if somebody was identified on a license itself and accept that as a preceptor identification.

And what you're really getting to is how often do we challenge the credentials of a preceptor and that's fairly rare.

MEMBER WILLIAMSON: Well, it's only rare

because, in fact, the country is being governed by Subpart J where this is a non-issue, and so, you know, you say that, yes, it's in the current regulation, but the reason we're all here discussing this today is because we all know that the current regulation is broken. That's why we're trying to fix it.

And so I think this is a -- I'm sorry if I don't find your answer satisfying.

DR. BROSEUS: But let me repeat. I understand that your issue is a person may never have been named as an authorized medical physicist, and so there's a potential problem. The definition requires that a person be an authorized medical physicist to serve as a preceptor, but no such party exists. Bottom line.

MEMBER WILLIAMSON: That's my concern, is how you're going to convert the existing user base. For authorized users, I presume this is much less significant a difficulty because that's a well established entity within both state and federal regulations. So it's sort of transparent to match.

CHAIRMAN MALMUD: We have presented you, Dr. Broseus with that dilemma, which we hop you will report back to us about at our next meeting.

MEMBER WILLIAMSON: So the fact that there

aren't ready answers to his, you know, shakes my confidence somewhat in, you know, giving an unqualified endorsement to this rule..

CHAIRMAN MALMUD: Dr. Miller.

MR. MILLER: Something you just said was troubling to me concerning reporting back at the next meeting. I think Ralph and Jeff have offered a concern in this area, and it sounds to me, if I understand the concern that you raise, if we go forward and promulgate the regulation as it's written, it's going to be problematic.

So reporting back at the next meeting is going to be an issue. I guess my question would be is there some recommendation that the committee could make to us to fix the problem.

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: We will give Dr. Williamson an opportunity as soon as we hear from Dr. Howe.

MEMBER WILLIAMSON: I would recommend --

(Laughter.)

CHAIRMAN MALMUD: Dr. Williamson is recommending we hear from Dr. Howe first.

DR. HOWE: I just wanted to make a comment as to the fact that the NRC had this same predicament

when we brought in the authorized medical physicist, and one of the things that happened when we did that was we already had -- and I don't know if the agreement states do it -- we already had physicists listed for teletherapy physicists, and because we line itemed remote after-loaders, we had physicists listed for authorization for HDR units and physicists listed for authorization for gamma knife units, and those physicists that were listed on licenses or recognized by broad scopes as being physicists for HDR and physicists for gamma knife were considered grandfathered, and the teletherapy physicists were certainly considered grandfathered.

So that gave us a small, but an existing basis for having authorized medical physicist precept.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Williamson.

MEMBER WILLIAMSON: Well, I think this sounds like I'm sure it was everybody's intention that the rule work this way, but the language is stated in such a specific way that it may not. So, you know, I think my proposal would be that you amend the license or the rule -- excuse me -- and change the grandfathering procedure to basically mean just what Dr. Howe said, that individuals who are now authorized

to serve as physicists for high dose rate brachytherapy, Cobalt 60 teletherapy and gamma stereotactic by whatever mechanism in the agreement states or in NRC states be grandfathered as authorized medical physicists in those respective modalities and avoid the language, the unduly restrictive language listed on a license, you know, and come up with some substitute language that captures the population.

Because my understanding would be even in California, fuel cycle 86-4, which came out in 1992, was an edict that basically said, created through underground regulation or whatever you call it an entity called HDR Physicists that had to be Board certified, had to attend treatments.

And so I would presume the agreement states, you know, essentially had some mechanism for promulgating those rules. No?

CHAIRMAN MALMUD: You've made a recommendation on discussion. Can you just make the recommendation, a brief recommendation to the --

MEMBER WILLIAMSON: I will restate my recommendation. My recommendation is that 3557 be modified to read as follows: that physicists who have been authorized to serve the function of authorized medical physicists for high dose rate brachytherapy,

gamma stereotactic radiosurgery and Cobalt 60 teletherapy be grandfathered to be allowed to serve as authorized medical physicists for those respective modalities.

CHAIRMAN MALMUD: Is there a second to that motion? And then we'll open it for discussion.

MEMBER LIETO: Second.

CHAIRMAN MALMUD: It's been moved and seconded, now open for discussion.

MEMBER BAILEY: Our biggest pool of medical physicists are not in those areas. They really are accelerator physicists, and I'm not sure why I would exclude one of them from being named.

CHAIRMAN MALMUD: Dr. Williamson, do you care to respond?

MEMBER WILLIAMSON: I'll try because I think the intent of the new regulations is to require the authorized medical physicist to have specific experience, clinical experience essentially with the modality in which they are allowed to precept in. So that a physicist who has never supervised a high dose rate brachytherapy procedure before and only does external beam therapy would not be considered a suitable preceptor, but someone who is currently -- and I'm sure California is full of high dose rate

brachytherapy units -- would be, you know, a suitable individual for serving as this preceptor.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I think Dr. Williamson would maybe agree with this change to his motion and it answered Mr. Bailey's concern if he replaced the word "Cobalt 60" with "teletherapy," and that would, I think, meet the intent of both groups.

MEMBER WILLIAMSON: Okay, yeah. Okay.

CHAIRMAN MALMUD: Are you willing to?

MEMBER WILLIAMSON: Oh, sure.

CHAIRMAN MALMUD: So your motion is amended to replace Cobalt 60 with teletherapy. Does the second remain intact?

MEMBER LIETO: So seconded.

CHAIRMAN MALMUD: All right. It has been moved and seconded. Any further discussion of that item?

Dr. Broseus.

DR. BROSEUS: I'd just like to clarify because you brought up the point, and that is as recommended by ACMUI for an authorized medical physicist to qualify as an ANP, an individual has to have training for the types of use which authorization is sought, and that includes hands-on device

operations.

And so I'm not sure if I hear your -- I'm not sure if I'm clear about where your motion is, and that is: would your motion allow all of those types of medical physicists?

MEMBER WILLIAMSON: No. It would not be --

DR. BROSEUS: Or would it be specific to use?

MEMBER WILLIAMSON: It would be specific to use. All I'm trying to do is suggest a more general formulation of the grandfathering language that, you know, gets around, you know, substitutes listed on the license for some more general concept of authorized currently by their license or licensee or agency, whatever it is, to perform the functions listed in 35.600. That's the concept, is that there is a pool of working physicists within the agreement state organization, within the agreement states that one way or another have been authorized to perform the required function sin 35.600, and those are the people that logically need to be grandfathered, and we have to alter the language.

CHAIRMAN MALMUD: Any further discussion of the motion? Do you want to call the motion?

MEMBER LIETO: I was just going to say the bottom line, I think, here, Roger, is that in the predecisional draft, it states that the NRC does not believe that it is appropriate to grandfather medical physicists to allow them to serve as AMPs, and what we're saying is that that cannot be. We need this initial pool of AMPs to be grandfathered, existing AMP medical physicists to be grandfathered as AMPs, both from the standpoint of continuing care and, two, to serve as the pool for preceptors for shall we say the second wave of AMPs?

CHAIRMAN MALMUD: Thank you.

Do you want to call the motion? All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It carries unanimously.

Are there other items under this topic?

May we move on or shall we take a break for lunch? How are you all feeling? Dr. Miller.

MR. MILLER: At the risk of having everyone in this room shoot me --

CHAIRMAN MALMUD: We're not armed.

MR. MILLER: -- I take it that our goal from this meeting obviously our original intent was not obtained. However, I'd like to be able to walk out of this meeting if possible and tell me if it's not possible with the knowledge that, with the exception of the issues that have been raised and voted upon, which we will take under advisement with regard to change, that other aspects of the rule are --

CHAIRMAN MALMUD: Acceptable?

MR. MILLER: -- acceptable and we can go forward.

You know, what I'd like to be able to do is to be able to say, you know, when we go forward with the rule, "Here's the recommendations that ACMUI made to us with regard to what you see before you, Commission, and here's how we dealt with those."

And absent those specific items, because the Commission will ask us this, is ACMUI okay with the rule as it's being proposed?

CHAIRMAN MALMUD: My feeling is that the answer to your question is affirmative, but let me ask the members of the committee.

With the exception of those items which

we've brought to the attention of staff, do we approve of that which we've reviewed to move forward?

Sally?

MS. SCHWARZ: I would like specifically to state rather than just generally; I would like to state for nuclear pharmacy since we really haven't mentioned this at all in the discussion. I mean, it's really the only specialty that's not been discussed; that we do agree with the regulations that are written for the training and experience for nuclear pharmacy. We have no problems with it as it is written.

CHAIRMAN MALMUD: Thank you.

Shall we entertain a motion to move forward with all of the items except those which have been brought to the attention of staff?

MEMBER EGGLI: So moved.

CHAIRMAN MALMUD: Dr. Eggli. A second to that?

MS. SCHWARZ: Second.

CHAIRMAN MALMUD: Ms. Schwarz.

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It carries unanimously. You have achieved your goal.

MR. MILLER: Thank you.

(Laughter.)

CHAIRMAN MALMUD: Now, is there a reward for that?

MR. MILLER: Let's go to lunch.

CHAIRMAN MALMUD: We'll reconvene at one o'clock promptly.

(Whereupon, at 12:12 p.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

AFTERNOON SESSION

(1:03 p.m.)

CHAIRMAN MALMUD: We are now back for the afternoon session, which begins with the second half of the morning session, and the item on the agenda now will be introduced by -- I lost my place.

PARTICIPANT: This is the proposed change on the AO criteria.

CHAIRMAN MALMUD: And this will A. Jones of the NRC.

PARTICIPANT: Andrea Jones.

MS. JONES: Yes.

CHAIRMAN MALMUD: Andrea Jones. I'm sorry. Is it Dr. or Ms. Jones or Ms. Jones?

MS. JONES: Ms.

CHAIRMAN MALMUD: Ms. Jones. Ms. Jones, and what is your role with the NRC so we may introduced you properly?

MS. JONES: Health physicist.

CHAIRMAN MALMUD: This is Andrea Jones, health physicist with the NRC, and the project is entitled "Proposed Changes to AO Criteria."

Thank you.

MS. JONES: Okay. Thank you.

Today I'm going to present new language

that, if approved by the Commission, will change the way the NRC classifies and reports to Congress medical events that we call abnormal occurrences.

Okay. What is an AO? The NRC defines an abnormal occurrence as an unscheduled incident or event determined to be significant from the standpoint of public health or safety.

An AO can occur at a nuclear power plant, a fuel facility, a radiography fill site, but in the majority of the cases that we get reported to us, they occur at hospitals or medical facilities.

Okay. Why should we revise the AO criteria? To appropriately classify and report to Congress only those events that the Commission considers to have safety and security significance; to reduce potential misunderstanding by the public of actual health or safety significance from medical event occurrences; and to acknowledge the introduction of evolving therapeutic treatment procedures delivering high radiation doses to portions of an organ or tissue.

Let me give you just a couple of examples to support a revisement of the AO criteria. In 2003, one of the cases that we included in the AO report involved an event where a patient received four

millicuries of Thallium 201 instead of the prescribed dose of four millicuries of Iodine 131.

What's the safety significance involved in this case? Well, the oncologist evaluating the case reported that no adverse health effects would occur.

Another case. During an intervascular brachytherapy treatment procedure, 2,300 rads was given to an area approximately one and a half inches away from the intended prescribed treatment site. If a member of the public were to read this write-up, they may think a high dose of 2,300 rads is really, really a bad thing, but the doctor evaluating the case reported that the threshold delivered to this artery was well below the threshold where adverse effect would occur.

Okay. This slide just gives the current wording for medical licensees. A medical event will be considered an AO if it results in a dose that is equal or greater than 100 rads to the bone marrow, lens of the eye of the gonads, or equal to or greater than 1,000 rads to any other organ.

And a dose that is at least 50 percent greater than that prescribed or the wrong radiopharmaceutical or is delivered to the wrong treatment site by the wrong treatment mode or wrong

route of administration. That's the current wording.

The proposed new language. I'm not going to read all of the different sections, but in summary, what we did was -- and when I say "we," meaning the AO working group -- we would add a new section which would be recognized as Section A, adding the phrase "unintended permanent functional damage by a physician."

The term "tissue" would also be added to "organ" to aid in classifying those areas where dose was delivered to an area that's not called and ordered.

B. The second change would be to increase the dose threshold for the gonads from 100 rads to 250 rads. The term "tissue" is also added.

MEMBER NAG: Excuse me. Do you have this in the handout? I'm trying to look for the handout. Under what section?

MR. ESSIG: It's called "Proposed AO Change."

MEMBER NAG: No handout?

MEMBER SULEIMAN: We have lots of no copies actually.

MR. ESSIG: Do you have one?

CHAIRMAN MALMUD: I have one. He has one.

A select member has one.

MS. JONES: I'm sorry. I thought that --

CHAIRMAN MALMUD: I have one because I have the distinct advantage of having left my book at home and received the book as I arrived here. So I didn't realize I had an advantage until now.

MR. MILLER: Trish, are there copies there?

DR. HOLAHAN: Yes.

MR. MILLER: Trish will circulate copies. We have an instant solution to this problem.

CHAIRMAN MALMUD: And may I ask a question while we're waiting for the copies to be distributed?

MS. JONES: Yes.

CHAIRMAN MALMUD: The wording that you have indicated has already been added in the second slide on page 2; is that right, where you said that the word "tissue" was added to "organ"?

MS. JONES: Yes.

CHAIRMAN MALMUD: Under B(3).

MS. JONES: Yes.

CHAIRMAN MALMUD: Very good. I have been following you.

MS. JONES: Okay. That's your question? Okay.

MEMBER SULEIMAN: Why are you using absorbed dose and not dose equivalent?

MS. JONES: That's the way the current criteria is classified, is stated. That's the current terminology that we use.

MEMBER SULEIMAN: So if it's an alpha or a beta source?

MEMBER NAG: Now, the word "medical event" and "abnormal occurrence" are two different entities or are they going to be used interchangeably?

MS. JONES: No. A medical event is the new wording for the previous term "medical administration." And "abnormal occurrence" is a different thing. It's at a higher threshold.

MEMBER SULEIMAN: Can I ask my question again? I'm questioning why you're not using dose equivalent rather than absorbed dose. Why not sieverts or REM?

If you're using an alpha or beta course technically the dose would be a factor ten times less when, in fact, the dose equivalent would be higher.

MS. JONES: Okay.

MR. ESSIG: We're talking about acute events here, I think, in which case absorbed dose is probably more accurate.

MEMBER SULEIMAN: No. Let's say it's an alpha source. It's in contact or beta, and so you know, if you're delivering 1,000 rads beta, it's maybe -- a wrong example. Let's say it is an alpha emitter.

MR. ESSIG: For a medical event?

MEMBER SULEIMAN: Well, I'm trying, but the dose would be ten times higher. In other words, 1,000 rads of an alpha source would be 10,000 rem, and so the actual equivalent would be ten times higher. So there's a risk that would be greater.

Nominally for gamma or X-ray, they're equivalent, but in those situations like a brachytherapy, don't you take that into consideration when you do your dose calculations?

MEMBER SULEIMAN: Do we have any alpha --

PARTICIPANTS: No.

MR. ESSIG: Betas are -- I mean, most of the time they're going to be equivalent, but I'm thinking of the situation where you have a contribution from some --

MEMBER SULEIMAN: It would only be alphas. The quality factor for betas is one.

MEMBER NAG: If I may as, (a), I guess it's quite clear the result is unintended permanent functional damage. The first thing is under B, the

problems which are created by radioactive implants that are closed to the eye because many times the eye just by having the sources a few millimeters away could increase the dose to the lens just quickly. A radioactive implant for parietal melanomas in the eye, that very easily can give, you know, more than that dose to the lens of the eye.

Secondly, for the gonad, if you are having an implant in the upper prostate, a gonad just by having the implant a few millimeters one way or the other can easily give a dose greater than what you are saying the gonads show.

We have to see how we are going to word this.

MEMBER EGGLI: Subir, this isn't "and" condition. You must meet A first before you even begin to apply B. This is an "and" condition so that the threshold is unintended damage.

DR. HOLAHAN: And also it has to meet the criteria for medical event.

MEMBER NAG: Okay, but I think A itself, if you are having a permanent damage even if it did not have any of the B, it would be a problem.

MEMBER VETTER: But if you prescribed this, then it's not a medical event. If it all was

administered in accordance with your prescription, then it doesn't matter whether the eye got 100 rads or 1,000 rads. If that was your prescription, it's not a medical event.

MEMBER WILLIAMSON: What if the GYN patient had a fistula, for example? That happens, say, two percent of the time. It's a complication, you know, at a frequency level with a properly administered treatment you would accept. You don't want this to count.

MEMBER VETTER: These abnormal occurrences, first of all, it's a medical event which means didn't go the way you planned, and it's a high level medical event.

MS. JONES: Right.

MEMBER NAG: Okay.

MR. ESSIG: And correct me if I'm wrong, but if I can make another clarification here, I believe that the B(1) is the same as is currently. Even though it's proposed wording, B(1), the 100 rads to major portion of bone marrow lens to the eye is the same as it now.

MS. JONES: Right.

MR. ESSIG: The only thing that was changed is that the gonads had previously been

included under that 100 rad statement.

MS. JONES: Correct.

MR. ESSIG: We have now moved them to the 250 rad, and so it's --

MEMBER NAG: My misunderstanding was the end because without the end, if it was either A or B, then it would have been a problem.

CHAIRMAN MALMUD: Dr. Miller.

MR. MILLER: Quickly,I think what Andrea is trying to do here is walk the committee through some proposed changes to the O criteria, and if I could ask for your patience, if she could walk through all of the criteria, then I think what we would like to do is to get your views on the new proposed criteria that the staff has developed, but I think it would be beneficial to hear the whole presentation because I think when we keep jumping in in the middle, it kind of discombobulates the --

CHAIRMAN MALMUD: Thank you.

Now that everyone has a copy of the slide, would you please continue?

MS. JONES: Okay. The proposed new language which is denoted in bold with a new element recognized as Section A, so NRC will consider a misadministration a medical event that results in

unintended permanent functional damage to any organ or tissue as determined by a physician and which results in a dose that is equal to or greater than 100 rads to a major portion of the bone marrow or the lens of the eye or equal to or greater than 250 rads to the gonads or equal to or greater than 1,000 rads to any other -- and I left the T out. I'm sorry -- to any other organ or tissue.

And there's a C: and represents either a dose or a dosage that is 50 percent greater than that prescribed in the written directive or a dose or a dosage administered in the absence of a written directive or a written directive was needed, but the dose was given in mistake. It wasn't an intended dosage.

And also we add the term "unsealed by product material" to three.

So really the proposed new wording, the major things that we're doing is we're adding A. The event has to result in some type of unintended permanent functional damage to an organ, and we add the word "tissue" because previously sometimes we get cases where there's not -- the area exposed isn't defined as an organ.

So you have to get A, first of all, in

order to even begin to meet the criteria for being classified as an AO. So B, what's the change in B, which was the previous A? We raised the dose to the gonads to 250 rads, and we added the word "tissue" for the same reasons that we added it in A. Okay?

C, what we really did here, we tried to capture those events that were given in error where the doctor, because of the quantities or the treatment, the doctor didn't even prepare a written directive because the facilities' procedures didn't require one. But there was permanent functional damage and the dose threshold was exceeded, and it follows the regular criteria.

MEMBER WILLIAMSON: Just a question of clarification. For any of these, A, B, or C, to be invoked, it already has to be a medical event per the definition in Part 35. So we're starting out with the assumption --

MS. JONES: Yes.

MEMBER WILLIAMSON: -- that this already meets the criteria.

MS. JONES: It reached the medical event.

MEMBER WILLIAMSON: Okay.

MEMBER LIETO: So is C just a repeat or what the definition is of a medical event?

MS. JONES: No, C adds. It adds a new "or" where there was -- you know, if you were -- where there was an administration given and a written directive wasn't prepared. So maybe the technologist didn't know that she was supposed to give five microcuries and she gave 500 millicuries. She didn't -- I mean, there wasn't a written directive prepared. So she didn't have the prescriptive directions in front of her.

MS. McINTOSH: Pardon me. May I make a comment right here? I'm on the working group with Andrea to propose these changes.

For that language right there that's highlighted, the purpose of that language is to capture events whereby the dose administered was at a level where a written directive was required, but because the intended dose didn't require a written directive, one was not prepared.

So stated differently, the doctor may have intended to give the patient a diagnostic level dose, but what wound up being administered was a therapeutic level dose.

Well, in that case, a written directive would not have been prepared because what was intended was a dose that didn't require a written directive.

So we want to capture events whereby the dose that was administered, there should have been a written directive prepared, and currently we're not capturing those events because of the technicality that we don't have that language in there. Yet a mistake, a significant mistake was made.

So that's the purpose of adding that proposed language there.

My name is Angela McIntosh, for the record.

CHAIRMAN MALMUD: Thank you, Angela.

May we continue with your --

MS. McINTOSH: Dr. Malmud, I believe Dr. Howe.

CHAIRMAN MALMUD: Oh, all right. Because we were going to -- okay, all right.

MS. SCHWARZ: This pertains to the statements, Dr. Howe. I think in this case the medical event that's at the top of the slide is not the definition of a medical event that's in Part 35. It is just the plain language medical event. It's really an event in a medical use licensee's site because of this additional part where we've had people receive therapeutic doses when they were only supposed to get diagnostic, and we want to capture those that

have permanent functional damage.

And OGC has interpreted the reporting requirements in Part 35 not to capture the case in which there wasn't a written directive because one was not intended, to start out with, and a therapeutic dose is given.

So this is to help capture those.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter.

MEMBER VETTER: Just quickly, if these don't meet the definition of a medical event as described in Part 35, they shouldn't be called medical events.

MEMBER WILLIAMSON: Here, here.

MEMBER VETTER: We should use some other term.

MS. JONES: Well, we call them abnormal occurrences.

MEMBER VETTER: No, I mean in the definition of this particular abnormal occurrence we're seeing, first of all, these are medical events. If these do not meet the definition of medical event as per Part 35, they should not be called medical events.

MS. JONES: Okay.

MEMBER WILLIAMSON: It should say "an administration of byproduct material that."

MS. JONES: I understand.

MEMBER WILLIAMSON: Good comment.

MS. JONES: Yeah.

CHAIRMAN MALMUD: Please go on.

MS. JONES: Okay. In conclusion, if approved by the Commission, the revised medical criterion will insure that -- and I'm just going to say "medical events" for the purpose of the slides already prepared -- insure that the medical events reported to Congress have resulted in permanent functional damage to a specified target organ or surrounding tissue as determined by a physician; will capture the current recommendations of ICRP 60; include medical events where the dose was administered in error and a written directive was not required for the intended administration; and include unsealed byproduct material commensurate with Part 35.

So I'm open to any questions or comments that you may have right now. However, I am requesting, you know, written comments to be submitted to Angela by the end of this month.

CHAIRMAN MALMUD: Thank you, Ms. Jones.

MS. JONES: Thank you.

CHAIRMAN MALMUD: Are there any questions or comments for Ms. Jones?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Now that I'm practicing all of the "ands" and "ors" and so on, if you have a place that this is no longer a medical event, you know, even just the administration of a routine radioactive material, you have now an unintended functional damage and at the same time there was, for example, if this was an implant in the eye, the lens would automatically or most likely have received more than 100 Gray; almost any event that is having some unintended functional damage in the eye will automatically be in there.

MS. JONES: Oh.

MEMBER NAG: Yes.

MEMBER WILLIAMSON: Not if you intended to damage the eye. If you did a treatment, say, of the organ of the right eye and you accepted knowingly and consented the patient and told them, you know, "Your lens is going to get this dose and you're going to have to have a lends transplant most likely," I think that Phrase A because of the word "unintended" in there would exclude this.

Now, if you treated the wrong eye by mistake, if the therapist made a mistake and treated the wrong eye, and that lens got a dose of 2.5 Gray and the patient had a cataract or some other damage, then I think it would be an abnormal occurrence, right?

MS. JONES: That's exactly right. This is not intended to capture therapy. This is intended to capture mistakes, and that's the reason why the word "unintended" has been included. Something happened that was not intended. So damage occurred to the patient.

MEMBER NAG: And in that I think it may be a good idea to have at the beginning that it had to be a medical event although, you know, you are saying that doesn't really mean medical event. Perhaps it would be better if the entry would be that it had to be a medical event in the first place.

MEMBER WILLIAMSON: But then they couldn't capture all of the events they want to because if one gives a diagnostic dose of radionuclide and, you know, makes a mistake and gives 100 times too much activity --

MEMBER NAG: That itself would be a medical event.

MEMBER WILLIAMSON: No, it is not. They just told us that the definition of medical event fails to capture that. So that's why they need to put some more neutral language like "an administration of byproduct material that."

MEMBER NAG: Yeah, you can put that. Administration of the byproduct material that forces a medical event, number one, and results in permanent damage. That I think will solve that problem.

MEMBER WILLIAMSON: It will exclude, you know, the bullet on her last slide insured -- where is it? "Include medical events where the dose was administered in error and a written directive was not required," because the medical event definition in Part 35 does not apply to cases where a written directive was not required. Am I right?

MEMBER VETTER: No, you can still have medical events.

MEMBER WILLIAMSON: You can have a medical event where --

MS. JONES: Yeah.

MEMBER VETTER: If there's 50 rads to an organ or more than five rads to the whole body and it's more than --

MEMBER WILLIAMSON: I thought someone just

-- I thought that Dr. Howe just said that the Office of General Counsel had ruled that a misadministration of a diagnostic dose that caused injury could not be a medical event per Part 35. Is that not correct?

DR. ZELAC: Dr. Malmud.

CHAIRMAN MALMUD: Dr. Zelac.

DR. ZELAC: What was excluded from her statement apparently is the condition relating to dose that results from this. If you, in fact, administered a dosage that exceeded on a percentage basis or was outside of the range that was intended, that by itself would not qualify as a medical event if we're talking about a diagnostic dosage.

However, if the variation from the intended dosage was sufficiently great that the resultant dose to an organ exceeded the 50 rad limit, then, in fact, it becomes a medical event.

So it's two conditions that are required.

MEMBER WILLIAMSON: All right. Then maybe Dr. Nag's point is a good point, that it seems unlikely you're -- what kind of a major complication are you going to have without the diagnostic administration satisfying the medical event criteria in Part 35?

MS. JONES: Probably none.

DR. HOWE: Dr. Malmud, may I make a comment?

CHAIRMAN MALMUD: Please, Dr. Howe.

DR. HOWE: We've actually had people that have given the wrong administration of the therapy, but they haven't had a written directive either, and this would capture those events also.

MEMBER NAG: That would automatically be a medical event.

DR. HOWE: No, it would not because our Office of the General Counsel reviewed these cases with us, and they said, no, the prescribed does didn't exist. So it can't be greater than the prescribed does because there was no written directive.

And it's a problem we need to come back and probably look at the rule language for again, but that's what this is trying to capture, is the fact that there are a few cases, and we've tried to set the bar very high -- in other words, there's permanent functional organ or tissue damage -- that will capture these cases for which for one reason or another there was no written directive, and so it doesn't meet the criteria for a medical event, but it certainly is a serious occurrence.

MEMBER NAG: Life threatening. If you

don't have a medical directive, that automatically becomes a medical event. A medical event is an occurrence where a written directive is not there, when a written directive is required.

DR. HOWE: Dr. Nag, there's clearly a violation of the regulations where to deliver a therapeutic dose you should have had a written directive. However, our Office of the General Counsel has determined that when you go to the definition of a medical event, it has to be a dose or dosage that differs from the prescribed, and the prescribed is that which is written in the written directive.

So if there is nothing written in the written directive, then you don't have a prescribed and you don't have a recording requirement because you didn't have a medical event.

You can have a violation of the regulations, but those cases would not be captured for the abnormal occurrence in severe incidences because they technically didn't meet medical event.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: Now, it strikes me that if you don't have a written directive that you have to have a standard dose by policy or procedure, and wouldn't that be covered if you exceeded your standard

policy or procedure dose?

DR. HOWE: In the cases that we've had, no, there hasn't been a standard.

MEMBER EGGLI: Because you can't just give anything for a diagnostic study. I mean either you have to have a prescribed dose or you have to have a policy that says for a bone scan we give 20 millicuries. I mean, you can't just willy-nilly give 100 millicuries and say that's okay.

DR. HOWE: This case also captures those therapeutic procedures that are given without a written directive.

MEMBER NAG: I know that the therapeutic procedure for which there is no written directive required. Could you tell me -- I'll give you an example. All the implants I do require a --

DR. HOWE: Dr. Nag, the point isn't whether you were supposed to have a written directive. The point is there wasn't one. You were supposed to have it, but it wasn't there.

MEMBER NAG: Yeah, but the definition of medical event includes having a procedure where a medical directive is not there. That automatically becomes --

MEMBER WILLIAMSON: That's what they're

telling you. That's not true.

MEMBER NAG: But there is. Why wouldn't you include that?

DR. HOWE: That's our problem. It's not there, Dr. Nag.

CHAIRMAN MALMUD: May I try and bring some clarity to this? The circumstance that you're describing, Dr. Howe, is one in which the physician should have written a directive, did not do so. The wrong dose was given. Since the current definition of a medical event includes not abiding by the written directive, it's not currently considered a medical event because there was no breach of the written directive which didn't exist.

DR. HOWE: That's correct.

CHAIRMAN MALMUD: All right. I understand the problem. This does address that problem, does it not?

DR. HOWE: Yes, it does.

CHAIRMAN MALMUD: Is there anyone who feels that this does not address that problem? Dr. Lieto.

MEMBER LIETO: I don't think it fixes it because what you should do is change the definition of the medical event to require a written directive, and

that doesn't seem to be in here.

CHAIRMAN MALMUD: Was that given consideration to changing the definition of a medical event?

DR. HOWE: We currently have a user need memo that we're in the process of finalizing going to rulemaking that would change the rule text, but in the meantime we would not have these severe events reported when they are a severe event and they should be reported under the abnormal occurrence.

So it's going to take us years to get rule language changed, and the priority for going in and opening Part 35, I believe, at this particular point is very low.

CHAIRMAN MALMUD: All right. So now we understand that the presentation by Ms. Jones is for a specific instance which is not covered by the current regulations adequately and that this would cover it until the definition of a medical event can be redefined. Is that a fair statement?

DR. HOWE: I believe that's clear.

MR. MILLER: Almost.

CHAIRMAN MALMUD: Almost. What did I leave out?

MR. MILLER: I think the distinction that

you have to make is the purpose for which it's used. What we're offering here is we have a definition currently of abnormal occurrence, you know. We're focusing on the medical abnormal occurrence at this point in time.

CHAIRMAN MALMUD: Yes.

MR. MILLER: We have a requirement to report to Congress the number of abnormal occurrences every year and what they are. What we're proposing to do here is to change the definition of abnormal occurrence as it relates to the medical area so that what we report to Congress truly captures all that we would intend to report and fix the problem for the definition of abnormal occurrence.

It doesn't fix the problem at this point in time of the definition of a medical event, and I think Dr. Williamson has offered a way around that for the purposes of the definition of abnormal occurrences as to, you know, not call it a medical event. I think you used the term "administration of byproduct material." Dr. Vetter identified the fact that you couldn't call it a medical event if it didn't meet the strict definition.

So the distinction is it's for different purposes. You know, it's not to replace the

definition of medical event.

CHAIRMAN MALMUD: We understand.

MR. MILLER: It's to fix the abnormal occurrence definition to more accurately report to Congress those things that are really of concern to us that meet the threshold.

CHAIRMAN MALMUD: Pretty straightforward.

Mr. Lieto.

MEMBER LIETO: Well, I'm going to take the devil's advocate side here. I have an event that does not have to be reported. In other words, I give ten millicuries to a patient of 131 that was only supposed to get 100 mics. I don't write a written directive.

I don't have to report it --

MS. JONES: Right.

MEMBER LIETO: -- according to this because it doesn't meet a medical event.

MS. JONES: Right.

MEMBER LIETO: So how do you capture something that doesn't have to be reported?

MEMBER VETTER: Excuse me. You said you're going to give ten millicuries instead of --

MEMBER LIETO: No, I gave ten millicuries and I was supposed to give 100 mics.

MEMBER VETTER: That is a medical event

because ten millicuries of I-131 to the thyroid is not insignificant.

MEMBER LIETO: No, I didn't write the written directive.

MEMBER WILLIAMSON: But it gives a dose of more than 50 centigrade to some organ, right?

MS. JONES: Well, it would have to result under the new wording.

MEMBER LIETO: See, what I'm saying is that you need to change -- what we're doing is we're putting a Bandaid in the wrong spot. Okay? We're not fixing what needs to be fixed because if I don't have to report it because I didn't have a written directive, what's --

DR. HOWE: This is Dr. Howe.

Just because you don't have to report it doesn't mean that NRC may not become aware of it because it is a violation of the regulations and we may become aware of it during inspection or at some other point at which the information comes forward. So it's a violation of the regulations and is a regulatory concern.

But you're right. It's not reportable under the medical event reporting requirements.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: What if you give a 50 rad dose without a written directive and that's what you intended? So you deliver the dose you intended, but there was no written directive. So what would that be?

MS. JONES: If there was no permanent functional damage, then it wouldn't be an AO.

CHAIRMAN MALMUD: It wouldn't be reportable, but it would still be something which the radiation safety officer --

MS. JONES: Yes.

CHAIRMAN MALMUD: -- within the institution would monitor and point out was an error.

MS. JONES: Right.

MEMBER WILLIAMSON: And if they found it during an inspection, you could be cited for a violation.

MS. JONES: Right.

PARTICIPANT: I also understand the legal argument in that you have never specifically prescribed the dose, how can you know that you are exceeding it by a certain quantity since there's no reference value to compare it against.

So that's dangerous, but I can sometimes understand their perspective.

MEMBER LIETO: I mean, I see what Andrea and Angela and the group is trying to do, but you know, I guess why can't you just -- I mean, we all recognize that this just simply needs to have that one line item in the definition of a medical event.

You're doing all of these changes to Part 35 right now. Why don't you just slip it in there?

(Laughter.)

MEMBER LIETO: It's not a significant change.

CHAIRMAN MALMUD: Well, I think experience, which Dr. Howe has reinforced by reminding us, indicates that it would take a long time to get that done, and here is a potential solution to a current problem which Andrea Jones has given us a solution to.

MR. MILLER: I think, again, what Ralph has offered is exactly on target with regard to a problem that we have to separate into two separate issues here because the definition of medical event needed to be changed, and I think we agree that it should be, and that will go through its due course in order to get changed.

What we're trying to focus on here is getting current and accurate wording for what an

abnormal occurrence should be so that the annual reporting of that to Congress reflects our current thinking on what an abnormal occurred should be, regardless of whether or not it's reportable to the NRC.

As we've pointed out, we may learn a matter by some other means even though it might not be reported.

CHAIRMAN MALMUD: Ralph, you wanted to say something?

MEMBER LIETO: Well, I was just going to say in the last occurrence report, I mean, you still have captured those events and reported them. I mean, it's not like this definition is not prevented the NRC from capturing these events and reporting them to Congress in line with this new proposed definition, and I don't have an objection there.

I guess, you know, the issues of getting the real problem fixed, which as Charlie pointed out is a separate issue.

CHAIRMAN MALMUD: Mr. Essig was next, I believe.

MR. ESSIG: Just to quickly add on, I don't know that we've clarified or made the point yet that the language you're looking at here is not for a

rule. It's for management directive, which is an internal NRC document. So a rulemaking would be a totally separate issue. This is just language and management directive which is much easier to change.

CHAIRMAN MALMUD: Thank you.

Dr. Holahan.

DR. HOLAHAN: Yes. The other thing, and I haven't talked to the working group yet, but the criteria for AOs also includes for our licensees human expose to radiation from licensed material. If the committee believes it's important to keep it to medical events, maybe we could put it in that criteria, the things that are not technically a medical event.

CHAIRMAN MALMUD: Thank you.

Dr. Essig.

MR. ESSIG: I think that this is good, particularly with the addition of Part A and the changing of the threshold to resulting in functional damage. I think this is real good, and I think we should endorse it.

You know, some of the wording may be convoluted. We may be trying to fix a problem incompletely fixed, but I think just the addition of Part A itself justifies our endorsing it.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER WILLIAMSON: Second.

CHAIRMAN MALMUD: Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any negatives?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: You have carried it unanimously. Thank you.

MS. JONES: Thank you.

CHAIRMAN MALMUD: The next item on the agenda, national source tracking.

MR. ESSIG: We were pulling that off the agenda because of time.

CHAIRMAN MALMUD: And then we're going to go to the ICRP recommendations.

MR. ESSIG: Yes, and I wanted to make a word or two of introduction.

CHAIRMAN MALMUD: Mr. Essig is going to introduce Dr. Vetter and the issue that is before us, and there is a handout which you all should have, and

we're passing around something else relevant to this discussion.

MR. ESSIG: And while that's being passed around, I should --

CHAIRMAN MALMUD: So there are two handouts to this; is that correct?

MR. ESSIG: No, not this one. It's in your packet.

CHAIRMAN MALMUD: It's in the book.

MR. ESSIG: Or it was given to you.

CHAIRMAN MALMUD: Or it was given to you, one of the two.

MR. ESSIG: I should just add that I really wasn't going to introduce Dr. Vetter since he needs no introduction. I was just going to introduce the topic.

The topic is next week you have one of your handouts, notes that the Advisory Committee on Nuclear Waste will be meeting, and they have a working group which will be reporting to them on Tuesday, the 19th regarding their comments on the proposed ICRP 2005 recommendations.

They've pulled together a large number of speakers, some NRC people, an NIH expert on biological aspects of radiation protection, and Dr. Keith

Eckerman from Oak Ridge National Laboratory, a number of very well known people in the community.

And you will notice on the agenda, page 2, at two o'clock your own Edgar Bailey, representing CRCPD, will be presenting, and then followed by him will be Dr. Vetter.

And the purpose of today was for Dr. Vetter to give an overview of the recommendations and some of his insights, and then entertain any comments from the committee that he should carry to the meeting next Tuesday representing really, although it says Mayo Clinic, he's really representing the ACMUI. That was asked for. They wanted a representative of the ACMUI.

So I believe we'll be asking you to empower Dr. Vetter to carry forward any comments that you may have or if you have no comments, to accept the comments that he has prepared.

CHAIRMAN MALMUD: Thank you, Mr. Essig.

Dr. Vetter.

MEMBER VETTER: Thank you.

I'm going to forego the formal slides projecting them on the screen. We'll just take a look at the handout because most of this I'll skip through rather quickly.

ICRP's fundamental aim hasn't changed much or basically not at all. The intended use might be worth emphasizing that their intention is to influence regulatory agencies, management bodies, and so forth. Oh, by the way, these slides, potential impact of ICRP 2005, they were provided for you. Okay. You have them.

So the intended use, ICRP intends for their recommendations to influence regulatory agencies. They're not in large measure directing these at us as individual practitioners, but there are certain aspects of it that do affect us individually.

They do define safety culture. They have some principles of protection which there are a couple of things that are worth mentioning. One of them is that they now more clearly spell out a restriction on dose from certain activities, and they call this a constraint.

And I must say, if you have the same reactions I do, you have to read through some of this several times before you really begin to understand what they mean by "constraint," but I'll try to point that out to you as we go.

So they do have some restrictions on dose called a constraint. This is not a dose limit for an

individual, but it's a constraint, dose constraint on particular activities. They want us to understand that their position is that achieving a constraint is an obligation. So it almost becomes a limit, a dose limit or it does become a regulatory limit of sorts.

And they also make it very clear that if a program does not maintain a constraint, then it is failing. The program is failing in that regard.

The scope of the recommendations, they do clearly define what they mean by various sources. A source is a cause of an exposure, not a particular radiation source.

I'm not going to read through most of these. Practice judgment. Judgment it's worth pointing out, I think. They're saying that the responsibility for justification falls on governments or government agencies, except for medical.

In other words, if the public is going to be exposed to a source of radiation through some proved activity, that is up to the government to justify that. For medical it's different. For medical they're saying that justification has more to do with not causing harm to patients, doing more good to patients than harm. They're saying that the practice must be justified, and the justification lies

more with the profession than the government.

So justification for implementation of computerized tomography, for example, or PET or a new byproduct material, introduction of a new source of radiation to a practice must be justified by the profession, but justification of the procedure, so applying that to a particular patient or in a practice must be justified by the practitioners.

Classes of exposure, the classified exposure by various groups of people and how they can be exposed. Occupational, pretty straightforward, occurs at work principally as the result of work, that being the responsibility of management. Medical, exposure of persons as part of their diagnosis or treatment, and there are no constraints for that particular class of exposure. There they clearly point out and emphasize that those exposures must be justified.

And then finally, public, all other exposures. That's a class of exposure.

Now to the point of dose constraints. Just the definition or the purpose of a dose constraint. A dose constraint is to provide protection for the, underscore, most exposed individual; so the individual who would get the

highest dose within a class of exposure. That would be occupational, medical or the public, whichever individual gets the highest dose within one of those classes, from a single source.

Now, it falls out of the purview of the NRC, but I will mention because some of you in this room would be very familiar with this issue. There is a very contentious issue in the radiation protection community right now that falls right square in this ballpark, and that is the design of diagnostic X-ray facilities to prevent the public from receiving a certain does, and the NCRP has recently approved a report that will allow a hospital to design a shield that could result in the highest dose to an individual member of the public of 100 millirem.

Now, that is the public limit, 100 millirem. Most states have adopted that, but the NCRP also has buried in one of its recommendations, we don't call it a constraint in this country, but it's sort of a sublimit; that if a member of the public could be exposed to more than one source of radiation, then each of those sources should be a fraction of that 100 millirem limit.

And so now the argument is, well, members of the public who sit in a waiting room, if they could

receive 100 millirem at this hospital, what if they're living over here and they're receiving 25 millirem from this source of air from a reactor or whatever it might be? I know they don't get that much, but it's a philosophical issue.

So this is a big deal. This constraint thing is a big deal, and I think we need to just be aware of that.

So relative to our own activities as it applies to public exposure, we need to keep in mind that a constraint means that the individual member of the public could be exposed. If the member of the public could be exposed to more than one source of radiation, then each of those sources can't expose the member of the public to the limit. The limit is a combination of all those sources, and each one of them must be constrained. That's the recommendation.

And that's where it gets confusing, because in the next table you'll see that the dose constraint, the maximum value of the dose constraint is the value listed. So, for example, for societal benefit, that would be a member of the public, societal benefit meaning people are not being informed; they're not being trained; there's no individual assessment as to what their exposure is.

The constraint is one millisievert or 100 millirem. That's the maximum constraint.

The next table shows you the limit, and you'll see the limit for a member of the public is also one millisievert or 100 millirem. That's the limit. So if the member of the public is being exposed to more than one source of radiation, then each of those must be constrained so that the member of the public doesn't get 100 millirem.

Do you see what I'm saying?

And that will be problematic in terms of agreeing philosophically with that. It really comes down to a very difficult problem on application. Does that mean that every hospital has to assure that a member of the public doesn't get one-tenth if they could go to ten different hospitals? I mean, where do you draw the line here?

This is going to require some significant discussion.

Now, just to point out again, as Tom mentioned, the purpose of my presentation here is to take your views to next week's meeting. So I don't know that we want to spend a whole lot of time discussing this because this is simply a recommendation at this point, but if you perceive that

this could be a significant problem, I want to take that to next week's meeting.

Dr. Miller, did you have a question?

MR. MILLER: I have a question out of ignorance. Would by that definition X-rays be included?

MEMBER VETTER: These recommendations apply to everyone.

MR. MILLER: So if someone went to get a dental X-ray or a medical X-ray --

MEMBER VETTER: Oh, I'm sorry. They don't apply to the procedure itself, to the patient's dose. They apply to the visitor waiting for the patient, the visitor in the waiting room.

MR. MILLER: Okay. So if you were the patient you wouldn't have --

MEMBER VETTER: There's no constraint on patient dose.

MR. MILLER: Okay.

MEMBER VETTER: An there's no limit on patient dose.

MR. MILLER: Okay.

MEMBER VETTER: This is a member of the public who would be waiting for the patient in the waiting room.

MR. MILLER: I understand, but if they by some means were to get some dose from that source, that would be counted?

MEMBER VETTER: If who? Oh, you mean the patient while they were in the waiting room?

MR. MILLER: Yeah, if I was in the waiting room.

MEMBER VETTER: Absolutely, yes.

MR. MILLER: Not that it's practical, I mean, but if by some means they did.

MEMBER VETTER: Right. Anyone sitting in the waiting room basically.

MR. MILLER: I guess from -- I'm sorry I'm interrupting.

MEMBER VETTER: No, that's okay.

MR. MILLER: But the thought that I have is how are you going to accumulate this. How are you going to account for this? People are going to have to walk around with dosimetry on?

MEMBER VETTER: No, I think --

MR. MILLER: From a practical perspective, how would you accumulate the fact that you have exceeded the hundred by all of those means?

MEMBER VETTER: No, that's a very good question, a very good question, and the medical

community, medical physics community is almost in an uproar over this because you can't. You can't possibly measure. You have to calculate it, and so the constraint is something that has to be -- it's almost an artificial thing. You have to design your facility so that the maximally exposed individual would not get more than the constraint.

MR. MILLER: The radiation safety community has been practicing this for decades. It's just that now they're trying to come up with some guidance and come up with some new numbers, but the fact is we're dealing with some very, very low numbers, and so it's not a completely new practice. It's just that the numbers are going to be downsized somewhat, and that's caused the anxiety.

MEMBER VETTER: Well, what's really different about it is there's very little data to support -- well, the data that has been collected suggests that anyone sitting in a waiting room is going to get almost an immeasurable dose, but when the waiting room is designed, when you determine the thickness of the shield on the wall, what criteria do you use for that?

One of them is what's the permissible dose to that person sitting in the waiting room, and

historically the medical physics community has used the public dose limit as the maximum dose to any person sitting in the waiting room.

The constraint would suggest that you must use a lower number because that member of the public might be exposed to more than one source of radiation. In other words, they might got to Hopkins and then they go to Georgetown and so forth. So each one of them would need to design their facility so that the member of the public would receive some fraction of the maximum permissible dose, not the maximum permissible dose.

MEMBER WILLIAMSON: I think there can be -- I'm sorry.

MR. MILLER: I'm sorry. I didn't mean to interrupt you.

CHAIRMAN MALMUD: That's the purpose of this.

MEMBER WILLIAMSON: Yeah. Well, I think an analogy can be made between this and prostate brachytherapy. In prostate brachytherapy, if you placed the regulatory limit at something, a minimum or maximum dose, that's a single point. The result will be notoriously unreliable and of no clinical significance.

So I think the problem with the system is the fact that it doesn't deal with a stochastic model of the patient population, but tries to base the whole idea on the concept that no single individual exceeding the maximum dose with 100 percent probability, which is, you know, a clogged procedure.

So I think that the fundamental suggestion one could make to inform this process better is to go to some sort of a probability based model where the likelihood of individuals being in three successive waiting rooms at Hopkins, Mass. General Hospital, wherever, is taken into account.

CHAIRMAN MALMUD: Dr. Miller.

MR. MILLER: Dr. Vetter, I'm sorry if I missed the innuendo, but this would be for more than just medical; is that correct, as you're defining it?

MEMBER VETTER: Yes, right. The ICFP 2005 applies to -- when they say the dose to the public, it cold be from any source.

MR. MILLER: So if I were a member of the public who was visiting a nuclear power plant, then the dose I received for that would have to be added to this by that. Okay?

If I had some business and I happened to be adjacent to an industrial radiography facility,

that would have to be added.

MEMBER VETTER: Yes, all of those are added.

MR. MILLER: I think that that begins to show the difficulty.

MEMBER VETTER: Well, the point they would make, Dr. Miller, the point they would make is it isn't right to expose that person to 100 millirem per year in each case. That's the point that ICRP would make.

MR. MILLER: Is it only from regulated activities as opposed to natural sources of radiation or is that --

MEMBER EGGLI: What if I live in a brick house?

MEMBER VETTER: Cosmic are excluded. Radon is not.

MEMBER EGGLI: So what about natural radiation in brick?

PARTICIPANT: That's background. So that's excluded.

MR. MILLER: Radon is not.

MEMBER VETTER: No, that would be --

MEMBER EGGLI: A brick house is going to give me --

MEMBER VETTER: That does not --

MEMBER EGGLI: -- in a year.

MEMBER VETTER: They don't specifically address brick. What they do is they address any activity that could increase your dose, and so they would probably say the brick should be included.

MR. MILLER: How about a flight, if I took an airplane?

MEMBER VETTER: A flight would be included, yeah, anything that -- what they're saying is their recommendations apply to anything, any new exposure or anything where you manipulate something and increase the dose. The example they use in that regard is radon.

DR. HOLAHAN: I'm going to ask Vince Holahan to speak to that because he's shaking his head.

DR. VINE HOLAHAN: Yes, good afternoon. Vice Holahan. I'm from Research.

The key point here is controllable sources. If it's not a controllable source, it doesn't come under the jurisdiction of the scope of these recommendations. A case in point, Dr. Miller had mentioned an airplane flight. That's not considered by definition a controllable source.

You'll also find that when we talk about radon, it generally tends to be the industrial applications, and they say if you fall below a certain level and they articulated what the maximum level should be, then that's considered now a noncontrollable source. So they've got some breaks in there.

MS. SCHWARZ: I have a question. Have they made any recommendations of how many sources in a year, I mean, or that there should be a limit to each occurrence?

MEMBER VETTER: No. My understanding is they are recommending to governments that each source of radiation, controllable source of radiation, should have a constraint, and the maximum constraint it one millisievert per year for a member of the public, 20 for occupational and so forth.

So each government would have to decide on how many constraints would be appropriate.

CHAIRMAN MALMUD: Thank you.

Please go on.

MEMBER VETTER: Did Ralph -- do you?

MEMBER LIETO: No, I was going to wait until you finished.

MEMBER VETTER: Okay. That's constraints.

Now, relative to dose limits, the occupational limit, they are simply reemphasizing that, 20 millisieverts per year or that's two rem, averaged over five years with a maximum of 50 millisieverts or five rem in any one year. I don't believe that's different, but they're simply reemphasizing that.

Now, relative to medical, I know Vince Holahan has taken a look at some doses from other sources where the NRC is able to track those doses, but relative to occupational doses in medicine, we have --

MEMBER VAN DECKER: No national database to track those.

MEMBER VETTER: People don't do a whole lot of publishing on what the doses are within their facility, except to say that our doses in cardiology were such-and-so, and we took the following action, and so now they're such-and-so. So they're lower. So this action was a good thing to do.

So they're very specific relative to cardiac lab dose or nuclear medicine personnel in the hot lab, that sort of thing.

We don't have a good idea of what average doses are in medicine, what maximum doses are in

medicine. I took a look at my own facility, and we would be able to live with this. The only people that get badge doses that exceed five rem in any one year are people such as interventional cardiologists who are wearing an apron, and when you factor in the apron, the effective dose is a couple hundred millirem a year.

In nuclear medicine, our technologists, the highest doses they get are a few hundred millirem per year. The imaging techs would get less than that. Those that work in the hot lab would be a few hundred millirem a year.

Their hand doses can get pretty high if you don't watch them, but nothing that -- so this is just looking at one facility, but I don't have a good handle on average doses -- I don't mean average dose -- on a distribution of doses among workers in medical facilities in this country, and I don't know if anybody does.

MEMBER VAN DECKER: Well, there have been some published studies, occupational for RTs, radiological technologists, and whatever, and the results are relatively --

MEMBER VETTER: They're all within these limits.

MEMBER VAN DECKER: Yeah, yeah.

CHAIRMAN MALMUD: Ralph?

MEMBER LIETO: I was just going to make the comment that medical exposures probably provide the largest group of individuals that are exposed ionizing radiation, but there's no requirement or any resource that keeps any type of a national either database or even just like the NRC requires, I think, for a fuel cycle and nuclear power and waste and so forth. They have to provide these -- what do you call it? -- not necessarily the individual exposures, but --

DR. HOLAHAN: Yes, but it's a rare database and they have to provide statistical data.

MEMBER LIETO: Right. I mean, there's nothing like that for medical. So, you know, there's really no central location that that's kept so we really don't have a good handle onto what that actually is when you start to look at, you know, the fluoroscopy exposures and so forth.

MEMBER VETTER: So based on the feedback or our knowledge in this room, we should be able to live with this occupational limit of 20 millisieverts per year averaged over five years.

DR. HOLAHAN: I have a question to that.

Are you sure that the interventional cardiologist can live with that? Because we were under the impression that they had troubles meeting the five rem.

MEMBER EGGLI: Yeah, they do. So do conventional radiologists.

MEMBER VETTER: To the bad, you mean.

MEMBER EGGLI: No, adjusted dose. There are a lot of procedures that are very high.

CHAIRMAN MALMUD: Dr. Van Decker, the question is are you familiar at all with the exposures of interventional cardiologists, your colleagues, with respect to annual dose?

MEMBER VAN DECKER: I would preface it by saying I'm not an interventionalist myself, but having been on enough radiation safety committees, I would say that most of them to badge break this number but on calculated effect of doses usually are much less, and so don't break the limits at that point.

CHAIRMAN MALMUD: Thank you.

I think we had some additional comments. Dr. Suleiman.

MEMBER SULEIMAN: Yes and no because I'm going back and forth with the medical exposure and the --

CHAIRMAN MALMUD: Oh, I'm sorry. I

thought you had your hand up.

MEMBER SULEIMAN: And I didn't. I was vacillating between whether I should say something or not, but the effective dose with the whole body dose and the organ doses there when you're dealing with the specific organ doses, you're introducing a factor of ten or so greater safety, you know, but I don't think this is -- as I said earlier, I think we can live with these numbers. I think it's just more of what we've been doing in the past.

The two rem per year, I think you can allow five rem in a given year. They just don't want you to exceed an average of two rem over a ten-year period of time.

So it's an effort to sort of impose more constraint, but it's not, like you said, a limit. So the interventionalist, I agree that you hear stories about them approaching the limits, but you also hear about some stories where good radiation safety practice can get those doses lower.

So aside from the academic debate about how you calculate the doses and what it's doing, I think those numbers are pretty realistic.

MEMBER VETTER: So it may be fair to say that anecdotally these numbers are realistic, but we

really don't know whether or not or what the impact this would have on individual practices.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I guess there's two other categories of workers. I'd ask the question whether this means we're going to leave the two rem limit, and that would be cyclotron workers, especially from positron emitting radionuclides where it's high energy and aprons aren't going to make any difference, and I think the other group where there may be some concern might be source handlers and manufacturers where I hear anecdotally workers do get pushed.

DR. HOLAHAN: Manufacturers and distributors are already required to input into the REARS (phonetic) database, and I don't know.

PARTICIPANT: I don't know what those doses are.

DR. HOLAHAN: But I think they're below the limits, but I don't know if they're below two rem.

CHAIRMAN MALMUD: Thank you.

MS. SCHWARZ: I would say for PET workers, not even the cyclotron operators, I mean, for the technologists, that would run about 200 millirem a month. So over a year, 200 millirem a month. I mean, that's not all workers, and probably if you look at

averages you'll be all right, but individual workers may have some problems.

MEMBER LIETO: I was just going to say that I think the two rem is going to create some difficulties, and I think people need to recognize that, you know, basically that's the dose. Even though it's constraint on one page, it's a limit on the other, and Dick's presentation here, and I think that it gets to the question what is wrong now with the current limits.

You know, we are for the most part living below the five rem and probably very close to below the two rem for even our worst case situations. What is the necessity; what is the driving force for ratcheting these down even further? Okay? Because it's just going to, I think, require I think the economic factors and so forth.

People are going to say, well, the limit is two rem. You know, if I'm going to implement ALARA, does that mean now the new ALARA levels should be 200 millirem?

You know, I just think this is really, really not a good thing.

DR. HOLAHAN: And I just want to note that this was the same thing that was in ICRP 60 that we

didn't adopt.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: Also, what is this going to do to the cost of construction of medical facilities when you have to increase the shielding to meet these new guidelines? Right now we have a new CT scan, and we're not going to install because the cost of adding the shielding to the space where we want to install it is equal to the price of the instrument. So it's not going to happen.

I mean, this could have problems as you ratchet down the public exposures. The cost of shielding medical devices is going to make a significant impact on the cost of health care.

MR. BAKER: I think that's a good point. In their recommendations ICRP does not address quality of life or any of those issues. They don't try to quantify benefit in any way. There's simply their mission. They have blinders on, and their idea is to try to keep doses as low as possible, you know, justify and so forth.

I think they tried to be reasonable, but they're very firm believers in the linear, no threshold dose response curve, and they're driving the doses down, and they don't look at these other side

issues.

MS. SCHWARZ: And another issue: have they quantified any risks? I mean, is there reason because they have determined the risks from ionizing radiation?

MEMBER VETTER: Well, they've indicated that they have examined the biological literature and so forth, and first of all, these numbers, as Trish mentioned, the two rem average over five years, that's not a change. They're simply underscoring.

MS. SCHWARZ: No, I understand.

MEMBER VETTER: Yeah.

MS. SCHWARZ: I understand.

MEMBER VETTER: No, they believe that that's what they have selected as an acceptable risk.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Yeah, I think especially given that this two rem has been instituted in their literature for some time, the area of most concern would be paring back the 100 MR limit for members of the general public, and I think that this is an opportunity to try to -- how shall I say it? -- at least delay their program to ratchet down dose limits in an ever more irrational way to zero, no matter what the cost to anybody.

So I'm wondering what your opinion would be, Dick, about what would be sort of tactically the most appropriate and -- how could I say? -- useful objections to bring up at this event that would make sense to them and resonate, would actually have some impact in modifying this, slowing down the approval of this effective lower limit for the members of the general public.

MEMBER VETTER: Well, this isn't new either. They've had a constraint for members of the public prior. So this isn't new either.

I think it might be a little different. Do you know, Vince? It's .3 millisieverts per year. What was the old one?

DR. VINCE HOLAHAN: Well, right now we already have constraints. We use constraints in our rulemaking, and an example of that is the decommissioning rule, and we're fighting with EPA as a constraint for decommissioning. The unrestricted release of those sizes should be 15 millirem or 25 millirem.

We have water standards that are four millirem. So these are already being used in this country, and we essentially call them constraints. So this is not a new issue.

One issue I would like to raise is there's another class of worker you've got to consider, and this is one of the few changes they have in their limits, even though they say there are no changes in the limits. That's to the fetus. The fetal exposure would not be 100 millirem.

So my question would be: what is the impact on the declared pregnant worker?

MEMBER VETTER: Yeah, that's in one of my later slides, but we can talk about it now.

DR. VINCE HOLAHAN: And right now in the United States, the fetal exposure for the declared pregnant worker is 500 millirem during the remainder of the course of the pregnancy.

Part 60, ICRP 60, which was published in 1991, is 200 millirem to the surface of the abdomen. Now these recommendations would say 100 millirem, and I would ask what impact would this have on some of your declared workers that might be, in particular, medicine and things like that.

CHAIRMAN MALMUD: Ralph.

MEMBER LIETO: I'll tell you right now they wouldn't be able to work. All right? Period. Because I have to assure that, and for me to say that a nurse, nuke med tech or whatever, I have not ever

had anybody in the decades that I've been responsible for this had a pregnant worker exceed 500, but I've had a few over 100. Okay?

Now, the fact that I know that it can occur means, one, that they would not be able to declare pregnancies, okay, if they wanted to continue on working, is basically what it gets to because if we have to meet this 100 millirem, you can't have declared pregnancies because they're going to be mutually exclusive in the training or practice of using ionizing radiation.

And I think it's catastrophic.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: I think along that line I agree with Ralph on a far broader basis. I think an interventional physician who is getting exposed to somewhere near the limit is going to be inclined to take their badge off and put it in a drawer and going to continue to work because if you damage my livelihood and tell me I can't work for the next five years because I've hit my limit, that ain't going to fly.

So I think that you have to look at what's the benefit, you know. I understand that if you believe in the linear nonthreshold model, then you can

calculate a mathematical benefit, but you have to look at the cost of that benefit, and the cost of that benefit, I think, as we ratchet these things down to ever lower levels becomes economically for society as a whole and for individuals within that society becomes prohibitive.

CHAIRMAN MALMUD: Thank you.

Another comment? Let's see. Dr. Suleiman and then Dr. Lieto.

MEMBER SULEIMAN: At FDA actually we're dealing with some ethical issues regarding young pediatric, the fetus, and the radiation risks, I've had that responsibility lately, but there's a whole other issue that has an element of what's probably driving this very thing. So my perspective on this is that I think I can live with the two rem, five rem because I think in reality it's obtainable.

But I am concerned when you're getting down to what we would consider background levels, when you're talking about a millisievert and you're going to pick up three during the course of a year and you're further restraining or constraining the fetus at an almost ridiculously low level for an occupational worker, I think that's probably if you're going to argue pick your battles, that's probably

where you ought to focus on it rather than the occupational limits.

CHAIRMAN MALMUD: Thank you.

Ralph.

MEMBER LIETO: Well, I was going to just say like Orhan had said that we're looking at fractions of background that they want to have these limits put at, which really makes it very difficult to understand the credibility for this, other than simply lower is better, and I wanted to go back to a point that I think Dr. Miller might have asked about with the shielding.

We've run into this already on the diagnostic X-ray side in my state, and what you have to also look at is not only future facilities, existing facilities that have already been designed in existence, especially in urban areas.

What you're now saying is that I think they're using a constraint of one-third in the ICRP. Putting the exact same machine in there with the exact same work load, everything else identical, you now have to put three times the shielding in to meet this constraint level. Okay? Just simply because they want to lower it to these newer values, and I think that what it basically is going to prevent, renovation

and reuse of existing therapy rooms. It will prevent facilities in urban areas from expanding because there's no place to go to. Okay? They have to basically use those areas that currently exist.

And, again, it gets to this what is the benefit that we are trying to achieve, and I just see it as being a blank answer as far as what the benefit is.

CHAIRMAN MALMUD: Thank you.

Dr. Eggli.

MEMBER EGGLI: And to speak to the benefit question, if you look at the incidences of cancers in occupational workers, they're, in fact, lower than the general population. So what are we trying to achieve here?

I think that we have achieved with radiation safety for both the public and for occupational workers, we've achieved a very high standard already. What better can we do than making occupational workers have a lower incidence of cancer than the general population? What are we trying to get to?

MEMBER VETTER: If you use that argument, they'll throw the healthy worker effect at you. You're looking at a subpopulation whose health is

better than the general public.

MS. SCHWARZ: I would like to make a comment about the pregnant female.

CHAIRMAN MALMUD: Dr. Schwarz.

MS. SCHWARZ: I'm concerned about just to add to the already stated facts. I think it's definitely going to be problematic in that if a woman does declare pregnancy, essentially will have to be taken out of the work area, I mean, and not be allowed to work. So this will essentially, though maybe not on paper, could discourage women from being hired.

I mean, there could be an element that could affect that, I'm sure.

MEMBER VETTER: Just in that regard there's the Johnston Controls case which prohibits us from doing that.

CHAIRMAN MALMUD: Prohibits who from doing that?

MEMBER VETTER: It would prohibit us from doing something that would affect the welfare of that pregnant worker. In other words, we could transfer her to another job temporarily that gave her the same amount of money and so forth, but we can't do anything to discriminate. We must protect that person so that that person has the same opportunity as a male who

can't get pregnant.

So, I mean, the Supreme Court did that one. We can't discriminate. We can't not hire a pregnant woman because she's pregnant.

MS. SCHWARZ: No, I understand that, but what I am saying --

MEMBER VETTER: Or prevent her from doing nuclear medicine or whatever.

MS. SCHWARZ: You could discourage her from being hired in general, not in writing, not in terms of policy.

MEMBER VETTER: Right.

MS. SCHWARZ: But in terms of the mental review of management.

MEMBER VETTER: I see what you're saying.

MS. SCHWARZ: Understanding that if they're dealing with a young female population, that it could discourage them from being the choice between two equal candidates.

CHAIRMAN MALMUD: That's a valid observation.

We do have a comment from the public which I'd like to entertain now if the committee will permit.

DR. WHITE: Gerald White. I'm here for

the AAPM, but speaking just personally.

I can't help but hang crepe on many of these issues about experiences of community hospitals. One issue about pregnant women that hasn't really been stated explicitly is that of pregnant radiologists and pregnant cardiologists.

If in my community hospital I go to a pregnant cardiologist and say, "You cannot do your patients in our hospital because we can't keep you below 100 MR," that woman and all of her patients will be at the hospital across town before you know it.

The pressures to ignore that rule or to find some way around that rule will be enormous. In order to encourage respect for the science of radiation protection, the rules have to be reasonable and enforceable, and if they're not, not to pick on physicians, but physicians will be the first ones to find a way around them and the hardest to control.

And these are the people in the hospital we look to for leadership, for sensibility, and we're going to lose that. It's going to be a net degradation in the radiation protection program in hospitals.

CHAIRMAN MALMUD: Thank you.

Would you like to go on, Dr. Vetter?

MEMBER VETTER: Sure. Okay. Anything more on dose limits?

CHAIRMAN MALMUD: No.

MEMBER VETTER: For physicists, the weighting factors for certain types of radiation will change a little, but I don't think that has a major impact on any of us. For protons, it goes from five to two, the weighting factor, and for neutrons, it's roughly the same. It's just they determine the weighting factor a little bit differently.

The tissue weighting factor has changed somewhat. I don't perceive that that would have much of an effect on how we calculate occupational dose. In fact, most of our doses are simply measured with badge. We don't have many up ticks or intakes. So we're not very often calculating internal dose.

If we do, ICRP would say we calculated a little bit differently the effective dose from prior because some of the tissues have been changed a little bit. I don't think it's significant enough to go into.

Do you want to flip to the last page, page 4? Application of dose constraints. This is where I perceive we've already talked about this. I perceive some of these areas to be problematic.

Occupational workers in controlled areas

are well informed and especially trained so that constraints are fairly easy to administer if we choose to appoint some constraints in our areas.

It should be pointed out that administrative and support staff should be treated as members of the public. There have been some who have suggested that relative to this issue of designing shields in diagnostic X-ray departments that a receptionist who is going to be sitting right outside the shield perhaps should be classified as an occupational worker, a worker for purposes of occupational dose.

The recommendations of ICRP are clearly counter to that.

Let's see. We've just talked about the working conditions should make it unlikely that a dose to the fetus would exceed one millisievert, and finally, relative to medical exposure, my second to last slide, no limitation of dose to the individual patient because it may actually reduce effectiveness of diagnosis or treatment. So that clearly falls under the arena of justification.

But related to medical exposure, constraints should apply to workers and the public, and this one, this is an area that we should probably

spend a minute on.

Some exposure may occur in patient care and support by members of the public, such as family, members of families who are caring for a radioiodine patient, and they're saying that a constraint of a few millisievert -- they don't get very quantitative about that -- a few millisievert is reasonable, but should not be used rigidly. For example, higher doses are reasonable for parents of a sick child.

Now, this came up yesterday in conversation, and I think the feeling of the advisory committee is that we should look toward NCRP commentary 11, which I think is dated what, about 1995?

PARTICIPANT: Yes.

MEMBER VETTER: So it's a few years old, but I don't think if you ask NCRP, I don't think the thinking would be much different from what they recommended back then, and they recommended that and the NCRP instituted a rule, in fact, that patients who are administered therapeutic radionuclides could be released to the public under the conditions that a member of the public would not receive more than 500 millirem.

NCRP also said that for members of the

public who are family members of the patient, that a higher dose would be justified in the care of that patient, and they said it could be as high as five rem, provided you instructed them appropriately in how to keep dose down and monitored them.

The NRC didn't adopt that condition, but the ICRP is suggesting without giving any numbers, they're suggesting that that is, in fact, justified. You can justify a higher dose to the parents of a sick child, for example. So there are a couple of constraints here that are saying that certain very small groups, members of the public can get a higher dose than the limit; that it is, in fact, justified, for example, in this case, and you would establish that maximum dose by some sort of a constraint.

And they're saying for a member of the public the constraint is a few millisieverts or maybe it's five. That would be the same as -- is that what they're saying now, two?

DR. VINCE HOLAHAN: It's a maximum constraint.

MEMBER VETTER: That is the maximum.

DR. VINCE HOLAHAN: Yeah, the maximum constraint for a caregiver is two millisieverts.

MEMBER VETTER: I didn't see that.

DR. VINCE HOLAHAN: Twenty millisieverts. I'm sorry.

If you look at the table where they have the maximum constraints --

MEMBER VETTER: Two rem, yes. That's two rem.

DR. VINCE HOLAHAN: That's correct.

MEMBER VETTER: Not 500 millirem, yeah. So that would be the maximum, two rem.

DR. VINCE HOLAHAN: That's the maximum constraint per caregiver.

MEMBER VETTER: Right. Oh, yes, I do remember seeing that, yeah. the maximum constraint for a caregiver would be two rem.

Now, current NRC rule is that the maximum limit is 500 millirem. I'm sorry. That's not quite the right way to put it. You base your release of the patients on assuming that no one would get more than 500 millirem.

DR. HOWE: Dr. Vetter, is it clear that it's for a whole year or is it per patient?

MEMBER VETTER: In this case it's per episode.

DR. HOWE: Okay.

MEMBER VETTER: For caring of patients

it's per episode. Now, you would normally anticipate that to be once in a number of years.

DR. HOWE: And for your other discussion that you had, it was clear that the radiation to the patient for the procedure the patient is receiving is not included. What about the dose from the patient to other people?

MEMBER VETTER: Yeah, they address that in two different ways. One is for patients who are sitting like in a nuclear medicine waiting room, that the dose to other people in the waiting room is -- they don't use the word "inconsequential," but it's low and it doesn't need to be worried about, and the same thing for transport of radioiodine patients on the way home, that those doses are low enough not to worry about.

But then the other group that they talk about is caregivers, from dose from patients. It's caregivers and they're saying a few millisieverts. It would be two rem in our case would be the maximum to caregivers, and possibly higher for parents of a sick child.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter, you've heard a number of comments from the committee. What is it that you were

seeking in presenting this to the committee as an end result?

MEMBER VETTER: What I'm interested in hearing from the committee are their interpretations of when these recommendations could be problematic for the medical community.

CHAIRMAN MALMUD: And you've heard that?

MEMBER VETTER: I've heard that. I've heard some very good feedback, and that's what I would take to the meeting next week.

Now, the meeting next week is the Advisory Committee on Nuclear Waste who is simply trying to get educated on this issue, and they're interested in our perspective.

CHAIRMAN MALMUD: And what we've heard is that there's no evidence statistically that radiation workers, despite the fact that they're classified as perhaps a healthier group than the population at large, has a higher incidence of cancer or mutations that result in deformed fetuses than does the population as a whole. Therefore, we are not encouraging reducing the safe limits in a theoretical pursuit rather than a practical one; that, in fact, there may be unintended consequences in reducing those limits, such as the inability of someone to maintain

gainful employment in the course of a pregnancy.

And, therefore, we are supporting your transmitting the message that we don't see the need to reduce these limits. Is that a fair summary?

Thank you.

MEMBER VETTER: We don't see a need to reduce the limits that are currently --

CHAIRMAN MALMUD: Currently established.

MEMBER VETTER: Right.

CHAIRMAN MALMUD: If that's a fair summary, we will accept that. If someone will make that motion other than the Chair, and that will be the message that Dr. Vetter would deliver on behalf of the ACMUI.

MEMBER EGGLI: So moved.

CHAIRMAN MALMUD: Moved? Did you second it?

MEMBER LIETO: I would second it.

CHAIRMAN MALMUD: Moved and seconded. Dr. Eggli moved it, seconded by (pause) --

MEMBER LIETO: Mr. Lieto.

(Laughter.)

CHAIRMAN MALMUD: -- Mr. Lieto.

Is there any further discussion?

MEMBER LIETO: I have a couple of quick

comments. One thing that I think also this does is convey a very negative aspect about radiation. If you're above this constraint level, you know, a few millirems, tens of millirems, it conveys the sense that you failed to meet good radiation safety standards and you're exposing people to harmful amounts of radiation that are within the normal range of variance of background itself, and I think that's a negative connotation that would be relayed by this.

Another point is that in looking over this document, we've always talked about dose equivalent and equivalent dose. Well, in their infinite wisdom, ICRP is saying, "Okay. We've not going to use that because it's too confusing. We're going to establish a new term." Okay?

So now we're on this merry-go-round of new terminology, and I agree about the confusion with dose equivalent or equivalent dose, but it has got to stop someplace. I mean we need to say this is the terminology and let's stick with it for more than five years.

And they've come up with another term, and that's another thing I think is going to, I think, related to a lot of confusion. I think a major change in a lot of the rules the way they're defined and

regulations the way they're written to adopt this new terminology, and again, I just think there's absolutely no benefit being derived from all of these changes. I think it's just a bad piece of -- well, I shouldn't say that, not overall.

I can understand the weighting figures, the factors, and some of these lower limits being established for natural sources, but you know, I think that some of these other things are just not very beneficial because I think they determine -- I guess de minimis is not the right term -- but a level at which you don't need to concern yourself, which is like one millirem. What is that? I guess you could climb up to the eighth story and get more than that. I just think it's an absolutely ridiculous number.

CHAIRMAN MALMUD: Any other comments with regard to the recommendation that Dr. Vetter will carry with him?

If not -- oh, yes.

DR. VINCE HOLAHAN: If I could just make one quick clarification, the limits that we're talking about in this draft document for all intents and purposes are not different than ICRP 60. So to go back to the main Commission and say 20 millisieverts for an occupational exposure is unreasonable, well,

they don't care. That's already on the table.

What will be important is several years from now, will the NRC adopt these recommendations, and that's the issue to be addressed with the Commission.

CHAIRMAN MALMUD: Thank you.

And that's your understanding, Dr. Vetter?

MEMBER VETTER: Yes.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: The point is well taken, and the only thing that's new about this is if you don't adopt these or I shouldn't say -- doses above these constraints are considered failures now by the ICRP, which is not the type of terminology that they used before.

So I find that very, very negative and, you know, really is sort of almost I don't want to say a strong arming, but sort of a way of trying to coerce national bodies and agencies to adopt their values, which, you know, many countries have not, including ours.

CHAIRMAN MALMUD: Thank you.

So we are encouraging of not tightening things, in addition to for the ICRP to look at the unintended consequences of some of their actions.

We still haven't given you a nod of approval for what you would like to take with you.

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(Show of hands.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It carries the majority.

MEMBER VETTER: Just one comment relative to the impact of these, what they really mean. Historically I think the NRC and regulators in this country had looked to the NCRP for guidance as opposed to the ICRP.

Now, in large measure they're the same, except that these dose limits have been different since ICRP 60. So in that regard I did ask NCRP when do they plan on taking another look at their recommendations. They are waiting for BEERS-7 to be published, and then they will ask them. Then they'll kind of ask themselves: are the limits that ICRP is proposing here appropriate or do they want to maintain the limits they have in NCRP 116 or whatever?

But I just wanted to throw that out for your information.

MEMBER SULEIMAN: When is BEERS-7 supposed to be published?

MEMBER VETTER: That's a good question.

MEMBER SULEIMAN: I mean a year, five years, ten years?

DR. VINCE HOLAHAN: The final chapters of BEERS-7 are being finalized now. The project director, Mr. Rick Jostice (phonetic) or Dr. Jostice, is hoping to put that out to peer review in the National Academies this fall. I would say it's possible to be released as early as the April time frame of next year. I'd feel a little bit better saying maybe June of next year.

CHAIRMAN MALMUD: To be precise, Dr. Suleiman, it's in the future.

Thank you.

May we move on to the next item on the agenda?

MR. ESSIG: Yes. The next item on the agenda, if I may introduce it, is the final item on the agenda.

CHAIRMAN MALMUD: Before you introduce the final item, may I once again thank Dr. Vetter for all of the effort he went to thus far and will go so again next week on behalf of the ACMUI.

MR. ESSIG: Okay. The final item on the agenda, we had wanted to go over if possible the action items arising from the meeting which based on the way we've captured them, it's going to take a more detailed review, and so we don't think trying to reach agreement on action items here more or less in real time would not be fruitful.

So we're not going to propose to you right now that we go over the action items. What we would go over is the recommendations that arose and that were in the form of a motion that was acted upon. We will summarize those. Angela will, and then the second order of business then prior to declaring the meeting adjourned is to discuss the meeting dates for the spring 2005 meeting, which hopefully those who have to leave left a vote sheet with somebody. Dr. Diamond or Mr. Bailey, I'm hoping that they left their preference behind somewhere, but maybe they didn't.

Because I think the preferred approach on the 2005 meeting was to either circle the dates that each member preferred or to cross out those that appeared to be unworkable.

MEMBER NAG: Tom.

MR. ESSIG: Yes.

MEMBER NAG: I thought the dates of the

26th and 27th of April was the main one and we wanted to see how many are not able to attend that because there are so many. We'll never come to consensus. It might be better off saying how many cannot make that April 26th-27th, and then go from there.

If a lot of people cannot make that, then we look for an alternative. Otherwise, I will be here for certain dates, and you will never have a consensus doing it that way.

MR. ESSIG: Okay. We can certainly do that, and we just more or less picked those dates because they didn't appear to conflict with our knowledge of the major society meetings at that time.

Now, we have to review our own schedule in house, which we haven't done, against those dates for Dr. Miller and Dr. Holahan's availability. So they're a little bit tentative in that sense.

But at least what we know is that the auditorium is available on those two days and we've preliminarily locked it in. So maybe next door to business then would be to discuss the recommendations that arose, and Angela will do that.

MS. McINTOSH: Bear with me a little. This is a matter of combing through some very rough information to capture what we believe are the motions

that arose from the committee meeting yesterday and today.

The first motion that the committee made was regarding the seeds electron guidance, and that motion basically stated that the seeds electron is appropriately codified in 10 CFR 35.1000, but that the staff should use the regulatory framework in Section 35.400 as a model for creating guidance for the seeds electron, adding only those elements of Section 35.600 as needed.

Looks like everyone is in agreement with that one.

The second one, the second motion, the committee motioned to have the 200 hours' worth of training and experience in Part 35.390 reduced to 80 hours.

CHAIRMAN MALMUD: That is correct.

MS. McINTOSH: Another motion that the committee made, it's almost general in nature, but the committee motioned that except for all of those issues identified regarding the draft 10 CFR 35, except for those issues that the committee identified as problematic, the committee motioned to move forward with the draft final rule.

CHAIRMAN MALMUD: That is correct.

MS. McINTOSH: And regarding the abnormal occurrence criteria --

MEMBER WILLIAMSON: You forgot the one on grandfathering. I think a motion was made on grandfathering of AMPs. There was some suggested rephrasing of the grandfathering text that would allow -- I can't remember exactly what was said.

MS. McINTOSH: Okay.

MEMBER WILLIAMSON: But that was one of the two problems that was identified with the 35.

MS. WASTLER: Let me try it.

MS. McINTOSH: We're working from meeting notes. So we don't have the -- the transcript will have the specific. Do you have that?

MS. WASTLER: If I can decipher my scribbled handwriting here, I think --

CHAIRMAN MALMUD: This is Sandra Wastler.

MS. WASTLER: Thank you. Sorry.

-- that the recommendation was that physicists authorized to serve as AMPs for HDR, gamma knife -- I messed up the appropriate title -- gamma stereotactic surgery --

(Simultaneous conversation.)

MS. WASTLER: All right. -- and teletherapy be grandfathered as AMP -- I've got as AMP

modalities. I don't think that's the exact right words -- for AMP modalities.

MEMBER WILLIAMSON: That's AMPs in the area in which they are practicing, which they are currently authorized to practice, I think.

MS. SCHWARZ: Jeff, was there something also mentioned about being preceptors for those AMPs?

CHAIRMAN MALMUD: It says they can supervise trainees.

MEMBER WILLIAMSON: They become preceptors automatically, yeah.

MS. McINTOSH: And then the last motion that we've been able to identify quickly was the motion regarding the proposed changes to the abnormal occurrence criteria, and the committee basically agreed to move forward with those proposed changes.

CHAIRMAN MALMUD: And we just did one for Dr. Vetter.

MS. McINTOSH: Okay, and that was a motion for --

CHAIRMAN MALMUD: Yes.

MS. McINTOSH: Okay.

CHAIRMAN MALMUD: And I think that's complete.

MS. WASTLER: Doctor.

CHAIRMAN MALMUD: Do you recall another one?

MS. WASTLER: Yes. It seems to me that there was a recommendation that you be provided, the committee be provided the research protocol for the I-25 users' markers to allow you to further evaluate that procedure. This was --

CHAIRMAN MALMUD: Yesterday.

MS. WASTLER: -- Robert Gallagher's presentation.

CHAIRMAN MALMUD: That's correct. The committee did request more information bout the use of I-125 seeds as markers for -- the specific indication that was reviewed was for localization of breast masses and breast surgery. And we would appreciate seeing more information regarding the use.

MS. McINTOSH: Okay. Can anyone think of anything else that the committee proposed or a motion that the committee made?

CHAIRMAN MALMUD: That's all that we recall at this moment.

MS. McINTOSH: Okay. And the other administrative item is the setting of the meeting dates for the spring 2005 meeting.

CHAIRMAN MALMUD: And we were given a

number of options based upon the availability of this conference room.

MR. ESSIG: The auditorium. Correction.

CHAIRMAN MALMUD: The auditorium. Excuse me.

MS. McINTOSH: Yes. I have since learned that the auditorium is actually not going to be available on one of those dates in April. So we would still have to go back and set a date for the auditorium.

MEMBER NAG: Was that the 26th?

MS. McINTOSH: We proposed the 26th through the 27th.

MEMBER NAG: And that is available or not available?

MS. McINTOSH: It's not available on the 27th.

MS. WASTLER: Excuse me. Can I just point out, I believe -- this is Sandra Wastler again -- that Dr. Miller pointed out, and I think we all agreed, that what we need to do is set a date we can all live with. The place we will deal with. All right?

CHAIRMAN MALMUD: Is that your point, Dr. Miller?

MR. MILLER: My point was that, yes, I asked my staff let's focus on setting a date for the meeting. Once that's agreed upon my staff will find a venue where we can hold the meeting, and let's not be restrictive; based upon what I heard yesterday, let's not be so restrictive as to be concerned whether it's in this room or the auditorium or some other suitable venue that's nearby. It's more important to find a date where we can get maximum participation.

CHAIRMAN MALMUD: Ralph?

MEMBER LIETO: A question for staff. Not knowing the days of the weeks that these are, is Monday-Tuesday better for individuals as opposed to a Tuesday-Wednesday?

MS. McINTOSH: Can I? The dates that are proposed are Tuesday-Wednesday or Wednesday-Thursday.

MEMBER WILLIAMSON: It can't be Thursday-Friday?

MS. McINTOSH: Well, it can. It's just that most of the committee members prefer to have it between Tuesday and Thursday because most people don't want to travel on Mondays or Fridays.

MEMBER WILLIAMSON: Teaching Monday and Wednesday.

MS. McINTOSH: Okay. Well, traditionally

that's been those days of the week that the committee has been amenable to having the meeting on.

MEMBER NAG: Since we had that 26-27 April, can we just maybe just have a show of hands whether anybody is not available on those dates, rather than saying when you're available and then you'll have people overlap?

MEMBER EGGLI: My concern with that, Subir, is that you've got two members that aren't here.

MS. McINTOSH: Well, actually Dr. Diamond did leave me his input, and his input was he's available for everything, for every date except for March 15th through the 17th.

MR. MILLER: I know I'm not available as it stands now. I think I have to go to IAEA that week; is that correct, Trish, based upon the information we have now?

DR. HOLAHAN: Twenty-fifth to 28th.

MEMBER WILLIAMSON: In theory, yes, I am not available on April 27th.

MS. McINTOSH: So, I mean, we can go in March if March is a little bit better. There's several March dates, 1 through 2, 2 through 3, 8 through 9 or 9 through 10.

MR. MILLER: There are earlier April dates, too, aren't there?

MS. McINTOSH: Well, 19th through 20th for the April or 20th through the 21st of April.

MEMBER WILLIAMSON: So we have to do it Wednesday-Thursday or Tuesday-Wednesday?

MR. MILLER: There's something that I need to introduce to remind everybody of. I need Angela to listen to this to make sure that I've got it correct.

Last year, while we talked yesterday, while Tom articulated yesterday that there's no requirement for the committee to meet with the Commission, there are times where the Commission desires to meet with the committee. And last year the Commission dictated a date that they wanted to meet with the committee, which dictated when -- which to a degree dictated when we had the March meeting because it allowed the committee to be in town one time rather than twice.

My anticipation will be that the Commission would probably want to meet with -- given where Part 35 has been and is coming, I would anticipate that the Commission would want to meet with the committee again.

Have you done any checking on that?

MS. McINTOSH: No, I haven't.

MR. MILLER: Because I wouldn't want to set a date for the meeting and then find out that the Commission wants to have a meeting with the committee, and then there's the concern of -- or is that a concern of the committee to come to town a third time for a Commission meeting?

MEMBER NAG: I mean, at one time, you know, we had to put this off until you had a tentative date with the Commissioner, and what you can do to speed up, you know, maybe us, not what -- you know, which of these dates we are not available.

MR. MILLER: Right, and I think having that information allows us to go to SECY and propose these are dates that ACMUI could be in town for a meeting. Do you want to have a Commission meeting with them?

And I guess the question I would ask the committee is: do you want to have a meeting with the Commission on the annual basis? And if so, could you arrange, could we arrange a Commission meeting that suits around one of those dates?

CHAIRMAN MALMUD: Well, we still remain -- Ralph?

MEMBER LIETO: I was just going to say I

personally don't have a problem with Thursday-Fridays. So if that turns out to help out members and the staff, I would be amenable to that just as an offering or a suggestion and, you k now, it might be that --

CHAIRMAN MALMUD: Which were the two days that you were offering is first, Angela? April?

MS. McINTOSH: Initially we offered April 26th through 27th.

MEMBER NAG: But now that's out.

MEMBER WILLIAMSON: Assuming that's a good date for any of you.

MEMBER NAG: And the other thing is I wonder why even, you know, Monday-Tuesday cannot be. I mean, there is really no reason why we can't have that.

MEMBER EGGLI: There may be some people who don't want to travel on the weekend day because the people who have to come in from a distance have to come in the day before. For me, you know, I just come down the evening before, but maybe somebody doesn't want to spend all day Sunday flying or something.

MR. ESSIG: Which Ed Bailey would have to do coming from California. Coming from California, it would take Ed a whole day, and Robert Schenter has to come from Washington, the other Washington.

CHAIRMAN MALMUD: Next choice after April?

MEMBER NAG: Well, I don't think we can solve anything because we don't know when the Commissioners are going to meet. So we have to shelve that. So I think there is --

CHAIRMAN MALMUD: I thought it was necessary for us to set a date so that you could get the room.

MR. MILLER: Yes, it is.

CHAIRMAN MALMUD: We can have this whole thing by E-mail.

MR. MILLER: I think what is important is knowing the dates. Angela has offered some windows of opportunity here, and I guess the question becomes are there some proposed dates that we can accommodate and then we can take and see if the Commission is willing to meet around those dates so that we can hold the meeting and have the Commission meeting at the same time.

MS. McINTOSH: What I was trying to learn is if out of the proposed dates if there were definitely dates where you knew that you would not be able to be here. Then we could just eliminate those, and we could have some options out of what was left over.

MR. MILLER: Yes, I would encourage you to move expeditiously on this because there was a wide range of dates, and I can't lock all of those dates on my calendar.

MS. McINTOSH: Right, right. So we were trying to get a feel of what we could walk away with, if possible right now, what we could walk away with.

MEMBER NAG: I know like in March 18th through 30 I'm not available.

CHAIRMAN MALMUD: Those weren't in the dates anyway.

MS. McINTOSH: I handed out an E-mail, if everyone has a copy of it. It has the range of dates.

CHAIRMAN MALMUD: How about April 12th and 13th? That's a Tuesday and Wednesday?

MS. McINTOSH: Is that fine with everyone?

MR. ESSIG: That conflicts with ACR.

CHAIRMAN MALMUD: That conflicts with the American College of Radiology.

MS. McINTOSH: It does.

MEMBER EGGLI: Is anybody planning to go to ACR?

PARTICIPANTS: No.

MEMBER EGGLI: Again, physicists don't

usually go to ACR. Radiation oncologists usually go to ASTRO rather than ACR.

CHAIRMAN MALMUD: The 12th and 13th is okay for us?

MS. McINTOSH: Twelfth and 13th.

MEMBER NAG: Twelfth and 13th, Tuesday-Wednesday. That's something I can live with.

CHAIRMAN MALMUD: Twelfth and 13th, Tuesday-Wednesday.

PARTICIPANT: When you're actually doing your taxes.

(Laughter.)

MS. McINTOSH: Would the committee like to propose an alternate date so that we have two sets of dates?

MEMBER WILLIAMSON: What about Thursday and Friday the same week?

MR. MILLER: Why don't we take that based upon the information that --

PARTICIPANT: Well, actually Thursday and Friday of that same week I'm unavailable.

MEMBER NAG: Question. For two days or three days? Usually when we meet with the Commissioners, three days.

MR. MILLER: I would argue given where

we've been in the last number of sessions, we can't even get through what's on the agenda in two full days. If you're going to meet with the Commission, you're going to want to have some time, I would think, as a group before you go up and meet with them.

MEMBER WILLIAMSON: Yeah.

MR. MILLER: So three full days is probably good for planning.

MS. SCHWARZ: So 12th, 13th, and 14th?

MR. MILLER: Or at least two and a half.

MEMBER NAG: Twelfth, 13th and 14th. The last thing you probably want to make it a half day anyway so that people can go home the same day.

MS. SCHWARZ: What about 11, 12, and 13, Monday, Tuesday, Wednesday?

MEMBER WILLIAMSON: I would advise us, even though at the moment maybe we don't have anything urgent we would like to talk to the Commissioners about, I would urge us to continue having the annual contact with them. I think it's always important to bring to the attention or your superiors the activities you're working on and not turn down opportunities to cultivate a relationship. I think it's just bad politics to not, you know, continue this tradition.

I'm sure we can find something to talk about.

CHAIRMAN MALMUD: It should be something of substance.

MEMBER WILLIAMSON: Yes, but, I mean, we deal with lots of substantive activities.

CHAIRMAN MALMUD: But do we have a firm date for the Commission's meeting?

MR. MILLER: No, that's the dilemma. What we're trying to do, what I was hoping to do, and I can't promise that we can deliver on this is get out ahead of what happened last year where the Commission dictated a date, as I recall, and then we had to force the ACMUI meeting to be coincident with that date so that you would only have to come to town once.

If we can get some potential dates now perhaps we could propose those to the Commission and get something, if they accept that, that's more under our control than their control.

MEMBER WILLIAMSON: Or you can work it the other way around and examine the Commissioners' schedules and come up with several.

MS. McINTOSH: I don't think it's out this far ahead.

MEMBER WILLIAMSON: Do they meet in April?

MR. MILLER: Pardon me?

CHAIRMAN MALMUD: Do they usually meet in April?

MR. MILLER: Well, it's a question of a number of things. It's not a question -- the Commission meets whenever the Commission deems that they need to meet, but they try to plan their meeting schedule so that it doesn't interfere with their individual travel activities or other obligations they have. So they try to hold their meetings -- currently there are three Commissioners -- they try to hold their meetings when all three Commissioners are available.

CHAIRMAN MALMUD: We will have to wait until they set their meeting date.

MR. MILLER: And so what it might mean is if we ask them to set a date, that will dictate when the ACMUI meeting will be, which may interfere with some of your availability. Understand that.

I mean, having -- I guess there was one member absent this time. I guess there were two counting Dr. Sukera (phonetic), but having maximum membership at the meetings I find opts for a more healthy, productive dialogue than if we have less members present.

CHAIRMAN MALMUD: Agreed. Ralph?

MEMBER LIETO: Would it be valuable, in light of the fact that the Commissioners may not do something or plan their schedule that far in advance, as I think Angela was suggesting, having a primary meeting time and maybe an alternate? In other words, we come up with two groups of dates and then just kind of maybe they can work from there with the Commissioners.

MR. MILLER: We will try, nd you know, it may or may not fit their schedules. They may come back and dictate something anyway, you know.

MEMBER LIETO: That's fine.

MS. McINTOSH: But as far as April 12 through 13, I think I head the committee say 12 through the 14th and then someone said, well, no, that's not going to work.

PARTICIPANT: I did. I'm unavailable on the 14th.

MS. McINTOSH: Okay.

MS. SCHWARZ: What about the Monday, 11th, 12th, 13th?

MS. McINTOSH: There was concern about Mondays because of travel, but we could. Should we go with the 11 through the 13th as one proposal?

MS. SCHWARZ: Yes.

MS. McINTOSH: Okay, and would there be an alternate proposal perhaps in March?

MEMBER EGGLI: You had also the week of the 21st of April.

MS. McINTOSH: Yes, I had proposed the 20th through the 21st.

MEMBER EGGLI: Are the important people, the prerequisite people from NRC staff available that week?

MR. MILLER: As far as I know, yes.

MR. ESSIG: Okay. So then three days during that week, right?

MS. McINTOSH: I haven't heard. I haven't heard one way or the other.

MR. ESSIG: You proposed two.

MS. McINTOSH: The second one, right.

MR. ESSIG: Two days.

MS. McINTOSH: The 11th through the 13th is the first proposal.

DR. HOLAHAN: We're talking about the second proposal.

MS. McINTOSH: Right.

MS. McINTOSH: I haven't heard one way or the other if that's okay.

Would the 20th through the 22nd --

PARTICIPANT: Of April?

MS. McINTOSH: -- of April be okay?

CHAIRMAN MALMUD: Any objection to that, 20th through the 22nd of April?

MEMBER WILLIAMSON: No.

CHAIRMAN MALMUD: As an alternative. Dr. Nag?

MEMBER NAG: Right now that looks okay now.

MS. SCHWARZ: What was the date again?

CHAIRMAN MALMUD: The 20th through the 22nd.

MS. SCHWARZ: Of March?

CHAIRMAN MALMUD: April.

MS. McINTOSH: As the alternative.

PARTICIPANT: And what's the primary?

MS. McINTOSH: The primary would be the 11th through the 13th of April.

MR. MILLER: So why don't we take those two proposals?

CHAIRMAN MALMUD: April 20th to 22nd?

MR. MILLER: Yeah.

CHAIRMAN MALMUD: I think that might be a problem. We have to reappoint the new modality

subcommittee, by the way.

MR. ESSIG: Yes.

CHAIRMAN MALMUD: April 20th to 22nd, what's our schedule look like?

MEMBER WILLIAMSON: I thought there were two other action items we had. Something I'm supposed to do with the medical event criteria.

MR. ESSIG: Jeffrey, are you speaking of action items or motions? We didn't talk about action items. We're going to dig those out.

MS. McINTOSH: Right.

MR. ESSIG: It was too much trouble to dig those out of the transcript at this point.

MS. McINTOSH: Okay. So the 20th through the 22nd.

CHAIRMAN MALMUD: Yes.

MS. McINTOSH: So the 20th through the 22nd is going to be the alternate proposed date for the spring meeting.

MEMBER WILLIAMSON: What is the initial date or primary date?

MS. McINTOSH: Eleventh through the 13th of April.

MR. MILLER: What we will do is we will check to see if we could arrange a Commission meeting

at that time. If the Commissioners offer an alternative date that they want to meet, well, then I think we'll probably need to get back to you and see if you can accommodate that.

It's always a challenge to do both.

CHAIRMAN MALMUD: Thank you.

The next item is the new modality subcommittee, which needs to be reappointed. Its chair has left the committee; is that not correct?

MS. SCHWARZ: Yes.

CHAIRMAN MALMUD: And who was on the previous subcommittee on modalities? Dr. Nag, Dr. Williamson, and Dr. Schwarz? Would one of you wish to be the successor to chair the committee?

Dr. Schwarz has been nominated by Dr. Williamson for that position.

MEMBER NAG: I second it.

(Laughter.)

CHAIRMAN MALMUD: Dr. Nag seconds it. Do we need one more member or is three adequate?

PARTICIPANT: It probably would help to have the agreement state person on.

MEMBER WILLIAMSON: The agreement state person.

CHAIRMAN MALMUD: Why don't we nominate

Mr. Bailey in his absence and essentially agree?

Yes, Dr. Nag.

MEMBER NAG: I would like Dr. Diamond taking out (unintelligible). I want to know if the NRC has talked to the board and tried to appoint a new Commissioner as part of this.

MR. MILLER: I think I can address that. One of the things that I am working with my staff to do is to address that issue. Of concern to me and I think to everyone is not to wait until people are rotating off in order to try to find a replacement. Do that ahead of time.

Also, recognizing that in some years there are multiple members that are rotating off, and that can really impact the committee, I've asked my staff to do thinking on how can we minimize that, and if there are some innovative ways we could minimize that, including coming up with proposals for extending people's terms beyond two terms in order to get through the initial dilemma that we found.

We're exploring all of that, and thirdly, the nomination process itself. There are some steps that we've looked at in the nomination process that we think make it more torturous than it needs to be. In other words, how many times we have to go to the

Commission during the process to seek approvals.

What we have to do is send a policy paper up to the Commission and get their vote on any changes to the process and to new nominations, and we're actively working that. As Mr. Essig can tell you, I've pushed to try to get that done.

So I hope to get that done in the very near term.

PARTICIPANT: And just to add to that, I know some of you had been approached probably a year or so ago and asked if we received approval from the Commission would you be willing to serve beyond your two term limit, and several of you indicated that you would be interested and available to do that.

We haven't forgotten about that. What we're probably going to have to do is because that was about a year ago, we would cast the net out once again, make sure that your offer if you did offer to serve beyond the two terms and we have Commission approval of that conceptually, take that offer that you still were willing to do that.

And so that will all be included in this effort.

MEMBER WILLIAMSON: I was under the impression that in my own case I was already beyond

the two term limit and I am now in my terminal years.

(Laughter.)

MEMBER WILLIAMSON: That this is now my fourth year of my -- I believe. Am I wrong?

MS. McINTOSH: No, you're in your second term.

MEMBER WILLIAMSON: I am? Oh, okay. I stand correct.

MEMBER NAG: Because you took six months off and you were reappointed. So you restarted on your reappointment.

MEMBER WILLIAMSON: No, I understand that.

MEMBER NAG: The old one was off.

MEMBER WILLIAMSON: So when does my term end?

MS. McINTOSH: In 2006.

MR. MILLER: So along those lines what we're also trying to think through is rather than just asking members who are rotating off if they're willing to serve more, we may be looking at staggered terms for reappointment so that we don't find ourselves in a continuing dilemma of having five people rotating off at the same time.

So we're trying to do some thinking in that regard as to what's the most logical path forward

on that so that we get continued representation from the various specialties that we have here and also seek new people, get some fresh ideas to the table that also are willing to serve and can work productively in this environment.

CHAIRMAN MALMUD: To that end, you might develop a matrix with the existing membership, their specialties, and their terms and then begin the preparation for exception.

MR. MILLER: And as we move forward and do that, if it's okay with the committee, we will probably have some initial discussions with your chair, who he can then decide how he wants to share those kinds of issues with the rest of the committee, but it's kind of part of the role of the chair, I think, to have some administrative discussions concerning that.

CHAIRMAN MALMUD: Fine. Dr. Schwarz.

MS. SCHWARZ: One other item that we appointed a group was for the best practice where we were looking at the I-131 events and some others.

CHAIRMAN MALMUD: Yes.

MS. SCHWARZ: And Dr. Eggli was appointed the chair and then Dr. Vetter, Malmud, and myself.

CHAIRMAN MALMUD: Correct.

MS. SCHWARZ: So that was --

CHAIRMAN MALMUD: That's in the minutes. I wasn't certain that the other one was, but I think that they both are in the minutes.

Thank you for --

MEMBER WILLIAMSON: It will take six weeks to find all of that stuff.

CHAIRMAN MALMUD: Oh, it won't take that long.

MS. SCHWARZ: It's due back in two months.

CHAIRMAN MALMUD: I have the minutes from the meeting, our phone conversation of last week, a week and a half ago, and they've already been processed.

MR. MILLER: We were told we can get the transcript in how many days? Three.

CHAIRMAN MALMUD: In how many days?

MS. McINTOSH: Three business days.

CHAIRMAN MALMUD: And Angela will get it out to me, and welcome back.

MR. ESSIG: Just one additional point on the committee appointments. What we have done in the past is that since the appointments have been on a fiscal year basis, the new appointments would take effect October 1 of this year. For example, Dr. Van

Decker is now on the -- I mean, his appointment was effective October 1st. Had Dr. Sukera been able to be here, this would have been a transition meeting. Dr. Sukera would have been able to do a mind meld or something to that order with Dr. Van Decker, and likewise Mr. Bailey. This was to be his. Had Ruth McBurney been able to attend, but she couldn't because of other obligations, this would have been her ability or opportune time to transfer her knowledge, and in the same way with the public advocate or patient advocate representative.

Unfortunately neither one could be here, the new nor the old this time, but that we'd like to have as kind of the transition meeting, but unfortunately it didn't work as well this time.

I just mention that for background information.

CHAIRMAN MALMUD: Well, if we get the matrix together, we can see whose terms might be extended by an odd number of years, if possible, and then create the transition, the smooth transition that you're seeking.

MR. MILLER: Right, and also it's probably time we do think about does the committee see any specialties that aren't represented here that might be

important to regulatory activities to be added to the committee or replace the specialty if one is not being utilized anymore.

So we're interested in your thoughts on that.

CHAIRMAN MALMUD: Yes. Dr. Eggli, are you going to address that issue?

MEMBER EGGLI: Yes. The question is do you have a statutory limit on the size of this committee, and if not --

MR. MILLER: No.

MEMBER EGGLI: -- again, the other thing to look at --

MR. ESSIG: Budgetary.

MEMBER EGGLI: Yes, but from the point of view of clinical practice, diagnostic radiologists are a major number of practitioners of activity in both Subpart 200 and Subpart 300, and it might be worth considering having a member of the diagnostic radiology community.

Although I am also a Board certified radiologist, in addition to being a Board certified nuclear medicine physician, I think my attitudes more represent the nuclear medicine community than the radiology community, although in the absence of a

radiologist member, I have been, in fact, quite vociferously, I think, representing the interests of the radiology committee or the radiology community.

But it might be useful to have that community speak for itself.

MS. McINTOSH: Might I also add that your self-evaluation is due in the spring, due next spring, the spring of 2005. So if you have any issues or suggestions about the composition of the committee, you can always add those comments to your self-evaluation that we forward to the Commission.

CHAIRMAN MALMUD: Thank you.

MR. ESSIG: And on that same topic, I know recently we broached the subject of endocrinologists and whether or not one was wanted, and I think the consensus was or the comment I got back was that, no, one was not.

CHAIRMAN MALMUD: We've heard nothing from that community regarding wanting to be on the committee, and they seem to be covered by the current regs. well; and we've heard no requests for exemptions or changes to practice.

I'm an inclusionary person, but I don't see the need for that at the moment.

If I may take the Chairman's prerogative,

it's 3:20, and it would be an astonishing accomplishment to finish before the adjournment time at 3:30. And we would like to thank all of those who have remained here to the end, as well as to the members of the NRC who are here: Dr. Miller, Mr. Essig, and staff, Angela and staff. We very much appreciate the opportunity to share and -- excuse me, Dr. Howe and Zelac.

We really appreciate the opportunity to exchange all of these ideas and to try and reach consensus on issues that are very difficult. Representation of this committee, excluding the NRC staff, is very diverse with very different interests and concerns.

At one extreme perhaps are the states' representatives, who are very concerned about prescriptive definitions, and on the other hand, there are those who are from the training programs which feel that those kinds of standards are best established by the boards.

So that reaching consensus isn't easy. You've made it a constructive engagement for us, and we appreciate that, and in the breaks that we've had at lunch and so on, the members of the committee of the ACMUI have commented on the improved relationship,

if you will, between NRC and the committee by virtue of the presence of the two of you, and we're very appreciative of that and your leadership role.

MR. MILLER: Thank you.

CHAIRMAN MALMUD: And so thank you and thank all of the members of the committee. And is there a motion for adjournment?

MR. MILLER: Before you do --

(Laughter.)

MR. MILLER: -- I'd like to reciprocate. One of the things that we've been designed to do more of is to get issues on the table that are important to you so that we can move to have a dual dialogue as opposed to the NRC staff puts issues on the table and you just comment on it.

And I think having presentations this time by Dr. Nag and Dr. Vetter moves the ball in that direction. So I think from our perspective, we were pleased with that, and we'd like to see continued activity in that area in the future.

CHAIRMAN MALMUD: Thank you.

Is there a motion?

MEMBER SULEIMAN: I so move.

CHAIRMAN MALMUD: Dr. Suleiman. Second to the motion?

PARTICIPANTS: Second.

CHAIRMAN MALMUD: All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Thank you very much.

(Whereupon, at 3:20 p.m., the meeting was concluded.)