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NUCLEAR REGULATORY COMMISSION

Title: Development of Proposed Rule to Amend Training and Experience Criteria in 10 CFR Part 35 for Recognition of Specialty Board Certifications

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING / ROUNDTABLE DISCUSSION

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DEVELOPMENT OF PROPOSED RULE TO AMEND

TRAINING AND EXPERIENCE CRITERIA IN 10 CFR PART 35

FOR

RECOGNITION OF SPECIALTY BOARD CERTIFICATIONS

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TUESDAY,

MAY 20, 2003

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The Meeting commenced at 8:30 a.m., in Room 01F16, One White Flint North, 11545 Rockville Pike, Rockville, Maryland, Roger W. Broseus, Rulemaking Project Manager, presiding.

PRESENT:

ROGER W. BROSEUS	NRC/NMSS/IMNS
HOWARD DICKSON	American Board of Health Physics
RICHARD FEIJKA	Special Board on Nuclear Pharmacy, Board of Pharmaceutical Specialties
WILLIAM HENDEE	American Board of Radiology

PRESENT (Continued):

PATRICIA K. HOLAHAN	NRC/NMSS/Deputy Director, IMNS
ALAN MAUER	American Board of Nuclear Medicine
ARMANDO RAMIREZ	American Osteopathic Board of Nuclear Medicine
GARY SAYED	American Board of Science in Nuclear Medicine
WILLIAM VAN DECKER	Certification Board of Nuclear Cardiology
KENNETH VANEK	American Board of Medical Physics
SANDRA L. WASTLER	NRC, Facilitator

ALSO PRESENT:

LYNNE A. FAIROBENT	American College of Radiology
WILLIAM R. UFFELMAN	Society of Nuclear Medicine
JAMES M. HEVEZI	Cancer Therapy and Research Center

C O N T E N T S

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

(8:36 a.m.)

MR. BROSEUS: There are a couple of people, Kathy Pryor and Dr. Van Decker, who haven't arrived yet, but we need to proceed so we can stay as close as we can to the schedule this morning.

Patricia Holahan, the Deputy Director of our Division of Industrial Medical Nuclear Safety, is going to welcome us this morning.

MS. HOLAHAN: Well, welcome. I trust that I've walked around and met everybody personally. I don't think I met you, but --

MR. HENDEE: I'm Bill Hendee from the American Board of Radiology.

MS. HOLAHAN: Yeah. But we're really glad you could be here, and we think it's going to be good to get your insights directly on the proposed rule as we develop it.

The purpose of the meeting is to obviously get early involvement of the stakeholders, i.e., the boards, to provide input on the proposed rulemaking to change the training and experience requirements for recognition and certifications of specialty boards under 10 CFR, Part 35.

And as background, the ACMUI originally

identified the problem in the Commission briefing last February of 2002, and Part 35 was published in April of 2002, retaining Subpart J to allow the boards sufficient time or us to develop a rule to allow the boards for recognition to develop new options.

The ACMUI spent considerable time, and I believe they met with all of you as part of their subcommittee on developing recommendations to develop new criteria during the summer and the fall of 2002, and the staff is now moving forward on the proposed rule based on Commission direction in the SRM, and the SRM was issued February 12th, 2003, and they approved Option 3, which was basically the ACMUI recommendations.

The exception was that the rule would have to -- the rule would allow boards to be recognized on the Web site, and also there was an issue with the preceptor statement. They felt that they wanted the preceptor statement as it was written in the original Part 35.

So the focus of the meeting, again, is on the T&E criteria and recognition of the boards, and we encourage participation from all of you so the staff may benefit from the knowledge of the

boards in developing a sound and effective rule.

Similarly, we had public meetings last year on the guidance, and they were well received, and Alan was there, and I think Dr. Van Decker was there, but it resulted in significant changes in the licensing guidance.

So anyway, I thank you all for your participation and your effort. So we're looking forward to having informed opinions, and I'll turn it over to Roger now.

MR. BROSEUS: Thank you, Trish.

I plan to go around the table and let everybody introduce themselves, but I'm going to hold off for a couple of minutes to see if a couple of stragglers come in.

Let me introduce myself. I'm Roger Broseus. I work in the Rulemaking and Guidance Branch. I am the project manager for this rulemaking.

I've been at the NRC for it will be three years on Memorial Day, ha-ha, and before that I had a long career working in the biomedical field as a health physicist, 28 years at the National Institutes of Health, and I supported our Radiation Safety Committee, amongst many other activities in

Radiation Safety Branch there.

So I'm quite familiar with many of the issues that come up, but I want to also thank you all for being here because some of you came from quite some distance, and I appreciate -- are you not picking me up properly? Okay.

I want to thank you all for taking the time to come and cover a couple of administrative items, too. We have public meeting feedback forms over on the table here, along with some other handouts. Members of the public who are here today are welcome to fill these out and send them back in if you wish.

We would like to have members of the public sign in. We have a meeting attendance sheet over on the side, and we'll keep one up here someplace, and the handouts, as I said.

I think we'll just go ahead and go around the table now. I've introduced myself.

You know Trish.

Sandy Wastler. Go ahead, Sandy. Introduce yourself and we'll just move around.

MS. WASTLER: All right. I'm Sandra Wastler. I'm Chief of the Rulemaking and Guidance Branch, Section A, and unlike Trish and Roger, I've

been in this position six months; been with the agency for 28 years; got a broad spectrum of background from reactors, uranium recovery, but this is a new era for me as far as being involved in the health field.

So I want to again extend a welcome to everyone, and thank you for coming.

MR. RAMIREZ: I'm Armando Ramirez from the American Osteopathic Board of Nuclear Medicine.

MR. BROSEUS: We need to make sure everybody has their button down so that the red shows so that we pick you up for the transcriptions.

MR. RAMIREZ: Thank you.

Armando Ramirez for the American Osteopathic Board of Nuclear Medicine.

MR. BROSEUS: Could you also -- excuse me for interrupting you -- could you also tell us where you're from and a little bit about yourself so that we'll have a little more context?

MR. RAMIREZ: Our specialty board is headquartered in Chicago, and we're a small board, but nevertheless our members are interested in maintaining its recognition by the NRC.

Thank you.

MR. SAYED: I'm Gary Sayed from the

American Board of Science in Nuclear Medicine. I'm the Dean of the College of Health Sciences and professor of radiology at Drew UCLA Medical School in Los Angeles.

MR. MAUER: I'm Alan Mauer here representing the American Board of Nuclear Medicine. I was here a year ago as President of the Society of Nuclear Medicine. So I have been involved with the NRC in reviewing the new Part 35 now for almost two years, both from the regulations and the T&E portion, but I'm here primarily representing the board as a member of the board today.

I'm Director of Nuclear Medicine at Temple University Hospital in Philadelphia.

MR. HENDEE: I'm Bill Hendee. I'm here representing the American Board of Radiology for which I serve as president for a two-year term at the current time. I'm also Senior Associate Dean and Vice President and Dean of the Graduate School of Biomedical Sciences at the Medical College of Wisconsin in Milwaukee, and all of the radiation safety responsibilities fall under my jurisdiction there, and they have.

I'm a member of the American Board of Health Physics and all those other things that you

all know so well.

MR. FEIJKA: I'm Rich Feijka. I represent the Board of Pharmaceutical Specialties, and currently serve as the chair of the Nuclear Pharmacy Specialty Council within the BPS.

I'm a practicing nuclear pharmacist. I work down the street at NIH and have been there for 22 years. I'm familiar with Roger because we work together, and NIH, and I'm here to provide direction and input from the nuclear pharmacy group.

MR. VANEK: My name is Ken Vanek. I'm representing the American Board of Medical Physics and also as a previous chair of the American College of Medical Physics. I'm here for them, too.

I'm currently the Associate Chairman of the Department of Radiation Oncology at the Medical University of South Carolina.

MR. BROSEUS: I'd also like to recognize the members of the working group who are doing this.

Sally Merchant is in the back. She's with the Office of Enforcement.

Susan Shedakel (phonetic) -- raise your hand so everybody can see you, Susan. You're short -- is from OGC.

David Walter is here from Alabama. He

is also a member of the working group representing agreement state interests.

There are a couple of people who aren't here at the meeting right now. John Zabkos (phonetic) from our Office of State and Tribal Programs. Betty Golden and Beth St. Mary represent some of our administrative and Information Office people.

A couple of administrative things. Because of the security here, sometimes you hit a couple of walls coming in, but I have been told by our security people that we will be able to circulate here on the ground floor. So there's a little snack bar next door called the NUREG Cafe, appropriately named.

(Laughter.)

MR. BROSEUS: And men's and ladies' rooms are right out here also. There's a cafeteria on the other end of the building which I'm told you can go to when we break at the end of the meeting today.

Sandy, you have a couple of comments that you want to make a our facilitator.

MS. WASTLER: Right. Roger has asked that I help facilitate the meeting today. So I just

wanted to run through a couple of ground rules just to make this as effective and efficient as we can and make the most of the time that we have this morning.

Obviously the first thing that we want to do is start on time and stop on time. So we want to try to keep to the agenda. Obviously keep to the purpose of the meeting, as has been discussed by both Roger and Dr. Holahan.

And with regard to the open discussions that will start at 9:45 and at 10:50 today, we want to try to provide everybody an opportunity to have a -- you know, provide their input because we're very interested in what you have to say, but we also have to balance that against the time that we have available.

There will be additional opportunities, as you all know, to comment during the proposed rule stage, and at the end of the meeting we do have an opportunity for audience or public comments that will happen around 11:30.

And as has been noted, we have a transcriber here. So if you could, you know, try to make sure that you have your speakers on, and if you can, say your name before you launch into your

comments. It makes it easier for the transcriber in the long run.

And I'd just say that if you, you know, as we open the discussions, if you have a question or want to make a comment, you can just sit something, you know, your name tent, on end, and we'll try to -- I will try to call folks as you've done that. I make my best effort to do that.

But we want to give everybody an opportunity to provide comment to us, but we also understand that there's other meetings today. ACMUI is going on starting at one o'clock. So it's really imperative, I think, that we try to keep to the schedule and make the best use of our time.

So thank you.

MR. BROSEUS: I'd like to proceed with the presentation to give you all some background before we launch into discussion, but before I do that, I want to reemphasize what Trish and Sandy have said, and that is that we're here to get your input early on in this proposed rulemaking. My ears are wide open, and I'm dedicated to having this come out to be the best possible rule, making sure stakeholder interests are balanced, and so on.

I've learned, by the way, at the NRC

that as an internal stakeholder the things don't always come out the way I want them to be, but we're going to try to make the best rule possible.

Let's go on to the next slide, please.

I'm going to go through and redefine the problem here a little bit. Trish touched on this, but I think that it's useful for people to know what the history is on this.

Part 35 is scheduled for publication in the spring of 2002 as a major revision of the medical licensing rule. This is the rule that the NRC exercises its licensing authority over the use of byproduct materials in medicine.

In February of 2002, ACMUI identified before the Commission in a briefing a problem, and that is that the specialty boards, who certify authorized users, radiation safety officers, authorize nuclear physicists, authorize medical physicists -- did I say it twice? -- nuclear pharmacists and medical physicists, okay, many or most of them wouldn't meet what was in the rule.

And so this concern and some other concerns, but primarily this concern, led to the reinsertion into Part 35 of Subpart J and which boards continued to be recognized in the rule.

Next slide, please.

MS. HOLAHAN: Copies are being made for all of the people around the table or around the room of the slides.

MR. BROSEUS: Sorry not to have those this morning. I was kind of putting things together at the last minute here.

Okay. So subpart J was retained in the rule effective through October 24, 2004.

The Commission also directed staff to work with ACMUI to come up with a solution to the problem. ACMUI put together a subcommittee and developed proposed rule text and other material to solve the problem, and this material was presented to the Commission in a SECY paper last year in the fall with three options.

And the three options, the first one I would call a non-option. That was to leave things in the status quo, and of course, that continued the obvious problems we see.

The second one was options developed by ACMUI which included some proposed rule text to set forth criteria for recognition of boards and some other matters.

The third option that went to the

Commission was essentially the second option, with the addition by staff of recommending that recognized boards be listed on NRC's Web site rather than explicitly in a rule.

Now, this had several advantages. One of them was you don't have to change the rule every time you list the board.

The Commission accepted the third option and communicated in a staff requirements memo, SRM, SRM-02-0194, which we have on the slide, and that's where we're at today. We're working with the SRM, the direction to staff, to develop a proposed rule.

The SRM -- next slide, please -- the SRM directed the staff to modify T&E requirements, training and experience requirements, in a proposed rule based on ACMUI's recommendations.

As I mentioned a moment ago, the SRM also said we should list boards on a Web site, not in the rule. Also, direction to the staff: keep the preceptor statement as written in the current rule, but clarify it to indicate that the attestation in the preceptor statement was not an attestation of clinical competency, but required that this attestation be sufficient to demonstrate that a candidate for RSO, AU, whatever had

sufficient knowledge to fulfill the duties for the position for which the certification was sought.

Now, some of these clarifying statements that I just mentioned and other matters, the staff approach to this is not to put them into rule text, but to have them in supplementary information, which will be published with a proposed and final rule.

When a rule is published, there's sort of what I call a preamble, which gives some background on the rule, and so on, but there's also the discussion of the rationale for the rule, and many times discussion of how a rule will be implemented. And this is where we expect to see the clarifications about the preceptor statement, in the supplementary information that accompanies the rule.

Next slide, please.

Some of the key points in the SRM were to require a clear regulatory determination that all boards meet the criteria that is the criteria set forth in the rule; that we should provide implementing procedures for addition to or removal of boards from our list; and if a board is to be de-listed, taken off the list, the staff is to examine certain things to figure out, you know, why somebody should or shouldn't be on the list. Okay?

But one of the directions to the Commission is not to inspect the boards, but to do such things as monitor trends in medical events and see if there's an association between a board certification process or whatever and maybe a root cause for a medical event.

We're going to talk a little bit more about the implementation later, but this is one of the areas where we're especially interested in testing your input on the implementation procedures for listing and de-listing boards.

Next slide, please.

We're now drafting a proposed rule, and the approach of the working group is to use the recommendations of ACMUI in Attachment 2 to the SECY paper. This is the options paper that went forward to the Commission, and there is a copy of this available. Most of you probably have this already. It looks like this.

I don't think it's particularly useful to dig it out right now and go through it and read it, but in this Attachment 2 has some rationale of ACMUI for where the proposed rule should go, along with some draft rule text.

The Commission and -- I'm sorry -- ACMUI

indicated that they felt that this draft rule test that used should serve as a starting point, but the working group was looking very closely at the rule text and incorporating as much as possible, making changes as appropriate.

In the staff's evaluation, we're finding a need for some wording changes. We've also identified a potential need for a change in the recommendation of ACMUI.

In some of the recommendations in what I'll call the alternate pathway, I'm going to use some terminology today to kind of make things -- how shall I say? -- to categorize the two types of training and experience requirements.

We have board certifications, and then what's in the existing rule now that's not the board's certification pathway, which I will for convenience sake term the alternate pathway.

ACMUI made some recommendations in the rule text for changes in the text in the alternate pathway, and the staff is looking at that pathway, too, the recommendations of ACMUI and the language that's there, and we have some suggestions for changes to ACMUI's recommendations in that area also.

One of the things ACMUI recommended in their discussion at the beginning of Attachment 2 and was reflected in their rule text was inclusion of what I would call some experiential requirements for various classes of authorizations in radiation safety officers and so on.

The idea is that when a person is coming on board as an RSO or medical physicist or whatever, they should have some training and experience in the modalities that a particular licensee would be using, and an example of where this comes in is in 35.390, in their recommendations.

And later on when you're looking at this and 390 in particular, this is their last paragraph, little D in parentheses, and when we get into writing the proposed rule, which we're working on now, our numbering system will be somewhat different from what ACMUI had, but I'd like to make sure you're aware that when we are plowing through the proposed rule, we're trying to be sure to reflect the intent of ACMUI in what we're writing.

Next slide, please.

ACMUI in their recommendations, and I'll call it in the alternate pathway, in Sections 490

and 690, added what I'll call a residency board as an approving entity. It's the Royal College of Physicians and Surgeons of Canada. This is added to the list of approving entities for recognition of residency training programs.

We are looking in the working group to establish a basis for adding that board. We need to have a basis, we feel, which we would probably put in our supplementary information for that.

So if there are any of the board members that are here that are aware of an appropriate basis for listing or not listing, that might be a topic of discussion today.

MR. HENDEE: Well, can I just interrupt for one moment?

MR. BROSEUS: Yeah.

MR. HENDEE: Just a point of clarification.

MR. BROSEUS: Yeah.

MR. HENDEE: An organization or entity that approves the residency program is not necessarily the same as a board that certifies individuals in the practice of a specialty. Are you making a distinction here?

You can come back to this if you want.

MR. BROSEUS: Yeah, let's hold the question until we get into the discussion.

MR. HENDEE: Okay.

MR. BROSEUS: Okay. Thanks.

Next slide, please.

There are a couple of additions that the staff was thinking about for the proposed rule, adding to what ACMUI had proposed. I shouldn't say an addition on the first one. The first one we're talking about the preceptor statement.

The SRM required a preceptor statement for both pathways. They also said, "Don't rewrite the preceptor statement." It should be retained as is in the rule.

The approach we are taking as staff members in drafting the proposed rule is to take the existing preceptor statement for what I will call the alternate pathway and using that for the pathway for board certification. We can't use it literally because there's some back references or cross-references and inappropriate references in the existing preceptor statement for the alternate pathway that don't quite fit, but we're keeping largely the language and the intent.

The other point in terms of I would call

this in addition to the ACMUI text is adding call it an "or" to the board certification pathway. Loosely termed, I see ACMUI's recommendations as substituting an academic plus experience as the basis for board certification.

I'm generalizing to simplify for a moment.

The current rule says if a board meets the training and experience requirements in Part 35, and there's a whole list of those, 700 hours of training and so on; it's essentially what we're calling today for the sake of simplicity the alternate pathway.

If a board meets those, that's the basis for approving certification being recognized. ACMUI's recommendation did not include that pathway.

One board is recognized now based on that pathway. It's the cardiology board.

Secondly, staff feels that if that pathway is appropriate now, it should be retained as a mechanism by which a board can be recognized. That isn't to exclude what I'll call the academic pathway. Okay? It's an "or" built into the board's certification.

Okay. So that's staff thinking, and I

see your hand raising already, and maybe we can save for discussion unless you have something you feel --

MR. MAUER: Well, one of my purposes --

MR. BROSEUS: Alan Mauer.

MR. MAUER: Yeah, this is Alan Mauer. I'm sorry.

In some of the documents it has been said that only one board has been recognized as having met the requirements. One of my purposes of attending today is to try and get some clarification because there was a lot of confusion at the American Board of Nuclear Medicine Office.

We have a letter to Dr. Van Heardon, who was Chairman of the board in July 2001, from John Hickey when the American board had written and was trying to clarify whether the ABNM would get the dean status.

This letter from Mr. Hickey does say that the American Board of Nuclear Medicine does meet the requirements, and it says, "After Part 35 is issued in final form, we plan to list on our Web site the boards which have been recognized. We will include ABNM on that list."

There seems to have been somehow lists dropped off the radar screen, and now that you're

mentioning it, I was going to bring -- I'm not sure when it's appropriate, but as a part of today's meeting, I would like to get clarification to take back to the board.

MR. BROSEUS: I don't think we're going to be able to clarify it in the meeting today. That's a surprise to me. I wasn't aware of it, but I'm sure that we can take this back as staff and examine this.

MR. MAUER: Because there's a lot of confusion at our board right now. We have a letter from Mr. Hickey saying that we do meet the requirements, but everything that I've been reading and I just hear you saying is that there's only one.

So I'd like --

MR. BROSEUS: I'll take that back after our meeting.

MR. MAUER: -- to get that clarified.

MR. BROSEUS: Trish is alert to it already.

MR. MAUER: yeah.

MR. BROSEUS: And we'll have to look at it, but it's not something we can resolve today. That's for sure.

MR. MAUER: Okay, and I'll show you a

copy of that.

MR. BROSEUS: Thank you.

If we could move on, so a major point here in this slide is that the staff feels that we need to retain, and we put in I'll call it an "or," the possibility that a board can be recognized or certification recognized if they meet the existing T&E requirements in the alternate pathway.

Next slide, please.

I'm getting into detail now. As we were going through ACMUI's recommended rule text, we found some additions and subtractions, and I'll call them at the wording level. One of them is in the training and experience requirements for radiation safety officers and 35.350.

Staff has added in in the board's certification pathway radiation dosimetry that was missing from -- I would say it wasn't included. It wasn't one of the criteria that ACMUI included in their wording.

Likewise they had dropped radiation dosimetry in 35.50(b)(1)(i)(E). I just love this, you know. I'm still partly from the other side, and we have one, two, three, four levels down in the paragraph numbering system. I used to admire people

from the Nuclear Regulatory Commission who could cite these things from memory. It just awed me in a certain way that only Dilbert could appreciate.

But the point here is in the alternate pathway the wording of ACMUI dropped radiation dosimetry as one of the training and experience elements, and staff feels that that's an essential area of knowledge for a health physicist, and so we plugged it in also into the draft text that we're working for the board certification pathway.

Also, in the alternate pathway, ACMUI did not include the phrase I have here on the slide, "permanent issue by a Commission master materials license." This is if a radiation safety officer is listed on this sort of license a pathway for recognition of a RSO if they go on to another facility, and I don't think it was ACMUI's intent to drop this pathway.

We'll be talking with ACMUI, by the way, about these things, too. So the staff is keeping that phrase that was, I think, inadvertently dropped by ACMUI.

Next slide, please.

Going to the next slide, we are looking at the terminology in 35.51, and this is for

certification of medical physicists. The text of ACMUI had radiation oncology physics as an area of training. Some staff members feel that medical physics is a more general term and, therefore, may be more appropriate for use in rule language.

Also I've noted that the terminology "oncology physics" seems to be tied somewhat to the language that certain boards use, but others don't. And so our feeling is that "medical physics" may be a more appropriate way of characterizing the training that's required for one to practice in this particular area and become an authorized medical physicist.

In 35.390, again, we're way down to the detail level now. In one of the sub-sub-subparagraphs, ACMUI is talking about the types of administrations of byproduct materials, IV or orally, and they use the terminology "therapeutic quantities."

Thirty-five, three, ninety is talking about in its rule administrations for which a written directive is required, and staff feels that quantities for which a written directive is required is better terminology than therapeutic quantities. Therapeutic quantities actually we feel narrows the

focus too much at least by implication using therapy because there are other types of use than therapy under 35.390.

Next slide, please.

We're fine tuning language again. ACMUI recommended using "performing quality control procedures" rather than "calibrate" in various parts of the rule when describing the T&E, the training and experience, that an authorized user should have. ACMUI specified changing "calibrate" to "performing quality control procedures" in some sections and paragraphs, but not in others.

Staff agrees that this more general term is appropriate because it's more encompassing and we feel that ACMUI made a good recommendation, but for parallelism it should also be incorporated into uses under 35.392 and 394.

Next slide, please.

Continuing with fine tuning of the language, in 35.490, ACMUI's language was talking about training experience in inventorying sources, and the word "running" was dropped, and staff feels that "running" should be retained as more meaningful.

Here we're talking about brachytherapy

sources and an annual inventory. It's probably not enough, and typically inventories are done on a periodic basis. We feel that a running inventory implies a continuous running inventory of sources and accountability of sources so that running should be retained in the rule.

Next slide, please.

That sort of covers the major and the minor or wording issues in rule text. Now we're going into the more general area of implementation, and by implementation we mean in this particular context we write into the rule criteria that boards must meet to be recognized by the Nuclear Regulatory Commission or an agreement state, but how does that happen? How does he get listed on the Web site? How does the staff look at the criteria?

If there's a reason to de-list the board, how does that happen?

Okay. So we have an outline of implementation process that we in the working group have developed, and, again, if you have comments on this and we have time set aside in the discussion, I would appreciate your feedback.

The thinking we have is the board would submit an application of some sort, maybe a form of

the check-off list, to the NRC. Staff evaluates that, compares it to requirements in the rule, and if needed, consult with the Advisory Committee on Medical Use of Isotopes during a process of listing a board.

The working group feels there's also a need of some sort to maintain this list, and at the very least, boards should notify the NRC or the agreement state that recognized them if they have changes in their requirements for certification.

I'm going to reflect back just for a moment on the direction of the SRM, and that was that the NRC would not be expected to inspect boards.

The de-listing process, removal of a board, how do we accomplish that? The SRM said to staff, "Monitor medical events. If problems develop, look for root causes if one of them is related to" -- they didn't say root causes. I'm interpreting that, but you know, look for the reasons.

And if it's tied to the certification process or some inadequacy therein -- Bill, thank you. Next slide. I'm talking ahead of the slides here. We're on de-listing now.

Look at medical events. Okay?

Also, changes in board requirements. If a board changes its processes or its requirements, such as they no longer meet the criteria in the rule, their certifications logically should no longer be recognized.

We want to add one point here just to flag it, and David will probably move his head up in anticipation on this. That is that the current rule says boards recognized by the NRC or in an agreement state, and the staff doesn't intend to change that. And so when we're looking at the rule and so on, we need to realize that agreement states will also be involved in the process.

In the process, one of the things that we're looking at is listing on the NRC's Web site a little bit more information than just a board is recognized. For example, what agreement state recognized the board; the length of time for which a board certification is valid.

As a certified health physicist, my certification is good for four years. The training and experience requirements in Part 35 include a recency of training, which is seven years, and so when someone is evaluating the training and

experience of a person, looking at the board certification, certification should be current, and having that information available would hopefully be helpful to people.

Continuing on with the process for de-listing -- next slide, please -- the de-listing process, obviously we'd have NRC staff identifying a potential problem. Interact with the boards to give them an opportunity to respond to findings by staff of some inadequacy on the board's certification process. NRC staff would then evaluate the response.

Consult with ACMUI about the problems identified by the staff, and if a decision is made to de-list a board, to notify the Commission of this finding and notify the board of the NRC's determination.

Next slide, please.

I've covered the major points that I wanted to get at with regard to rule text, as well as with regard to implementation, but let's look at where we go next.

We are now writing the proposed rule, and we're getting your early input at this point to make this as good as possible. After we finish the

proposed rule, this will be distributed to agreement states for a 30-day comment period, which we anticipate being in June.

These comments will come back. We'll review and prepare the final proposed rule. It will go forward to the Commission in late July. The Commission makes a decision. They send down probably another SRM with maybe some direction to the staff like we received for preparing the proposed rule.

Then we will make any changes the Commission requires and publish the proposed rule in the Federal Register. And it will be there for a 75-day comment period. You all get a chance to comment again, as well as everybody else in the public.

After the end of the comment period, the staff will analyze the comments, reconcile them, put them into -- make adjustments as appropriate in the final rule, and we'll go forward with publishing a final rule, and our goal is to have that final rule in place before Subpart J expires in October of 2004.

In terms of getting input at this stage now, the staff needs to get input quickly. If you

decide you want to make an additional comments after this meeting -- and I'm addressing this especially to members of the boards that are represented here -- please get this back to us by May 30th because we've got a really tight time schedule. You can appreciate that, but it's important that we get this rule out so that it's in place to solve the problem.

Okay. That concludes my slides. I want to thank the person back in the booth for taking care of the slides, and we can turn those off.

Thank you.

MS. WASTLER: I would point out, first of all, that with regards to the comments and the time frame, you know, should you have additional comments, we would encourage you to send them by E-mail to us. At this particular stage, it is, I think, more efficient, and we don't need to be quite as formal as in the proposed rule.

So we can get you --

MR. BROSEUS: If you have a comment, send it to me, rwb@nrc.gov.

MS. WASTLER: That's rwb@nrc.gov.

MR. BROSEUS: Roger W. Broseus.

MS. WASTLER: All right. With that

we're actually a little ahead of schedule. So we're going to open it up. I think Roger has got the discussions broken up into two parts, talking this morning until about 10:30 before break on the SRM, criteria for recognition, especially the didactic training and experience, and talk about implementation later, but we'll kind of go through and see how things develop.

With that, Mr. Mauer.

MR. MAUER: I had a question. Roger, in your review towards the end there when you were talking about the de-listing process, you mentioned about what's often referred to in medicine as maintenance of competency or the recentness of training.

Were you indicating that you would expect the boards to reevaluate the board certified candidates in terms of maintaining some form of recertification process?

MR. BROSEUS: No.

MR. MAUER: Or you actually will have the boards recertify on a regular --

MR. BROSEUS: This is a responsibility that rests with licensees basically to make sure that their radiation safety officer, authorized

users, whoever have training that is recent. That's a more pervasive thing. That's not a burden on boards, as I read it.

MS. HOLAHAN: And you asked about the recentness of the board certification. I don't think we're going to ask the boards to recertify unless something is changed.

MR. BROSEUS: I'd like to keep any implementation issues for later in the discussion if we can. The first topic we have for participant discussion is Option 3, list boards on our Web site. I don't see a need for a lot of discussion on this because it's sort of dictated in SRM, and I think the staff feels pretty strongly that that's an appropriate one.

A lot of people, I feel, in the public also think it's a good idea to list them on the Web site, but are there any comments or questions or issues with regard to listing boards on the Web site rather than rule text?

MS. WASTLER: Dr. Hendee?

MR. HENDEE: The response of the American Board of Radiology to that specific issue is we're fine with that. If the NRC believes that that's the best way to let people know that you

recognize these boards as default pathways, we're very comfortable with that. We would support that, putting them on the Web site rather than building them into the rule itself.

That's not why I had my card up.

MR. BROSEUS: Why do you have your card up?

MS. WASTLER: That would be fine.

MR. HENDEE: I want to discuss -- I want to give some clarity on exactly what does it take for a board to be considered a default pathway to recognition of any of the categories, radiation safety officer, authorized user, authorized medical physicist, authorized nuclear pharmacist because I can't tell from reading this rule.

MR. BROSEUS: Okay.

MR. HENDEE: Are you saying that for a board to be recognized by the NRC as default pathway the individuals who are certified by that board must receive and you must have some documentation that they received all of the training, that they meet all of the requirements that you list in the alternate pathway for boards to be recognized?

I'm talking about the ones that are listed here. In other words, for the American Board

of Radiology, let's just take radiation safety officer. For the American Board of Radiology in its certification process, to be recognized as a default pathway to radiation safety, does that mean that we have to show that the board has to require candidates coming into the board process to meet all of the requirements that you have listed down here as an alternate specialty board recognition: five years of experience in health physics, a Bachelor's degree or a graduate degree, a written statement?

And does it also mean the they have to have an educational program that consists of 200 hours of didactic training?

So I'm trying to understand --

MR. BROSEUS: To make it a short and sweet answer I think that gets at is that part wouldn't change actually. It's a continuation of a board -- this is staff thinking now, okay? -- that would still exist, that is, that a board would meet the existing criteria on the alternate pathway, all of those that are listed.

We're not changing that, except with some minor wording changes that ACMUI has introduced. So there would be two things that a board could do to have its certification recognized.

One would be to meet the criteria that ACMUI has developed, and I'll loosely term that substituting academics and other training and experience for the long list in the alternate pathway, or the board could do what's in the rule now.

So the staff thinking is to preserve what's there now, but allow a board also to do the other pathway, which ACMUI has developed. Now, we're not really changing anything in that particular "or" pathway. Is that getting at your --

MR. HENDEE: Well, we're getting there.

MR. BROSEUS: Or are you asking how the NRC would evaluate today the training and experiential requirements for an RSO in that alternate pathway?

MR. HENDEE: It's any of -- I mean, I just chose the RSO. We could talk about any of the other categories.

I guess my fundamental question is this. If, in fact, for a board to be recognized as a default pathway by the NRC, that board has to demonstrate that it meets all of the requirements that are otherwise listed here for candidates to be recognized in these categories. Then what's the

point of having the default pathway as a mechanism?

It's perfunctory. It becomes relatively meaningless because --

MR. BROSEUS: Well, the advantage is that an individual, who may want to be board certified anyway, can get his or her certification by that pathway. They don't have to submit an application to the NRC to review training and experience, et cetera, and then the board certification serves to establish the credentials of that individual.

Trish, did you have something you wanted to add?

MR. HENDEE: Yeah, I'm not done with this issue, but go ahead.

MS. HOLAHAN: Yeah, I think I understand your question, and it's asking is there anything different in the alternate pathway versus the board pathway, and that was one of the things that ACMUI recognized last year at their meeting.

They said they didn't want to marginalize the boards, and the thinking is that they put in the boards to be recognized assuming that you could meet the intent of the alternate pathway, but you don't have to have specific hours.

But you have to cover all of the things that are listed in the alternate pathway.

MR. HENDEE: So to apply to be recognized as a default pathway, what does the American Board of Radiology or any of the other boards have to submit to the NRC to get that recognition?

MR. BROSEUS: Today?

MR. HENDEE: Well, I mean whenever the rule becomes effective. You'll have boards applying to be recognized in the default pathway.

MR. BROSEUS: Oh, that's what we want to talk about in the implementation discussion. Right now I'd like to concentrate on --

MR. HENDEE: Okay.

MR. BROSEUS: -- what are the criteria and so on.

MR. HENDEE: Okay.

MR. BROSEUS: Well, actually I think there are two questions going on simultaneously. Part of it is the process. How do you get recognized? And the other one was how does it get measured.

I really think how does it get measured is later. We set forth criteria, and you know,

we're working with ACMUI's recommendations, and if we look at ACMUI's recommendations in the Attachment 2, it's certified by a specialty board. It requires all diplomates to hold a Bachelor's degree, to have five or more years of professional experience. There's about four criteria there.

And this is substituting for all of the other things that are in the rule now. And ACMUI and I think board representatives in the past felt that that was a desirable alternative, and so the staff's task to them would be to say, you know, "Collect the information from the boards and measure it against that particular set of criteria that ACMUI has developed.

MR. HENDEE: Okay. Now, if a board does not satisfy these requirements exactly, then it would be the expectation of the NRC that to be recognized as a default pathway, the board would have to change its admission criteria to board certification if it wanted its board certification process recognized as the default pathway.

In other words, the NRC would require the board to change after years and years of experience of the board establishing criteria for what it considers to be assurance that its

diplomates in practice safely and effectively, but in spite of that ACMUI and the NRC would want the board to change its admissions criteria in order to be recognized as a default pathway for acknowledgement as a radiation safety officer authorized user, authorized nuclear pharmacy.

Is that what you're saying?

MR. BROSEUS: I don't think that if a board's certification process didn't meet the rule -- they'd almost have to. Otherwise how could they be recognized by the NRC or an agreement state.

However, the word I've got is that the expectation is that most boards will be able to meet what ACMUI has written in their draft and their recommendations, and so I don't see it as a real issue from what I understand.

MS. HOLAHAN: Looking at the B pathway, you have to hold a Bachelor's or graduate degree from an accredited college. I'm looking at 35.50.

MR. HENDEE: Yeah, me, too.

MS. HOLAHAN: Have five or more years of professional experience in health physics; provide a written statement, preceptor statement.

MR. HENDEE: Okay. Can we just stop with that one because that's a good example? That's

a good example.

The American Board of Radiology has certified physicists since 1947. Many of those physicists serve as radiation safety officers, a lot of them. There are probably more physicists certified by the Board of Radiology to serve as radiation safety officers in the clinical environment than are certified by all of the other boards put together in the clinical environment.

The Board of Radiology does not meet this requirement. It does not require five years of experience prior to board certification. Therefore, in spite of 47, 53, 56 years of experience, we would have to change our admission criteria in order to meet the five years of experience.

Our requirement is a graduate degree and three years of experience, and we give credit for the graduate degree up to one year, but that doesn't constitute five years of experience as you've defined it.

So that's a good example of where we're in discordance.

MS. HOLAHAN: Okay.

MR. HENDEE: And I'm hearing you say that we would have to change and actually require

additional experience prior to board certification for our diplomates to be acknowledged as radiation safety officers according to your criteria; is that correct?

MS. HOLAHAN: Well, you say you have three years, and the rule actually allows for graduate training to be submitted for two years, and you indicated that there's only one year given. Unless you can change your requirement for graduate training to be giving two years of credit, you probably have to change your --

MR. HENDEE: You don't think that's overly prescriptive?

There are other examples. This is just an example. Please understand I'm not just picking on this one point.

MS. HOLAHAN: Yeah.

MR. HENDEE: You don't think you're being overly prescriptive here in setting up the -- in ACMUI and NRC setting up themselves as the -- in a position where you're forcing the boards to actually change their eligibility requirement in order to meet your requirement? Don't you think that's a bit overly prescriptive?

MS. HOLAHAN: Well, I understood that

the ACMUI met with all of the boards. The subcommittee met with all of the boards last summer.

MR. HENDEE: We did. We discussed this issue then.

MS. HOLAHAN: Oh, did you? Okay. So I can't answer that.

MR. HENDEE: Perhaps we can discuss that this afternoon.

MS. HOLAHAN: Yeah.

MR. BROSEUS: You're going to bring this up with ACMUI, right?

MR. HENDEE: I am.

MS. HOLAHAN: Okay. That's good.

MR. BROSEUS: Yeah. So --

MR. HENDEE: I'll take my card down. I have a lot of other issues, but we'll stay on this issue for a while.

MR. BROSEUS: Yeah. So I think let's keep it with ACMUI also.

MR. HENDEE: Yes.

MR. VANEK: Ken Vanek.

I'm going to pick up a little bit with what Dr. Hendee was saying here because I guess perhaps because of some comments and so on that were made on the original rulemaking thing that the

number of hours specifically versus just topics -- now, Trish, you mentioned that number of hours wouldn't necessarily be descriptive within the board, but I'm reading another message through some of this documentation that they feel that the board should at least meet these number of hours of instruction.

So is that the intent here?

MR. BROSEUS: Are you talking about what I have loosely termed the alternate pathway?

MR. VANEK: That's correct.

MR. BROSEUS: No. A board could be certified, have its certification recognized using other criteria, and those are the criteria where here -- and he was addressing those; Dr. Hendee was -- and that would be for health physicist, hold a Bachelor's degree, et cetera, et cetera, and there are the other areas, medical physics, nuclear pharmacist, and so on. Have alternate criteria set up also.

It doesn't have those 700 hours of training and so on as a way of a board being recognized.

MR. VANEK: Okay. Because, I mean, I go back historically as well as to what we've

historically been doing because the board process itself being the fact you have to have a certain amount of training and experience, but then the board process itself of actually going through having a general written examination part, then having your specialty examination part, then having an oral examination part.

Whereas alternate pathways, you can sit into a special course and just pay your tuition and get your certificate that said, "I have X number of hours of experience and, therefore, I am now qualified."

You know, there's a whole big difference between those two pathways. Just because you sat in a course doesn't mean that you have actually been examined by peers, et cetera, and have been found to have a basic level of knowledge.

MR. BROSEUS: Well, I think that particular pathway you're talking about was examined and evaluated during the rulemaking process, and it's there. It's on the books. That's not part of what we're changing now.

We're just looking at the board certification.

MR. VANEK: Okay. So in order for a

board to then get approval, then again going back to the guidelines that the NRC is going to look at to say, "Okay. Well, this is what we're going to approve," then are we just talking then about what your initial comment was, just the fact that these topics have been covered in a training program, and that they have been examined over these topics?

MS. HOLAHAN: Yes, for the board certification pathway because we're assuming that you cover all of the individual things in your five years of experience because that's what's here.

MR. VANEK: So we just really need to say that during the examination process that we have actually examining over these areas?

MS. HOLAHAN: Yes.

MR. VANEK: Okay.

MR. BROSEUS: Do you think that's something that should be part of the supplementary information?

MR. VANEK: Well, I do. It's just sort of like --

MR. BROSEUS: You know, you get into an area where it becomes very prescriptive, and you have people looking, reading your exams, too. There's two sides to that.

MR. VANEK: Well, but we give our examinees, you know, "This is what you're going to be examined over. These are topics you're going to be examined over." So I mean that's not really saying you're telling them what the questions are.

You're saying you're going to be examined over these particular areas. So I don't think that that's anything that would be proprietary from that point.

Now, and it's a little bit different, too. I mean, if I was going to be an RSO for a broad scope license, I think I would have to have a certain amount of extra training and experience compared to just a little nuclear community hospital with nuclear medicine, but --

MR. BROSEUS: But there's another part of this that gets to the issue you're raising, which is, as I understand it, in the alternate pathway, but the potential is there in the board certification pathway. Does the person really have the knowledge and the experience that's needed?

And that's an awfully hard thing to measure, but an additional step the Commission has taken is to say, "We require a preceptor statement that says this person has got what it takes."

MS. HOLAHAN: In radiation safety only. The Commission has focused on radiation safety. They're not focused on clinical competency.

MR. BROSEUS: Yeah, right.

Alan.

MR. MAUER: Yes. This question of competency and the preceptor statement is one that has been discussed on and off and people have struggled with. Certainly the boards which have very rigid criteria, usually the places that provide training, undergo examination through a review process, there are formal examinations. The boards go through very expensive evaluation of their own training programs and how they evaluate the candidates and require an examination.

On the other hand, the alternate pathway just says you have to have experience and training. There is no examination process. There is no measure of competency.

So I think, on the one hand, the boards are holding themselves to sort of a higher standard in many ways, and the alternate pathway basically just says all you have to do is have had some experience and training, but there's really no examination.

We're dancing around this question about an examination process and what's going to be required for the boards. The NRC seems to have not wanted to get into the examination area, but the question of competency keep coming up.

How do you demonstrate? I think we really need some guidance and some definition of how both the boards and the alternate pathways will demonstrate competency because the preceptor statement as it now appears on the Web site and is worded says this person is competent.

And I think the boards know how to go about examining for competency. We have examinations, and we actually test people. The alternate pathway doesn't have a way to measure competency.

So if you're going to establish criteria at the board, I would like a much better definition of how you establish competency, both for the boards and for the alternate pathway, but certainly if we were going to talk about how the boards get approval, we need some definition of what is meant by competency.

I mean the boards do it in many more ways than the alternate pathway, but if you're going

to say that the boards are going to be held to the same standard as the alternate pathway, how does the alternate pathway establish competency?

MR. BROSEUS: Do you have a suggestion about how that definition would come out?

MR. MAUER: I think it's very difficult. Ways people demonstrate competency usually is by taking an examination and showing that they have the knowledge and can demonstrate that, and the boards do do that.

But what I'm hearing on one hand is the boards are going to be held to all of the things that are in the alternate pathway. Those are the standards and the training requirements. They go a step beyond, but this problem of competency and how you certify that is a big one.

MR. BROSEUS: Well, I think though to me what you're saying sounds circular because you're saying the board is able to do this job, and in fact, I think that's the way the rule is being written, with some degree of trust.

And so what can we add that isn't there already? How do you measure competency?

MR. MAUER: The board would do it in a traditional way, but when you're looking at

competency in particularly radiation safety, I guess what I'm struggling with is -- and it goes back to the preceptor statement -- the preceptor is going to have to say this person is competent. By what criteria are they going to demonstrate competency? And how are you going to tell the boards to do that?

MR. BROSEUS: Dr. Sayed.

MR. SAYED: If I may follow up, if I'm understanding Alan correctly here, you're expecting the board to verify competency, which they do by the process of examination, and you're expecting the boards to meet the criteria that you've outlined under the alternate path, but you're not holding people who qualify under the alternate path to the same standard you're expecting the boards to live up to.

The candidates who become RSO through the board certification process would meet all of the requirements, plus take the exam and verify their competencies. Whereas those who qualify through the alternate path would take the curriculum as outlined and no exam, no verification of competency. Yet they're qualified as RSOs?

MS. HOLAHAN: There is a verification of competency. Somebody has to sign the precept

statement.

MR. SAYED: So you have a definition for the or a way to benchmark competency here.

MR. HENDEE: I really want to get in on this discussion pretty soon here.

MS. HOLAHAN: Okay. Go ahead, Mr. Hendee and then we'll come to Ken.

MR. HENDEE: Fine. And I want to come back also to this issue of qualifications that has been raised.

But the issue of competency is a very important one. The Board of Radiology has debated whether or not it's possible through any process other than one-on-one supervision of an individual in the practice setting, whether he is a technical person or a clinical person, to really attest to competence. And we have concluded that the board examination does not test competence.

I will speak to this at the ACMUI meeting this afternoon. We believe that specialty -- I'm probably going to be in conflict with my colleagues here -- but the Board of Radiology believes that specialty boards evaluate education, training, experience, and mastery of a body of knowledge and its potential applications in a

clinical setting. That's what the board process measures.

It does not measure, it does not evaluate the competence or diligence of individuals in conducting technical or medical procedures. We evaluate whether they have the body of knowledge to be competent, but we don't observe the individual on a day-by-day basis practicing his or her specialty and, therefore, we can't really test or evaluate competency in that definition of the word.

So I think my recommendation to you is that you should not be addressing the issue of competence either in your rulemaking unless somehow you have a way to test it. You can require a lot of things here, and I think what you do require is exactly what the board process evaluates, but I don't think you require competence because I don't think you have a way to measure it any more than the boards do.

MR. BROSEUS: Dr. Vanek.

MR. VANEK: Ken Vanek.

I'm glad that was clarified because that's one of the things that I was going to ask about true competency versus examining a basic level of knowledge, having the experience and meeting a

baseline.

But both the American Association of Medical Physicists, the American College of Medical Physicists, and even the American College of Radiology have all had this talking for quite some time, and we have now all agreed that the definition of a qualified medical physicist is a board certified medical physicist because of the absence of anything else to be able to define a certain baseline of knowledge, training and experience.

And many of the states who are now starting to license medical physicists, which is a different issue, but the ones who are do look at board certification as their baseline, and to try to establish, for lack of a better word, competency for meeting that baseline without any examination process, like I said, it only means that somebody attended courses.

And that is why I think those three organizations have recognized the board process as the defining thing of being a qualified medical physicist.

MR. BROSEUS: Let me come back to the direction that we have from the Commission about the preceptor statement. It says, "Require sufficient

attestation to demonstrate the candidate has knowledge to fulfill the duties of the position for which the certification is sought."

And that's what we are going forward with. It's not competency. It's knowledge, and that seems to be what the critical issue that you have.

Did I miss something?

MR. HENDEE: I agree with you, and I know that you have taken it out of the attestation statement just as you just declared, but there are other places in this document in which you do talk about evaluation of competence, and it includes the board certification default pathway and alternate pathway.

So I would just recommend that you go through this document and where the issue of competence comes up you think about changing the wording so that you don't put yourself in the position of measuring something that we all agree really is very difficult to measure.

And you substituted wording appropriately in the attestation statement. Now substitute it in other parts of the document similarly.

MR. BROSEUS: And you hit on something that's really important for me as leading the working group. We're doing our very best to get this right and have the right words in.

MR. HENDEE: I know.

MR. BROSEUS: The problem is I'm human and I'm working with humans, and so if you see something where we didn't hit it, let us know, and that opportunity will be there during the proposed rule process.

Okay. Let me see what we had here on the agenda and where we are.

MR. HENDEE: I don't want to lose -- can we just come back to one issue? I need clarification now because here's what I hear you saying.

I hear you saying that if a board tests candidates in areas that are listed here, then that board could be considered the default pathway without any statement as to the number of hours of experience or training that the candidate would have to have coming into that board exam.

As long as the board is testing the candidates for their knowledge of these areas, you would accept that as meeting the conditions for

default pathway. Is that what you're saying?

MS. HOLAHAN: That's right.

MR. BROSEUS: I really didn't add in hours or anything. It's just what it says here, and the working group hasn't changed that. We've done some fine tuning on words that I talked about earlier today, but the basis is here.

Trish, I'm sorry.

MS. HOLAHAN: And I believe in some previous discussion we said that in the statement of considerations we can make that clear.

MR. HENDEE: Yes.

MS. HOLAHAN: The differentiation.

MR. HENDEE: Yeah, yeah. That's a great help.

MS. HOLAHAN: Dr. Van Decker?

MR. VAN DECKER: Yeah, I apologize for being a little late here this morning. The train from Philly doesn't run as quickly as I'd like.

MR. BROSEUS: Excuse me for not recognizing you when you came in.

MR. VAN DECKER: That's okay.

I'm going to need some clarification. I guess I'm hearing some of this conversation. You know, I've actually been somewhat amused that in the

last year and a half some of this has heated up in this discussion when this process has really gone on for seven years now, and the initial five and a half years when I was at the table there was much less of this type of a discussion going on.

But I guess my question when we're talking about this default pathway and number of hours and boards, the initial thought process that had gone through a lot of consensus building was that there should be some level playing field body of knowledge across a broad body of practitioners that we all believed was core essence to understanding radiation safety and going on with appropriate use of ionizing radiation.

And some of the early concerns had been that boards being deemed boards in the rule, what that meant compared to people who were in alternate pathways or other boards. Were they fulfilling the same criteria and was there an equivalent body of knowledge or at least some gross equivalent body of knowledge that was being tested?

And that was the attempt that was coming out of all of that. I think that clarification-wise the alternate pathway was something that had been left in there even after this redo because it's my

understanding that on a legal basis you have to be able to allow people an ability to go through radiation safety training, board certified or not.

But I guess my last question was if the boards now are able to regenerate as the years go by their own core for what it takes to sit for the board, then there's no longer this same idea of, you know, what is it across all of these different things that a certain core knowledge base that's going on, although they're on different ways to some degree.

And I'm just trying to get a hint of whether that was what this last piece of the conversation was heading towards.

MR. HENDEE: Could you just reframe? I lost track of the question.

MR. VAN DECKER: Okay. The question was I guess I heard comments to the degree of that a board certification as long as it's testing in specific areas that we consider knowledge base, that the board does not have to specify to those people sitting for the boards what they needed as far as training and experience to sit there.

Was that the comment that I --

MR. HENDEE: Not at all the intent. We

have a very specific set of criteria for eligibility, for board certification. It includes experience, and it includes experience in the range of areas depending upon which board certification process you're sitting for, and it also requires mastery of body of knowledge on which you will be tested.

And we give some general guidelines as to that body of knowledge, but we are not overly explicit because we don't want to be prescriptive in what the person studies.

We're not proposing that that be changed at all. The discussion was focused on whether or not if, in fact, as part of the certification process there is one or a series of examinations that test the candidates in terms of their knowledge in areas that are considered to be important to the Nuclear Regulatory Commission in terms of those individuals accepting responsibilities as authorized users, as authorized medical physicists or as radiation safety officers or authorized nuclear pharmacists.

And if the board is actually testing those people, that in fact is a better way of measuring their mastery of body of knowledge than

simply hours of training, and I've heard the NRC respond by saying, yes, that would be adequate for a board to be acknowledged as a default pathway to NRC recognition.

That's what I've heard.

MR. VAN DECKER: In other words then, whatever has been written so far as far as hours or training would not be necessary if one were board certified, testing the appropriate field of knowledge.

MR. HENDEE: That's what I understand.

MR. BROSEUS: If you look at the -- we're kind of retracking over some ground, but if you look at ACMUI's recommendations, I would characterize what they did in certain areas as substituting academic plus experience to the long, detailed list that's in what I have called the alternate pathway.

Patricia.

MS. HOLAHAN: I just wanted to add but assuming that the examination covers all of the things that are here.

MR. HENDEE: Yes.

MR. VANEK: And so that, I think, gets back to what is in the understanding when we apply

for approval. We just basically have to say the examination process will cover these things.

MS. HOLAHAN: Yes.

MR. BROSEUS: You think that's an appropriate thing to have in our discussion of supplementary information.

MS. WASTLER: Dr. Mauer?

MR. MAUER: And I think what I was hearing in the question of competency, I keep looking at the preceptor form. What I understand is that that term will be removed from the preceptor statement and it will just say that the person has completed the required training. There will be no attestation of competency.

MR. BROSEUS: Correct.

MR. MAUER: Okay.

MR. BROSEUS: And that's determined from the Commission.

MS. HOLAHAN: Yes.

MR. MAUER: Well, no. The confusion was that I think the ACU -- I can never say that.

MS. HOLAHAN: ACMUI.

MR. MAUER: -- ACMUI had recommended or said that we didn't want to talk about certification of clinical competency, and then the question was if

you look at the preceptor statement, it says "is competent to independently function, you know, and follow good radiation safety."

I just want to be clear that the term "competency," that the preceptor statement is not going to require a statement of competency. It will only require a statement that this candidate has completed the training program.

MS. HOLAHAN: And has knowledge to fulfill the duties of the position for which certification is sought. That language would be put into the form there.

MR. BROSEUS: It's knowledge based.

MR. MAUER: Yeah.

MR. BROSEUS: There are some people around the table who haven't really brought up any issues. Rich or Dr. Van Decker, Dr. Sayed, Dr. Ramirez, any comments from you all on these issues? I want to make sure everybody has a chance to speak

Sandy, did you?

MS. WASTLER: I was just going to recognize Dr. Hendee again. He had his card up.

MR. HENDEE: Well, I did have my card up because I wanted to raise another issue, and that is as a follow-up to what Alan has brought up having to

do with the training.

Most individuals --

MR. BROSEUS: Time out.

MR. HENDEE: I'm sorry.

MR. BROSEUS: The transcriptionist can't --

MR. HENDEE: Yeah. The mic is on, but I was this far away from it.

I'm Bill Hendee.

Many individuals receive their training that would be necessary to be recognized as authorized users or the other authorized categories as part of their education and training program, part of their actual experience in an educational program either as a resident or as a fellow or as a graduate student.

Let's just stay with the residents and fellows programs for just a moment. Those programs are by and large all accredited through the accreditation mechanism, and there is a person who is appointed as the program director, program director for this residency program and this medical specialty or for this fellowship program and this medical specialty.

And that program director is really

responsible for assuring to the residency review process and to the Accreditation Council for Graduate Medical Education that, in fact, the education and training of these individuals that are in this program are as represented in the description of the program for which that program is accredited.

So the program director is really the responsible individual, and in those situations it's our belief at the American Board of Radiology that that person, that program director is by far the most knowledgeable and most suitable person to sign off on an application to become -- sign off on the attestation statement. Better than an authorized user because an authorized user may be an individual who is working in a particular specialty area, but is not responsible necessarily for the education and training of the individual.

So we would recommend that for individuals who receive their education and training in an accredited program or in a recognized fellowship or residency program, that it be the program director who signs off the attestation statement, and then for individuals who receive their experience and training outside of an

accredited program, then it would be appropriate for the authorized user to be the individual signing the preceptor statement.

Now, we don't think this is a big deal, but we just think for the NRC's -- I think it makes more sense for the NRC to require the program director to sign off for those individuals who were trained while they were residents or fellows.

MR. BROSEUS: Anybody around the table have a comment on that? That's a significant issue. It's an authorized user versus a program director doing that attestation.

MR. HENDEE: For those circumstances.

MR. BROSEUS: Yeah.

MS. WASTLER: Dr. Vanek.

MR. VANEK: Actually in the residency programs I think that's a very valid point. From purely a radiation safety point of view, perhaps the medical physicist that teaches it, but the program director does have that responsibility more so than somebody who only taught component of that because as the residents go through at least radiation oncology and os on, they'll have maybe a GU guy and a head-neck guy and this and that, all of which can be an authorized user, but don't have the overall

program and responsible for that program.

So basically I think it's a very valid point and for residency programs and fellow programs, it would be very pertinent for that to be.

MS. WASTLER: Dr. Sayed.

MR. SAYED: That's a good point, but I supposed there should be a statement also including the scientists who do not necessarily receive their training in an accredited or a formalized program where there is a program director who could sign off on that.

In other words, these people, the diplomates of the ABSNM are not graduates of accredited residency or fellowship programs. So there are no program directors there. The mentors or their supervisors who they would train and work with in the nuclear medicine clinic would sign off.

MS. WASTLER: Right. That would be the authorized user.

MR. BROSEUS: That would be the authorized user, yeah.

MS. WASTLER: Right.

MR. SAYED: As long as that clarification or statement is there.

MS. WASTLER: Okay. I think we're

consistent.

MR. SAYED: Okay.

MR. BROSEUS: So it really says authorized user or program director.

MS. WASTLER: Because what we're hearing, at least what I'm hearing, either authorized user or a program director of an accredited residency program or fellowship program would be the two that you're proposing.

MR. VANEK: I don't think it's really an "or" when it comes to a formal residency program. If you're from a formal residency program or fellowship program that has a program director, it should be the program director. If a program director is not applicable or whatever, you know, then an authorized user who happens to be the mentor could do it.

MS. WASTLER: Okay. I understand.

MR. VANEK: So it's not just an "or" type of thing.

MS. WASTLER: Right.

MR. VAN DECKER: And the only down side to that is what's the life expectancy of the program directors in the current year, and I can tell you across the board it's not usually real long.

I mean, I guess I would kind of prefer in a consensus building of saying someone has really been trained, at least a list of who was involved as the authorized user, oversight people at that period of time that they came out; that somebody has really been personally involved in this person so that we don't have people trading in and out and we know who has really been involved in the training process.

But you know I can see why there would be, you know, some utility to that.

MR. BROSEUS: How can a person go through a residency program without being under the supervision of an authorized user?

MR. VANEK: I mean, you can be under the supervision of an authorized user, but the person who is responsible for the overall training and to make sure that they do get all of that training is the program director, and in an accredited program, even though there may be a turnover of program directors, there's always somebody that has to be the program director if you're going to be accredited.

MR. BROSEUS: You're not permitted to allow somebody to use material unless they have proper training, and that's an authorized user

responsibility.

MR. VANEK: That's correct.

MR. BROSEUS: And so it's kind of going in circles for me.

Alan?

MR. MAUER: I was going to say I think what you're getting the sense is the way most residency programs work is that the program director is responsible for making sure that the body of knowledge that's required is provided to the trainee. So I think it is much more appropriate to the program director to certify that the body of knowledge has it.

In terms of the actual -- and in the preceptor form I had questioned this about a year ago. It says the supervisor. There's a supervisor and then there's a preceptor. When residents work in nuclear medicine or in an area where they're using licensed material, that is under the direction of some other supervisor, which may not be the program director.

So we really need to separate body of knowledge and educational training, which is the responsibility of the program director in the actual application of licensed material, which is usually

under a different supervisor.

But what I'm hearing is that the NRC is only looking at the body of knowledge that this person has completed a training program and received a certain body of knowledge, and that is the program director's responsibility.

If you want to get into certifying adequacy of training in terms of handling and other things, that may be a different individual.

MS. WASTLER: All right. I'd just like to take a minute. We're a little bit ahead of schedule, and I've been asked if we could take a short break. So if we move our break up a little bit and take a 15-minute break right now, and we'll come back in 15 minutes and start the discussion again.

Would that be acceptable?

MR. HENDEE: That's fine. When we come back, I have several issues related to specifically radiation safety and authorized medical physicist --

MS. WASTLER: All right.

MR. HENDEE: -- in the rulemaking. So we don't want to --

MS. WASTLER: No, we won't forget.

Thank you.

MR. BROSEUS: So we'll plan in reassembling by the clock on the wall at 10:25.

MS. WASTLER: That's right, 10:25.

MR. BROSEUS: Ten, twenty-five.

MS. WASTLER: And, again, there's coffee. You go out this door, right across the hall, the NUREG cafe.

(Whereupon, the foregoing matter went off the record at 10:07 a.m. and went back on the record at 10:27 a.m.)

MR. BROSEUS: If we could all reassemble, we're going to resume.

We are going to go back on the record. We're resuming after adjourning.

I'd like to welcome to the table Howard Dickson. Kathy Pryor was unable to make it, and, Howard, would you identify where you're from and your affiliation and so on?

MR. DICKSON: Yes. My name is Howard Dickson. I'm the president of the American Academy of --

MR. BROSEUS: Wait. Something is not happening.

Can you not hear him? Is the red light on?

MR. DICKSON: The red button is showing.

MR. BROSEUS: Can you hear him now?

MR. DICKSON: Can you hear me? Well, maybe we can share.

MR. BROSEUS: You can maybe share with Dr. Hendee because I think that mic is not working properly.

Thank you. Thanks, Bill

MR. DICKSON: Once again -- oh, that works -- my name is Howard Dickson. I'm the current president of the American Academy of Health Physics. The American Board of Health Physics is the certifying board within the academy. Kathy Pryor was the outgoing chair of that board.

The current chair is Ed Bailey. Neither of those individuals were able to make it. So I'm here sort of in their stead. I certainly didn't want you to get the impression that the American Board of Health Physics was not interested in this meeting or did not want to contribute to this meeting.

Certainly our certification program is an elderly one, like Dr. Hendee's, and so we're very proud of the tradition and certainly would like to see the Nuclear Regulatory Commission recognize the

certification process in this particular rule.

MR. BROSEUS: Well, we appreciate your stepping forward and volunteering to sit in for Kathy.

Somebody brought up just a little fine point. We were talking about wording earlier in my presentation, and I think it was Dr. Sayed that indicated that the word "diplomat" is used throughout -- sorry. He said "diplomate" -- throughout the options paper, the SECY paper, and the staff caught that, and we are using the word "diplomate."

We may have diplomatic diplomates, but we're using "diplomate."

(Laughter.)

MS. HOLAHAN: I'd like to make a clarification from what I said earlier. The board recognition process doesn't recognize number of hours for the American -- no, for the RSO and for the medical physicist, but they do recognize a number of hours for 290 and above.

And I just wanted to clarify that point, that it was --

PARTICIPANT: Thank you.

MS. HOLAHAN: Okay.

MR. BROSEUS: Sandy, did you have?

Okay. Somebody pointed out during the break there has been a lot of discussion of the using of the word "competency" in our preceptor statement, and the impression was left with some people that we're going to remove that word from the rule, and that's not the intent because the Commission said, "Don't change the wording of" --

MR. MAUER: I was just reading --

MR. BROSEUS: -- "the preceptor."

MR. MAUER: -- Chairman Meserve's comments here.

MR. BROSEUS: However, we are going to clarify in the Statements of Consideration what that means, and it's to fulfill the duties, and that's present in the SRM that came down from the Commission. That's the direction to the staff.

MS. WASTLER: We can change the preceptor statement itself, but the word "competency" will remain because of the commission's directive, but we will clarify.

MR. MAUER: Sorry. That raises problems with some of the earlier discussion that we had. During the break I was reading Chairman Meserve's comments here, and he clearly says he wants to keep

some sort of statement of competency, for lack of another word there.

It goes back to the discussion we had earlier about whether the program director then is the one who's the most appropriate to sign the preceptor statement or the authorized user.

If the concern of the Commission is to say that this person has had adequate training and has demonstrated the ability to function well as a radiation safety person, the program director in terms of the physician's training, does not work with these candidates in terms of handling radioactive materials and in nuclear medicine.

So we get back to this dichotomy between who should be doing the preceptor statement. The program director can best certify the adequacy of the training program and the educational material, but many radiology residents when they rotate to nuclear medicine are not under the supervision of the program director, and there's a disconnect there.

So I see a problem.

MR. HENDEE: Well, I think the problem is the definition of "competency" and how you are going to define it and how you are going to require

it, and unless you have some insight into this issue that's different from the boards', who have wrestled with this issue for a long, long time and have concluded that really all that you can really measure is mastery of a body of knowledge and its applications.

My suggestion to you is that you stay with the wording, but you define competence to be exactly that, mastery of a body of knowledge and its applications, and not try to get into something more subtle that is very hard to evaluate.

So I think if you define competency in that way, then it addresses the issue, and you could do that.

MR. BROSEUS: Well, I think that we've zeroed in, first of all, in following the SRM, which is having attestations say the candidate has the knowledge to fulfill the duties, and the word "competency" is not there. And it might be useful to expand upon it a little bit using some words like you have suggested in our supplementary information.

PARTICIPANT: Some of us can't hear you.

MR. BROSEUS: Sorry about that.

Are there other comments about this?

MR. HENDEE: About this?

MR. BROSEUS: Do you have a new issue?

I think we've covered the competency thing now, and I'd like to move on. We need to spend some time also on the implementation, but in our schedule we were scheduled to do that around 10:50, and I realize there's some overlap, but do we have any other comments about the criteria, that is, the requirements that the board --

MS. HOLAHAN: I think Dr. Hendee had indicated before we broke that he had some issues that he wanted to bring up.

MR. BROSEUS: Yeah.

MS. HOLAHAN: So why don't we start there?

MR. HENDEE: Good.

MS. HOLAHAN: And then go forward.

MR. HENDEE: I had two issues, both of which pertain to who's qualified to be a radiation safety officer. The first issue you may be able to put to rest very quickly, and that is the in ACMUI recommendations there were, I think, three or four boards listed as default pathways to becoming recognized by the NRC as a radiation safety officer. They included certification in medical health physics by the American Board of Medical Physics,

certification in health physics by the American Board of Health Physics, and certification in radiation protection or something like that by the American Board of Science and Nuclear Medicine.

Omitted from that list was the certification board that probably has been responsible for more individuals serving as radiation safety officers than the other boards put together, and that is the American Board of Radiology and its certification process in radiological physics and also in medical nuclear physics.

MR. BROSEUS: I think I need to make a clarifying comment right at this point. Excuse me for cutting you off, but the direction in the SRM is not to list in rule text the boards that were listed in I'll call Paragraph A in the ACMUI recommendations.

MR. HENDEE: I understand that.

MR. BROSEUS: And so the boards will need to meet the criteria that we define in this proposed rule and make application individually, and so it's not predetermined that they're going to be named in the rule. They won't be there.

MR. HENDEE: That's possible.

MR. BROSEUS: And so it may be that, you know, these various boards could come forward with their information and meet the criteria and be ready.

MR. HENDEE: You're saying that there's no default pathway to becoming a default pathway.

(Laughter.)

MR. HENDEE: That's fine. That's what I thought you might say, which means, you know, it's all up for grabs now, and every board has to now make its case, and that's fine.

So now I will go to my next point.

MS. HOLAHAN: Okay.

MR. HENDEE: But that was an important point to get clarified.

My next point has to do with authorized medical physicists because you point out or it was pointed out that one pathway to becoming a radiation safety officer is to be recognized as an authorized medical physicist, and you might be recognized as an authorized medical physicist by being certified, and there are several possibilities there. I understand there's been no default yet.

But it's not clear to me if you are an authorized medical physicist, which means that you

are working in radiation oncologic physics, you're in radiation oncology. By the way that those specifications are worded, it's not clear to me what you can be radiation safety officer of because you can be radiation safety officer of similar types of byproduct material and similar applications of those materials, similar to what you are actually responsible for overseeing as an authorized medical physicist.

Well, those sources are typically therapeutic sources, usually sealed sources. So the question is this. Can an authorized medical physicist who is probably a radiation therapy physicist, can that person serve as a radiation safety officer for an institution in which there are uses of unsealed radionuclides in diagnostic medicine, which that individual being a therapy physicist really doesn't have day by day responsibility for, and can he also be responsible for research applications of radionuclides which may be in the unsealed form even though those are not similar types of byproduct material and similar applications to what he deals with in radiation therapy?

That needs to be clarified.

MR. BROSEUS: My first answer to that is would that person meet the board certification criteria that we're working on in the proposed rule. If so, yes.

Secondly, the alternate pathway still exists, and if a person were listed, you know, if a licensee came forward to the NRC or an agreement state and listed their training and experience and it met the criteria in the rule and the alternate pathway, the answer would be yes.

I think you might be getting at another sort of issue where that person wouldn't have that T&E, and therefore may not be qualified to be an RSO.

MR. HENDEE: Well, I mean, the issue is the way you have it worded, which is if you are recognized by the NRC as an authorized medical physicist, you can then also be recognized as a radiation safety officer for similar -- I'm not quoting it exactly -- but for similar types of byproduct material used in similar applications.

And I don't know what "similar" means. We need clarification of "similar."

MR. BROSEUS: I think this really gets into interpreting the existing rule and it's kind of

in Q&A space also, question and answer space, but my guess is that if an individual came forward and their only experience were in some narrow area of radiation oncology physics and they didn't have training and experience for a broad medical program to present the extreme case, they probably wouldn't meet the requirements for T&E to be a radiation safety officer.

Trish, do you want to go further with that?

MS. HOLAHAN: No.

MR. BROSEUS: Alan?

MR. MAUER: I'd also like to bring up an item which I think requires some clarification. My understanding is that ACMUI has recommended some modifications to the Part 35 training requirements. So that there may be some changes in the training requirements that come out in the final form.

MS. HOLAHAN: In the alternate --

MR. MAUER: Yeah.

MS. HOLAHAN: -- criteria or the alternate pathway?

MR. MAUER: Yes.

MS. HOLAHAN: Yes, they did.

MR. MAUER: Okay. One thing I want to

bring up that's similar, that there's confusion between brachytherapy, sealed sources, unsealed sources in terms of training.

Currently the American Board of Nuclear Medicine is only recognized, and I know that that will change, in terms of meeting requirements for unsealed byproduct material for which a written directive is required for therapy.

There are some new therapies that have come along, particularly TheraSpheres. They were classified by the FDA as brachytherapy devices, but, in fact, they are administered in the way unsealed source material is for therapy.

And candidates or people at least who have trained through the American Board of Nuclear Medicine training program certainly get all of the physics and training requirements to use unsealed source, but because one thing happens to be classified as a brachytherapy device, they would not be qualified to administer them under the brachytherapy requirements.

I can go into the details, and I think that needs to be addressed because training for the use of manual brachytherapy sources excludes and potentially under the new listings would exclude the

American Board of Nuclear Medicine.

MS. HOLAHAN: So you're saying that it's listed in 490, and --

MR. MAUER: It's listed under 490 which has training requirements that currently, I think, are met by the American Board of Nuclear Medicine, except for some specific things about removal of sealed sources because most things are administered as an unsealed source.

MS. HOLAHAN: Yes.

MR. MAUER: And it's raised problems for those who were certified by the ABNM right now in terms of getting permission to use these unsealed sources.

So I would recommend that the term "unsealed" under 35.390 be removed, and it just says training for use of byproduct material and get rid of the word "unsealed" because some things now are considered sealed sources, but are administered as traditionally unsealed sources.

Do you follow that?

MR. BROSEUS: Well, one thing I recall from back in the days of doing the guidance. It isn't necessarily so that the NRC will consider our source to be a brachytherapy source because it's

classified that way by the FDA.

MR. MAUER: But that's currently the way it's being handled

MR. BROSEUS: Okay. It is?

MR. MAUER: Yeah.

MR. BROSEUS: I'm not familiar with that.

MS. HOLAHAN: Yeah.

MR. MAUER: So there's a lot of -- between sealed and unsealed sources and brachy, those definitions get to be a little blurred.

MR. VANEK: You know, for your example though I think one thing might be like a GliaSite with the Iotrex. It's a liquid source that is put into a sealed catheter for treatment.

MR. BROSEUS: Okay.

MR. VANEK: Leoblastomas.

MR. BROSEUS: Right.

MR. VANEK: And a clinical perspective in that, it's considered sealed because it's within this catheter and it's removed, and the training and experience for delivering therapeutic doses for something that has also received external beam radiation therapy, I think, are whole different issues.

I mean if that's what you're -- one of the things that you're referring to, I don't think that really accomplishes a lot of the stuff specifically for that, but I think there's a whole bunch of other issues with that particular one.

So anyway, but basically I have to look at a lot of ramifications of that.

MR. MAUER: I'm just saying that if ACMUI is recommending some changes to the T&E requirements, particularly in the language, maybe we shouldn't be limiting the training requirements of 35.390 to unsealed byproduct material but just say byproduct material, which would include those that are under 490 now when appropriate.

MS. HOLAHAN: We can certainly take that into consideration.

MS. WASTLER: Dr. Vanek?

MR. VANEK: I'd like to go back to just a comment that Dr. Hendee was talking about and whether or not, for instance, someone who has as boards and therapy physicists could be included as far as an RSO for nuclear medicine or something like that.

It brings up an interesting concept because as far as board exams are concerned, you do

have your general board before you go into your specialty board so the basics of radiation safety and so on should all be covered within that general part of the board exam.

But when you take RSOs and, for instance, our RSO at our university is a Master's level health physicist who does not have training and experience with HDR or a lot of the other isotopes specifically, but does that then disqualify him from being an RSO?

So, you know, having to have that experience, personal experience and training on every single thing within that license could be a very interesting ramification.

MS. HOLAHAN: But if you --

MR. VANEK: That's why I'm trying to get what you stated there, Bill.

MR. HENDEE: It's a question of similar. It's a question of what do you mean by "similar."

MS. HOLAHAN: Yeah, if he's an RSO for the whole facility --

MR. VANEK: Yeah, I mean, he's RSO for the whole facility.

MS. HOLAHAN: -- you'd want him to have experience with all of the modalities that you have

there.

MR. BROSEUS: Well, I think also you're talking about the circumstance if the RSO may have the training and experience for all modalities, and a new come comes along, stereotactic, for example, and he doesn't have experience or even knowledge about the hazards associated with that. Is he now disqualified as the RSO for that particular application?

MR. VANEK: I mean, new modalities is a whole other issue because they never become new modalities unless there's somebody that starts using it and developing it to begin.

MR. BROSEUS: Well, let's not talk about new modalities. Something he doesn't have experience with.

MR. VANEK: Correct.

MR. BROSEUS: It hasn't been an institution before.

MR. VANEK: Correct.

MR. BROSEUS: Then what happens is the question.

MR. VANEK: Especially when you're talking about an overall RSO for a large institution who then has within that institution his personal

expert so you could have an RSO of sub-specialty areas, et cetera.

But when you're talking about he's the primary RSO for the institution.

MR. BROSEUS: I think that that problem existed today independent of the rulemaking we're working on.

MR. VANEK: Right.

MR. BROSEUS: And it's really, well, what would an institution do if this new modality or let's not call it new modality; this new use came in that they had lacking experience for, and when they go forward with a license application, what would they tell the agreement state or the NRC was the basis for licensure of that particular application?

And there would be a need to demonstrate some sort of training experience to be able to license that material.

MR. VANEK: And it raises the issue about your having enough RSOs to do what you need. Because I got a little concerned with getting this thing so restrictive that now you have an RSO that's covering 35 institutions and on 35 different little, small community hospital licenses that he may go in once a year or twice a year, is that really

providing what an RSO is supposed to do?

Do you know what I'm saying?

MS. HOLAHAN: Un-huh.

MR. VANEK: You know, I get concerned about that because I think that that is negating what you really want an RSO to do.

Now, if you had three levels of RSOs, let's say, and you had an RSO-3 and then maybe he had to be looked at by, you know, someone with more experience periodically, like a quarterly basis or something, but to have guys go around covering multiple institutions just because he's the only one that can really meet all of these requirements, I think, is really taking away what you want an RSO to be doing.

MS. HOLAHAN: Yeah. Well, of course, we always say they can delegate their duties, but they don't delegate the responsibility, and they have to sign something that they're responsible for the facility.

MR. BROSEUS: Do we also have input on this particular issue?

MR. HENDEE: Well, I think the authorized user can qualify as a radiation safety officer as well, right?

MS. HOLAHAN: Yes.

MR. HENDEE: So I think this is an issue. It's probably a manageable issue, in general. I'm not so concerned about the radiation safety officer not having experience in sophisticated new applications in radiation oncology because I would hope that there would be a therapeutic physicist.

I mean, when you send your license in you've got to demonstrate who is responsible for the use and for the safety of this new device, and in most cases it would be -- certainly in almost all cases it would be an oncology physicist present. You might want to comment on that.

I think the big problem is the other way, which is you have an institution that has a therapy program with therapy physicists, and the question is can that therapy physicist also serve as a radiation safety officer for nontherapeutic applications.

And I've heard the answer, and I'm happy with the answer, which is if you have the demonstrated experience or training, then you can extrapolate to a wider range of responsibilities in radiation safety.

Now, you might want to rebut that. I don't know.

MR. VANEK: No. I mean, it gets back down to what the boards are examining in the general part of the board exam, as you know, and I think that has a big key to it because we do have that general portion in the board exams, and then you get into your specialties.

MR. BROSEUS: Our agenda calls for talking about implementation before we finish off today.

MS. WASTLER: Dr. Mauer, did you have a comment on another issue or was it on implementation? You have got your --

MR. MAUER: Oh, no. That's still standing from the -- I'm sorry.

MS. WASTLER: Okay. Dr. Sayed.

MR. SAYED: I have a follow-up question on what Dr. Hendee stated earlier under 35.50. I understand that the Section A will be removed and will be listed on a Web page. It specifically states --

MR. BROSEUS: We will list boards on a Web page that meet the criteria.

MR. SAYED: The criteria, okay. But

within those boards it lists specific specialty areas. Under the new evaluation that you will be implementing and the board will propose to you, will the board be able to add to it the other specialties?

For example, here under A-3 it only lists radiation protection, but I believe nuclear medicine or medical nuclear physicists are just as qualified and trained to be radiation safety officers as those who sit only for the radiation protection specialty of the ABSNM exam.

MR. BROSEUS: That's what we were talking about in my answer to Dr. Hendee earlier. You know, if a medical physicist or an oncology physicist or whatever meets the requirements, then, you know, for RSO, then they --

MR. SAYED: So that's my intent, is just to clarify this. When the board submits to you all of the criteria and you will list those specialties as communicated to you by the board that meet these criteria?

MS. HOLAHAN: Yes.

MR. SAYED: Okay. Thanks.

MR. BROSEUS: And they will be aligned with 50, 51, you know, RSO, medical physicist,

nuclear pharmacist, or the areas of use, 190, 290, and so on for an authorized user.

Sandy?

MS. WASTLER: According to the schedule or to the agenda, at 10:50 we wanted to start discussion or take your comments on the implementation, on the process for board recognition, but before we do that, do we have any last minute clarifications or points on the issues that we've discussed up to this point?

MR. BROSEUS: There was one I think Dr. Hendee might address that was the basis for the Canadian board that we talked about. Did you have something to say about that?

MR. HENDEE: I think that the way I read this I just saw this this morning. Are you recognizing an accrediting agency rather than a certifying board?

I think the Royal College of Canadian Physicians accredits residency programs, does it not?

MR. BROSEUS: Yes.

MS. HOLAHAN: Yes.

MR. HENDEE: It would not be an individual board. That is not a board that

certifies individuals the way the --

MR. BROSEUS: Correct.

MR. HENDEE: -- that you're talking about recognizing here.

MR. BROSEUS: Correct, yeah, yeah. I mean, like this particular board was added to the list, and it is in Subpart J now, for those entities that -- and I'm going to use terminology kind of loosely here -- that accredit residency programs. It's not in the area that we're addressing as the bigger part of our rule, a certification board. It's not for the specialty boards to be recognized to be an authorized user or whatever. Okay?

MS. HOLAHAN: Well, it's both because --

MR. BROSEUS: Yeah, it is.

MS. HOLAHAN: -- they have the Royal College of Physicians and Surgeons of Canada recognizes the board, and then also a certification specialty.

MR. BROSEUS: Yeah, for one of the areas. Which area was that?

MS. HOLAHAN: Three, ninety.

MR. BROSEUS: Three, ninety.

MS. HOLAHAN: They list it under A-3. It's specifically listed, and then certifying in B,

they list the Royal College of Physicians and Surgeons of Canada, and we want to know if there's a basis to list the Royal College of Physicians and Surgeons of Canada in the rule text.

MR. BROSEUS: We'll raise this with ACMUI this afternoon, too, but if there's anybody that has a view on this here.

MR. HENDEE: Thirty-five, three, ninety?

MS. HOLAHAN: Yes.

MR. HENDEE: I'd have to read that.

MS. HOLAHAN: Okay. It's listed elsewhere, but specifically I caught it in 390

MR. BROSEUS: Thanks for clarifying it.

MS. HOLAHAN: Okay.

MR. BROSEUS: I'm sorry.

Well, we can come back to that after we talk about implementation. Shall we move right on into the implementation?

MS. WASTLER: Yes.

MR. BROSEUS: Because this is an important area, and it's the one where things are a little fuzzier, especially for the working group, and so I briefly outlined the approach of the working group this morning about the processes that we're considering, and please step forward with any

comments or recommendations that you have.

Alan.

MR. MAUER: I guess I'm unclear a little bit when you're talking about implementation. You want suggestions from us as to how things will move forward?

MR. BROSEUS: Let me clarify first.

MR. MAUER: Subpart J disappears in?

MR. BROSEUS: October 2004.

MR. MAUER: 2004.

MS. HOLAHAN: So the boards are going to have to resubmit to meet the new criteria in the rule.

MR. MAUER: Okay, and I had one particular question. I'll just bring it up again because it was one of my goals today, is that the ABNM had submitted a letter and received a letter that it would qualify and would be listed on the Web site.

So if that was premature, we need to know that. Will they need to resubmit?

And I guess there will be some time line.

MS. HOLAHAN: We need to get clarification.

MR. MAUER: Yeah, we need clarification on that because I have to go back to the board and say, "Oh, you're going to have to resubmit this whole thing."

MS. HOLAHAN: Are you here this afternoon for the ACMUI?

MR. MAUER: I will be only for the first hour or two and then I have to leave.

MS. HOLAHAN: Okay.

MR. MAUER: Do you think it's appropriate to bring it up at that time? It's not the ACMUI that's going to.

MS. HOLAHAN: No, no. It's not the ACMUI. I was just thinking of timing.

MS. WASTLER: To see if we couldn't get you the answer.

MR. MAUER: Oh, yeah, I'll be here.

MS. WASTLER: We may not be able to in that time frame.

MR. MAUER: But I need to go back to the board in terms of procedures, and do we need to do something.

MR. BROSEUS: Give me a copy of the letter.

MR. MAUER: Okay.

MR. BROSEUS: And we'll make sure that you get an answer back.

MR. MAUER: But so then in terms of the implementation question, the boards need to know that as of a certain date, they're going to have to have submitted what materials and what documentation?

My understanding, and I think this is pretty simple actually, I think the NRC has lain down minimum training and education requirements. Basically my understanding is the board just has to say, "We're going to meet all of the training requirements in the alternate pathway, which is the minimum requirements, and if we do so, we will receive what people call deemed status.

MS. HOLAHAN: And the preceptor statement.

MR. MAUER: And the preceptor statement. But, again, I would like to see some -- and again, there is a preceptor statement that's on the Web site. That's the one that I downloaded, and I would like -- I think everybody well ahead of time ought to see what the exact wording is. Is it going to say "competence"? Is it going to say "completed the training program"? Does it say "completed the

training program and can function"?

We need to know that because you're going to get a lot of feedback from people based upon what that final language looks like.

MR. BROSEUS: Well, the competency statement -- I mean the preceptor statement is not to change. That's a direction from the Commission. So to clarify this as we talked about before --

MR. MAUER: So what is on the Web site right now is the form that will go into effect?

PARTICIPANTS: No.

MS. WASTLER: The form we can change. What we can't change is in the preceptor statement. It's to be as written. That was the Commission's statement.

But we can clarify what was meant in the Statement of Considerations, and we can change the form so that --

MS. HOLAHAN: To clarify.

MS. WASTLER: -- to clarify as well what we mean.

MR. BROSEUS: Actually you're looking at a Form 313(a). We're talking about the possibility of a new form, Alan, that -- in other words, looking at the process, what would a board do to get

recognized? How would the information be conveyed to the NRC?

And one possibility is to invent a new form with check-off boxes or something, you know, that says, you know, "Identify the board contact," et cetera, and check-off boxes and maybe some supplementary information about how they meet the criteria and the rule. Okay?

It's not a 313(a). It would be a new form. This form would probably not change because if you're board certified --

MR. MAUER: This is the preceptor form right now.

MR. BROSEUS: Yeah, okay. So you're saying there might be some content in the preceptor form that needs to be changed also.

MR. MAUER: Yes.

MR. BROSEUS: Okay. Good point.

MR. MAUER: Yes.

MR. BROSEUS: Okay. Thanks.

MR. MAUER: Definitely

MR. BROSEUS: It took a while to get into my thick skull.

MR. HENDEE: So how much interaction will there be? If a board submits an application,

we'd like to do this sooner rather than later, actually, and you compare what's in the application to what you believe is the requirements to be recognized as default pathway, and then you say you will consult with ACMUI if necessary, which is fine.

But how much interface is there back with the submitting board? I mean, can we negotiate this? Is there -- you don't just get the application and then it goes through a process and we either get an answer, yes, you are a deemed pathway or, no, you are not.

I presume there is some dialogue that goes on; is that right?

MS. HOLAHAN: Yes.

MR. HENDEE: Especially at the beginning when we are all trying to figure out how to do this.

MR. BROSEUS: So staff would logically, if they think something is missing or some insufficiency, go back to the board and identify that and give them a chance to respond.

MR. HENDEE: Great. That's wonderful.

MR. BROSEUS: Yeah.

MR. MAUER: Just to clarify, it's under 11(b). The current form says, "The individual named in Item 1 is competent to independently function as

an authorized user," and that's the language that I think really needs to be --

MS. WASTLER: And that's what we've said that we can change, we will be changing.

MR. DICKSON: This is Howard Dickson.

When do you think this new application might be available for us?

MR. BROSEUS: Well, after the rule is final.

MR. DICKSON: Okay.

MS. HOLAHAN: Well, it's after the --

MR. DICKSON: Oh, a draft.

MS. HOLAHAN: Yeah.

MR. DICKSON: I think you want comments probably on that form.

MR. BROSEUS: Yes.

MS. HOLAHAN: Yes.

MR. DICKSON: And so we would need to have a form to comment on.

MS. HOLAHAN: We can get it out with the proposed rule.

MS. WASTLER: Were there any other comments on the implementation process or the process that or the issues, reasons for de-listing a board that were presented earlier?

MR. MAUER: Well, just some general comments. The trend that I got and in reading some of the Commissioners' comments that you handed out, it really seems like if the boards submit and say, "We're going to meet all of the requirements," they're going to get approval unless there's something glaring that they've left out, which is kind of hard to imagine because they're just going to send back to you and then hopefully implement through their own processes the training requirements.

In terms of de-listing or not certifying, actually the language is that they don't want to examine the boards. They're just going to look at the medical events rate, and I don't know. That seems kind of vague to me.

MR. HENDEE: That's an impossible criterion.

MR. MAUER: Yeah. To hold a board to what individuals, you know, at different institutions are doing, and medical events, as we all know, can be caused by a myriad of things that may not necessarily reflect even what the authorized user did or did not do.

So I think the requirements and how the

boards are going to be judged have to somehow be firmed up a little bit more than that.

MS. HOLAHAN: Well, that's what we're coming to for advice.

MR. MAUER: Oh, okay. You want us to actually tell you how to --

MS. HOLAHAN: Well, if you have thoughts, you can share them.

MS. WASTLER: Concepts or thoughts, if you could share them.

MS. HOLAHAN: Yeah.

MR. HENDEE: Okay. This is Bill Hendee.

I couldn't agree more with Alan on this point. This one requirement that somehow you're going to have some kind of an evaluation of effectiveness of the board's certification process and let that be a criterion with which you decide whether or not to de-list a board I think is setting up an impossible objective for all of the reasons that you can imagine.

But it would certainly be a reason to disqualify a board from being listed if, in fact, they don't adhere to the standards that they have proposed to you in being recognized as a board. I think that would certainly be one thing you could

ask.

I mean, in other words, if they require -- if the board says you have to have three years of experience before you can sit for the qualifying examination or you have to graduate from an accredited residency or fellowship program before you can sit for the examination, and then you find out that they're letting anybody come in whether they are accredited from an accredited program or not or whether they have the requisite experience or not, that would certainly be a reason.

I mean I think you have to hold the boards to the standards that they agree to be held to when they submitted their application process, and that includes if they change their requirements in a substantial fashion.

Because we're always modifying our requirements a little bit here and there just to keep up with the times because new things come into the field. We have to add those.

But if you change the requirements in a substantial manner, then we would be obligated to tell you about that. You would be obligated to review whether or not that causes you any concern.

Those are the kinds of things, I think,

that you could hold a board to. You're really holding the board to what it said it would do when it became recognized by the NRC.

MR. BROSEUS: I'm a staff member now. How would I evaluate the term "substantial"?

MR. HENDEE: I'm sorry?

MR. BROSEUS: What does "substantial" mean? What should it mean to the staff member evaluating? How would they do that?

MR. HENDEE: I think if it has the potential of having an impact on the qualification of individuals to serve in the capacities for which you are recognizing that board as giving deemed status. So, for example, the fact that we decide in radiation oncology that people who are declared authorized users must have experience in a new area would be something that you might want to know about, and we would do that.

On the other hand, if we decide that we're going to make some minor change, it might not be. I understand that it's a subjective term, but it would certainly seem to me that anything that would have an impact on the qualifications of those individuals to serve in the capacity for which you're recognizing the board as giving it deemed

status would be how I would define "substantial."

MS. HOLAHAN: And I would also add, if I may, that only in the areas of radiation safety.

MR. HENDEE: Right.

MS. HOLAHAN: Not in clinical competency.

MR. HENDEE: Exactly.

MR. MAUER: I was going to comment further. I think you need to go beyond just the submission of what the board says. I'm sort of from Missouri. Show me.

As Dr. Hendee mentioned, the boards go through -- there is a quality control through the ACGME were there are site visits of the programs, where inspectors go in and actually collect data to show that the program directors are providing the appropriate educational material and training.

And I think if you wanted a way to actually see that the boards were doing what they would say, you would require some annual or some review process to show that the programs have been inspected by the board, that they're meeting the training requirements similar to what the boards, most of them, are imposing upon themselves right now to make sure that the programs are performing

adequately.

And that requires some form of on-site inspection.

MS. HOLAHAN: And do you think we could do that through ACGME or some other --

MR. MAUER: Some similar mechanism, yeah. Every board goes through a review process that their training programs meet their requirements, and those training requirements are documented by a site visit, and it's reported back through the ACGME process.

MR. BROSEUS: Does that include examination areas of radiation safety?

MR. MAUER: That includes everything. You know, when the site visitors go, they so through and the program directors have to provide documentation, list the hours, the lectures, who gave the lectures, the time, and they're going so far as requiring attendance records.

Now, I'm not sure that you want to get into it to that level, but you would want to have some mechanism for making sure that that kind of review process is taking place.

MS. HOLAHAN: Having been through one, I understand.

MR. MAUER: Yes, right.

MR. VAN DECKER: The only comment I was going to make is I think that there's some utility to that, but I think we need to recognize that a lot of those site visits are more for the clinical side of things beyond just the radiation safety, and so obviously if that's a piece of it, that would help you, but there may be other instances where people are just attesting to radiation safety that are not the clinical portions of the program, and so there may be a variety of ways to do that.

But I agree with Dr. Hendee. I think that, you know, outcome stuff would be great, but it would be difficult to do, and I think that the real goal is to be sure that everyone is fulfilling the minimum requirements across the board so that there's one standard of care across everyone who's involved in the field.

I think that the sticky part of this actually becomes, you know, always the fear that people are going to start going their own ways, and things will kind of look a little different across the field, and if you de-list somebody, what does that mean to those people who were certified at the time that the board was an acceptable form of doing

what they do? Are they now -- have to have a time part on -- you know.

Hopefully this is all abstract because we hope we never come to anything like that, I'm sure, across the table, but you could have a situation where you have people who have an old SIR certificate and now their board is no longer recognized and what do they do from there. There are issues.

MR. BROSEUS: Let me address that because that did come up in our working group. Can you hear me okay over there?

Yeah, because the possibility exists, and one of the things that we plan in the working group is to include some information in the implementation and list that in our supplementary information to deal with that particular topic.

It's also why -- underlies additional information the working group feels should be on the Web site, which is how long is a board certification good for, you know.

But we plan to look specifically at the circumstance of an individual. It's certified when a board is in good standing, and they shouldn't be left out in the cold if the process was good at one

time.

MR. VAN DECKER: This raises an interesting question of recertification of boards the same way we do.

MR. BROSEUS: Well, that's it, you know.

MR. HENDEE: I want to exercise a word of caution here. I think the American Board of Radiology is probably not different from most boards in that the board certifies individuals to be sure that they have mastery of a body of knowledge and they have knowledge of the clinical utilizations of that body of knowledge for the welfare of patients.

And the board admits into its certification process graduates of accredited training programs, residencies, fellowships, or medical physics training programs.

Certification, the boards certify and another agency or other agencies accredit the training programs, educational programs, and that's done through the ACGME, and under the ACGME, that's the Accreditation Council for Graduate Medical Education. That is a multi-organizational sponsored council. It stands independently.

And then under that, there are many residency review committees, one for each medical

specialty. The residency review committees review the residencies and the fellowships in order to accredit them.

The board does not get involved in judging or reviewing or examining the educational programs. That's done by the residency review committee under the ACGME. That's a separate process.

So we take the word of those processes and accepting candidates into the board exam, but we don't independently verify the education and training. That's not our role.

If, and I think this would be foolish, but if the NRC decided that it wanted to actually go in and evaluate the education and training, you would then have to work with the ACGME and the residency review committees, not with the boards because we don't do that.

The education and training is separate from the board's certification process, and I think you can't hold the boards to the responsibility that they are somehow verifying that what they understand is being done is being done.

We depend on the ACGME and the residency review committees to take care of that.

MR. VAN DECKER: Which is an argument for authorized user over program director.

MR. BROSEUS: Yeah. Aside from that point, I don't see anything that's in the proposed --

MR. HENDEE: No, there's not.

MR. BROSEUS: -- stuff and so on. So I don't --

MR. HENDEE: This was responding to the discussion.

MR. BROSEUS: Okay. More comments on implementation, de-listing?

One of the things that the Commission pointed out was something they called due process, which makes the lawyers' hair stand on end, but we need to make sure that if a board is to be de-listed, that there's a procedure there, and the working group has worked through something that we think is pretty good, offers boards opportunity to come back and so on to consult with ACMUI and bring this information to the Commission, not just summarily take them off the list.

MS. HOLAHAN: But what I'm hearing you say, and I hope I'm not speaking for anybody in particular, but you think of review process as

probably the best way rather than review of medical events. Okay.

MR. HENDEE: Why set yourself up with an impossible criterion to satisfy.

MS. HOLAHAN: Yeah.

MR. HENDEE: I did have another question. It's on a different issue slightly. Is that okay?

MS. HOLAHAN: Un-huh.

MR. HENDEE: I'm still a little confused. It's actually in Part 35 as it currently exists. Maybe you can help me with this. I know you're going to extrapolate it, but it's the 70 years of experience, 70 years of education before you can become recognized as an authorized user or as an authorized --

MR. BROSEUS: Well, no, seven years is the recentness of training.

MR. HENDEE: Yeah, recentness of training. Who does that pertain to and what do you mean by "training" and "recentness of training"? Can you just clarify that?

MR. BROSEUS: Suppose somebody got board certified eight years ago, and that's what they used as their basis for wanting to be an RSO. If they

didn't have training and experience that kept them up along the way, they don't qualify.

MS. HOLAHAN: Or worked in the field.

MR. HENDEE: Of course, you recognize that at least from the Board of Radiology's point of view, and the other boards can comment, our recertification process is on a ten-year cycle.

But I think what you're saying is that if you're an authorize user, you are by definition gaining experience and training. So you would meet that seven years' requirement.

So how do you not meet it? You stop practicing for several years?

MS. HOLAHAN: Yes.

MR. HENDEE: And then you come back?

MS. HOLAHAN: Un-huh.

MR. HENDEE: And then you would need to have within the last seven years some additional education and experience.

MS. HOLAHAN: Yes.

MR. HENDEE: And what would that -- what would constitute that? Just some CME?

MS. HOLAHAN: I haven't checked.

MR. BROSEUS: What does a board require?

MS. HOLAHAN: No, I'd have to check.

MR. BROSEUS: To maintain certification. That's part of it, too, really.

MS. HOLAHAN: Well --

MR. MAUER: It would seem to me that you would have to redo the minimum training requirements all over again.

MR. BROSEUS: Okay.

MR. HENDEE: Yeah, the problem here is I think the answer would be, yeah, we've got a maintenance of certification process underway now, but it's on a ten-year cycle, and yours is on a seven-year cycle. I think the only problem here is the difference in the cycles.

I mean if you had it at ten years --

MR. VANEK: I don't know. I think if, for instance, you know, years ago I was RSO on a broad scope license. Well, now I've been doing radiation, just strictly radiation oncology for a while.

So if I came back and said now I was to be RSO on a broad scope license again, does that meet the seven years or is that -- I mean I've been still active, but it's just that I've not specialized primarily in radiation oncology. Does that mean I'm not --

MR. HENDEE: We're all kind of guessing as to what it means. We're looking to you to help us under --

MR. VANEK: Right, right, and I'm trying to throw out another example on that seven years.

MR. BROSEUS: That's kind of a Q&A for the existing rule really as how would one evaluate the training and experience. What does it take to be -- and it varies between authorized user, radiation safety officer, et cetera, because the American Board of Health Physics certification is good for four year, physicians for ten years.

Is it a real issue?

MR. HENDEE: It's only --

MR. MAUER: Doesn't the language say "training and experience or equivalent experience"?

MS. HOLAHAN: Yes.

MR. MAUER: It says "equivalent." So it gives a lot of flexibility, and that's -- well, I think the way it's worded is adequate.

MR. BROSEUS: Okay.

MS. HOLAHAN: Okay. Sally?

MR. BROSEUS: Come to the mic.

This is Sally Merchant from NRC's Office of Enforcement.

MS. MERCHANT: Is this turned on?

I would only comment that that's unchanged from the previous, and it's very, very seldom that we look at training and experience for an applicant to be an authorized user where recentness of training even comes in as a question.

In the past when that has happened, it has to be reviewed on an individual basis, and we've most frequently taken to the ACMUI and said, "Here's Dr. So-and-so. Here's what he has been doing the last seven years. Doesn't quite meet. What do you think?"

And they generally come up with, well, if he does, depending on the individual, this, this, and this, then he will meet. So it's something that the staff generally -- it's not within their expertise for each individual physician who -- I don't know if I'm being clear.

He obviously doesn't meet. So the licensing reviewer can't just put him on, but they also would not make some sort of decision because it's not within our expertise to say that physician X should then do this, this, and this, and we think he would meet.

We do take it to the advisory or have

taken it the advisory committee in the past, and there has never been an issue about it. I mean, this is not new.

MR. HENDEE: I'm very happy with that answer. I didn't understand it then. I understand it better now. I'm perfectly happy with the answer.

MS. HOLAHAN: Okay. Thank you.

MR. BROSEUS: Do you think we're ready to open it up for public --

MS. WASTLER: I was going to suggest --

MR. BROSEUS: One more.

MR. VAN DECKER: I only want to say one last thing here. I just want to make sure that we just touch base on it, and that's agreement state recognition. I guess there's nothing that we've said here that has kind of changed with our beliefs we're rolling into this, that we would have one standard of care across the United States of America at a certain point in time with agreement state acceptance of some of this.

MR. BROSEUS: Let me state it a different way. The training and experiential requirements and so on -- and correct me if I say it incorrectly -- are Category B.

MS. HOLAHAN: Compatibility B.

MR. BROSEUS: Compatibility B, yeah.

And so we're not changing that, what they're held to, the states. Okay?

Now, states may implement somewhat differently, okay, but they can't change the basic standard.

And I think we mentioned a little bit more about this before you came in, Dr. Van Decker, and that is, you know, now in the rule agreement states may list or recognize boards, and there's no change to that.

The working group was also looking at tying de-listing primarily back to the state that listed. That's something that you may want to think about, but you know, if a state recognizes a board, we're thinking about, you know, having the primarily responsibility for maintaining, so to speak, the listing be with the agreement state, and also to list on the Web site the state that recognized the board.

Yeah, Howard.

MR. DICKSON: Just one other thing. I just don't feel like we've covered the maintenance aspect quite adequately. I'm not sure what you're looking for there.

I understand that you would expect the boards to make an initial application, but it looks like you're expecting some continual dialogue with the board with regard to any change in the requirements for certification.

Now, I realize those are slowly evolving kinds of things for the most part. So there wouldn't be a lot of communication, but is there going to be some obligation on the board's part to reveal any changes to the NRC which may happen ten years down the road?

MR. BROSEUS: Well, that's one of the things we talked about earlier, and that we would see it as being a responsibility of the boards to notify the Commission if --

MS. HOLAHAN: If there are substantive changes.

MR. BROSEUS: Yeah, for substantive changes in their process.

MR. DICKSON: What would the penalties be if they did not?

PARTICIPANT: De-listing.

MR. BROSEUS: Well, then I would --

MR. DICKSON: Would they be de-listed?

MR. BROSEUS: No, no. Then the staff

would have to deal with it on an individual case.

MR. DICKSON: Well, I'm thinking that there are certainly minor changes that do occur, like passing point determinations. I'm not sure that you --

MS. HOLAHAN: That, yes.

MR. DICKSON: -- would be particularly interested in those kinds of changes.

MR. VAN DECKER: I suspect if you took your radiation safety questions off your test.

MS. HOLAHAN: Yes.

MS. WASTLER: That might create a problem.

MS. HOLAHAN: Yeah.

MR. MAUER: It's rare that the boards would be changing things. Usually it's adding things, if anything, but as long as they continue to meet the minimum training requirements, it wouldn't -- I assume you'd have to inform the NRC.

MR. BROSEUS: And require preceptor statements

MR. MAUER: And require preceptor, but any -- so it may be that the language that you use in specifying that would make clear that changes in the board training program --

MS. WASTLER: You can add all you want.

MR. MAUER: You can add as long as you don't change the core requirements for the T&E that are required by the NRC and the preceptor statement.

MS. WASTLER: Well, those are very specific words that I think might be appropriate. No?

You're shaking your head.

MR. BROSEUS: You talked about what the board's process is in the training area.

MR. HENDEE: Did you write them down?

MR. BROSEUS: Well, we'll have them in the transcript.

I'll bet they're in your testimony for this afternoon. No?

Okay. We'll go back and look at, you know, what people said here.

MS. WASTLER: Unless there are some additional points the boards at the table would like to discuss, I think it would be a good time to open it up to questions from the audience.

I'd just ask that when you come to the mic you please identify yourself for the transcriptionist.

MS. FAIROBENT: I'm Lynne Fairobent.

I'm the Director of Federal Programs for the American College of Radiology, and I'll give you my card afterwards.

There's a couple of things that I think do need clarifying that perhaps weren't brought out in the discussion earlier.

First, just by way of clarification on your recentness of training discussion, there is a response in the Statements of Consideration on page 20294 of the April 24th publication of the final rule that addresses this, and in fact, it does say that these would be referred back to ACMUI on a case-by-case basis as necessary.

So there is, has been deliberation on that issue.

The other thing i would like to get some clarification on is recognizing the fact that the agreement states have an additional three years to promulgate their compatible regulations with NRC, I find it a little hard to imagine that an agreement state would, in fact, be the first one to recognize a board that NRC has not already reviewed and determined whether recognized status should be granted.

I think that it would be helpful in the

discussion on the rule, especially on the implementation criteria, to have language included that addresses if a board is recognized by NRC. If this is correct, then there is no need to apply to a specific agreement state to obtain recognized status by that state or vice versa.

If for some reason a board applies to let's just say the State of Texas first for recognized status, and Texas grants recognized status, there then is no reason to apply to the other 31 agreement states and/or NRC for recognized status.

I think that that would be helpful to have that clarification in there, and along with that there may be some reason to consider the case that if a board applies to NRC for initial deemed status and is denied, what happens if they then apply to an agreement state and are accepted, or is that even an option?

For example, so if NC has denied deemed status and rather than the board coming back and working with NRC goes to the State of Texas and Texas finds their process acceptable and grants deemed status, I don't know if we're getting into a potential area. Hopefully that would never happen,

but in looking at all of the previous statements of consideration and responses to comment, I have not seen discussion on those items, and I think that that might be very helpful as you're refining the implementation criteria for review and approval of board status.

And the only other thing I would ask is in looking at de-listing criteria is to consider there has to have been some criteria used over the multitude of years when the original Part 35 and Subpart J was in existence, and although the boards were hard wired in, I can't imagine that there hadn't been consideration given to what would happen if a hard wired board no longer should be hard wired.

And I would just think that if there is history on that, that that should be reflective in how one goes forward in a de-listing process.

MS. WASTLER: Okay. Thank you.

MR. BROSEUS: Thanks, Lynne.

MS. WASTLER: Thank you very much. We will consider those.

MR. UFFELMAN: I'm Bill Uffelman, General Counsel and Director of Public Affairs in the Society of Nuclear Medicine. You have my card.

I guess following on my 29 years' experience of drafting regulations and laws, Part 356 is a toughie, and I guess a couple of comments.

And Dr. Mauer raised the issue, and you responded. One of the things that I think you ought to give some consideration to in this or make some forward thinking how we're going to deal with it in the future is that the reality between unsealed source and sealed source is more a reality of the route of administration rather than whether, in fact, it was deemed to be a sealed source in the case of a SIRSphere or TheraSphere, and as you said, the unsealed material that, in fact, is administered as if it was a traditional sealed source.

Whether that means there needs to be a point three-something or other that says that physicians who are trained in this route of administration, you know, can, in fact, be qualified to use these materials or something, there ought to be a way to, in fact, you know, spell out in the rule that there are people who are, in fact, qualified to do things that don't fit exactly in the .390, .490 breakdown that you have established.

There's a space in between, if you will, that both, in fact, can cross into.

Going back to the de-listing, I'm not sure and maybe I missed it somewhere, who initiates the de-listing process. Can, in fact, there be a complaining witness, if you will, that writes you and says, "I've noticed that people who are going through a program" -- and perhaps it's -- you know, one of the issues I have is that -- and let's step away from the board. Let's just talk about an alternate process, the B process, if you will, as it is in most of these.

Whether in fact there's a preceptor out there who is signing off on people, you know, we have the training program du jour, if you will, that somebody said, you know, "I can make money doing this," and they're doing it, and they are, in fact, signing off as a preceptor.

Who, how do you identify an individual who perhaps is abusing the system that, as former counsel of Medical Malpractice Study Commission of the State of Indiana, you know, it may not be malpractice, but there's something fishy, you know, going on, and you perhaps need to, whether it's in the rule or, God forbid, guidance that you spell out, how, in fact, that process -- you know, that there are a list of people who are deemed to not be

qualified to sign off on certain activities and individuals.

MR. BROSEUS: Do you have a suggestion?

MR. UFFELMAN: What the process would be?

MR. BROSEUS: For identifying these people.

MR. UFFELMAN: These people?

MR. BROSEUS: Yeah. You said don't put them in the rule and don't put them in guidance. What would you do?

MR. UFFELMAN: Well, I'm saying it could be in the rule, but I don't see lots of words in the rule about de-listing, but you, in fact, should have a provision that a method for complaining, for a complaint to, in fact, be filed, and it puts it into due process; that an individual who is acting as a preceptor under, you know -- pick a number -- 50, 290, 390, that they, in fact, are not qualified, and then you would have to have a hearing process by which you would determine whether, in fact.

And that then may mean that they get referred back to their appropriate -- you know, how did they become a preceptor? Did they get it by board? You know, do you go back to their original

board that certified them and have them de-listed?

You know, you'd have to think about all of the train that that entails, but there ought to be a process that there are people who can't do this.

I think those would probably -- you know, you've discussed and highlighted and cussed and all of this. I think you're doing a good job, and I commend you for that.

MR. BROSEUS: Thanks.

MS. HOLAHAN: Thank you very much. Those are very good --

MR. BROSEUS: Great comments, yeah.

MS. HOLAHAN: Great comments. Thank you.

MR. BROSEUS: Yeah.

MR. HEVEZI: Hi. I'm Jim Hevezi, representing the American Society of Therapeutic Radiology and Oncology, and I'd just like to make a couple of comments.

With Dr. Uffelman and Dr. Mauer, radiation oncologists are also part and parcel of the users of some of these unsealed sources. There are a lot coming into the fray now with monoclonal antibodies and the like.

Either specialty if they have the required training can use these to help patients, and they probably come from a different direction, but nonetheless, I think the comments made are appropriate in terms of allowing either/or or both to use these radionuclides.

The second comment concerning the radiation safety aspects of new technologies Dr. Vanek and Dr. Hendee addressed, and I'd like to support that. Being a radiation oncology medical physicist, we have a radiation safety officer that oversees all of the compliance that we as practitioners need to adhere to during any particular procedure.

For example, high dose brachytherapy. Certainly the radiation safety officer can't do what we do in the planning and administration with the radiation oncologist for patient care, but he or she can insure that we're complying with all of the rules and regulations that in Texas -- we're an agreement state -- that Texas has set out for us.

And so even new technologies, and as Roger mentioned, new compliance issues will come to the surface as these new technologies get implemented, and the radiation safety officer will

have to insure that they institution and the practitioners are complying with those issues.

That's my comments.

MS. WASTLER: Thank you very much.

Are there any other comments?

(No response.)

MR. BROSEUS: If there are no other comments, there's one member of the working group who joined us midway through. Ron Zelac over here is with our Materials Safety and Inspection Branch, and I'd like to recognize his contributions to the working group.

They're actually our client. At Rulemaking and Guidance, we write the rules, and we have clients, and they are the ones that execute these things, including the implementation.

Sandy, I want to go ahead and wind up.

MS. WASTLER: Well, unless there are further comments.

MR. BROSEUS: I want to express my gratitude to all of you for the time you've taken to think about these issues, to come here and give your considered opinions, and know that we are going to work to do the best we can to give you a good rule.

MS. HOLAHAN: I'd just like to say,

again, my thank you, and if you think about anything on the way home, we'd appreciate your comments by May 30th.

MR. HENDEE: Well, can we respond by expressing our appreciation for your openness today? We're all trying to accomplish the same thing here, working together, and I think this has been a good meeting, and I think you have certainly clarified a lot of issues.

I think you've made it possible for us to work with you and function with you to get this rulemaking going.

So we appreciate very much the open atmosphere in which we've had this discussion.

MS. HOLAHAN: Thank you very much.

MR. HENDEE: Thank you.

MR. BROSEUS: If there are no further questions or comments, we're adjourned.

(Whereupon, at 11:36 a.m., the meeting was concluded.)