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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TUESDAY,

APRIL 12, 2011

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The Advisory Committee convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., LEON S. MALMUD, M.D., Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chair

BRUCE THOMADSEN, Ph.D., Vice Chair

DARRELL FISHER, Ph.D., Member

DEBBIE GILLEY, Member

MILTON GUIBERTEAU, M.D., Member

SUE LANGHORST, Ph.D., Member

STEVE MATTMULLER, Member

JOHN SUH, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

JAMES WELSH, Ph.D., Member

PAT ZANZONICO, Ph.D., Member

MEMBERS ABSENT:

CHRISTOPHER PALESTRO, M.D., Member

NRC STAFF PRESENT:

JIM LUEHMAN, Deputy Director, Division of Materials Safety and State Agreements

MICHAEL FULLER, Alternate Designated Federal Officer

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

NEELAM BHALLA

JUNE CAI

SUSAN CHIDAKEL

SAID DAIBES, Ph.D.

SARENEE HAWKINS

DONNA-BETH HOWE, Ph.D.

ANDREA KOCK

VARUGHESE KURIAN

ED LOHR

JULIE MARBLE, Ph.D.

PATRICIA PELKE

JOSEPHINE PICCONE, Ph.D.

GRETCHEN RIVERA-CAPELLA

GLENDA VILLAMAR

SHIRLEY XU

MEMBERS OF THE PUBLIC PRESENT:

KEITH BROWN, University of Pennsylvania

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association of Physicists in Medicine

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Mercy Hospital

CANDI MCDOWELL, Georgetown University

JANETTE MERILL, Society of Nuclear Medicine

HERBERT MOWER, Ph.D., American Association of Physicists in Medicine

MIKE PETERS, American College of Radiology

AMANDA POTTER, American Association of Physicists in Medicine

JOE RODGERS, Theragenics

GLORIA ROMANELLI, American College of Radiology

CINDY TOMLINSON, American Society for Radiation Oncology

ANN WARBICK-CERONE, MDS Nordion

JENNA M. WILKES, American Society of Nuclear Cardiology

GARY E. WILLIAMS, Veterans Health Administration

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

(8:09 a.m.)

CHAIR MALMUD: Good morning, everyone. Welcome to the second day of this session. And we'll get started now with the opening remarks, which Mr. Fuller will give.

MR. LUEHMAN: Mike.

CHAIR MALMUD: Mike, you are on.

MR. FULLER: Thank you.

10) OPENING REMARKS

MR. FULLER: Just briefly I wanted to say welcome, you know, to the second day of our meeting with the Advisory Committee on the Medical Use of Isotopes and also to kind of recap just a little bit in very general about yesterday.

I think, in my opinion, we had a very fruitful discussion yesterday and some good outcomes. I will also mention that we are working the issue and are if everything works out planning to move one of the public workshops from June to August, the specific dates and locations to be determined soon. And no one that we talked to yesterday seemed to think that there was a problem with that.

Again, the critical point was whether or not the Brachytherapy Subcommittee, the Permanent

Implant Brachytherapy Subcommittee, would have ample time to gain what they might gain from the deliberations at the workshops, but given yesterday's discussion and what we anticipate will most likely come from the workshops with regard to the ASTRO physician and others, then it looks like that a month or six weeks between the August workshop and the September meeting should be ample time. So based upon that, we're going to work and plan to move one of the workshops.

Again, I think yesterday was a very good, very fruitful meeting. And we gained a lot of information. And we appreciate your insights and comments.

Today we are going to start. I'll give just a very brief overview. We're going to be talking for a while about efforts in rulemaking space for extending grandfathering to certain certified individuals.

And then after that, we will have a discussion on some efforts underway for rulemaking in the preceptor attestation requirements. And then after lunch, we will have a discussion on the public dose limits for patients released who have administered potassium iodide or radiopharmaceuticals

and whether or not we need rulemaking in that area.

So, with that, again I'll say thank you for yesterday. I look forward to today. And I'll turn it back over to you.

CHAIR MALMUD: Thank you.

The next item on the agenda is entitled "Extending Grandfathering to Certain Certified Individuals, the Rulemaking." And that will be presented by Ms. Bhalla and Mr. Lohr.

11) EXTENDING "GRANDFATHERING" TO CERTAIN CERTIFIED INDIVIDUALS RULEMAKING

MS. BHALLA: Good morning, Dr. Malmud, members of the ACMUI, and members of the public. The topic we are going to be opening for discussion is the issues that were brought forward to NRC through a petition for rulemaking. Mainly the petition is Ritenour's Petition.

A little bit about the background. Again, Part 35 was revised in 2002 in its entirety. There were issues related to training and experience requirements. And so that part of the rule was finalized in 2005. And to provide continuity between the old Part 35 and the new Part 35 T&E requirements, the subpart J of the old regulations was effective under October of 2005.

Now, what are the pathways for authorization? There are three pathways. And an individual may be certified by a recognized board. Another one is the approval based on an individual's T&E, which we call it -- mostly it is referred to as the alternate pathway.

And then there is the third one, and this is the identification of an individual and then NRC or an Agreement State license. And, of course, in the regs, not only just the licenses, you could be on master material license. You could be a permittee on a broad scope license and so on.

So that is the third pathway. And the petitioner referred to this third option as the grandfathered pathway. And in our regs, it's under 10 CFR 35.57.

Petitioner's concern was that 2005 T&E regulations have inadvertently affected a group of those certified professionals. And these individuals must now apply through the alternate pathway. And alternate pathway places an undue burden and could result in short data, AMPs and RSOs, AMP being the authorized medical physicist, RSO being the radiation safety officer.

NRC resolved the petition in May 2008 and

concluded that 2005 position may have adversely affected some board-certified professionals, including the authorized users.

NRC said that issues raised in that petition will be considered for rulemaking if a technical basis can be developed.

I think in your books these slides are supplemental information, but, nonetheless, here they are. So we are going over these.

So in October 2008, NRC staff asked certifying boards to survey their diplomates, who are already affected by the 2005 T&E provisions.

Then responses were received from five of the nine. And from the data collected, we believe that approximately 10,000 individuals may potentially be affected. And potentially, you know, it's not that these people are affected right now, but maybe in the future, they could be.

So the petitioner requested to medically clarify 57, to recognize both 35 medical physicists for the modalities they practiced as of October 24, 2005 and also to recognize all diplomates for RSOs providing the appropriate preceptor statement.

So what is for discussion here is that in the 35.25 expanded rulemaking, one of the items under

consideration is the attestation requirements. And you will be hearing more discussion on that in the next talk.

So what is for discussion? However the staff proposes to maintain attestation requirements for grandfathered individuals. Okay. So that is for discussion that we believe that although the board certification may go away for the certified individuals in the expanded rulemaking, but for this particular group of people means those who could come in that are grandfathered, that we do maintain the attestation requirements.

And we would like to hear ACMUI and members of the public discuss this.

CHAIR MALMUD: Thank you.

Would it be helpful if we took the items in your slide number 8 under discussion and separated the two and first dealt with the first bullet, which is in Part 35, expanded rulemaking removal of the attestation requirement for board-certified individual is under consideration. Would it be helpful if we just got that first and then --?

DR. HOWE: Dr. Malmud? I have a talk coming up right after this on the attestation issues.

CHAIR MALMUD: All right. So, then, just

--

DR. HOWE: If you defer it to mine.

CHAIR MALMUD: So this is just for discussion at this point. Is that correct?

MR. FULLER: I think we should focus primarily on bullet number 2. And, then again, we'll have this next discussion. Dr. Howe will lead the next discussion on the question about removal of the attestation requirements for board-certified individuals if that's okay.

CHAIR MALMUD: That's fine. That's fine. Then Dr. Howe is going to deal with that. Should we defer the discussion until Dr. Howe's presentation, --

MR. FULLER: Yes.

CHAIR MALMUD: -- rather than discussing it now?

MR. LUEHMAN: Yes

MS. BHALLA: Yes, maybe there is -- maybe I can explain this a little bit. What is for discussion is really that if the Commission is considered to take away the requirements of attestations for the board-certified individuals, then technically this, for the grandfathered individuals, technically that would go away.

But what we are presenting here is that

for the grandfathered individuals for this particular class of would-be applicants, that we maintain the attestation requirements. And this is up for discussion.

CHAIR MALMUD: Yes. I understood that. My question is not about the two bullets. It's about when we should discuss them. If Dr. Howe is going to be presenting --

DR. HOWE: I have bullet number 1.

CHAIR MALMUD: I'm sorry?

DR. HOWE: I have bullet number 1.

CHAIR MALMUD: All right. So, then, Dr. Howe will discuss bullet number 1.

MS. BHALLA: Correct.

CHAIR MALMUD: So, then, the current discussion should focus on bullet number 2. Would that be acceptable? Okay. So we're now going to discuss bullet number 2 first because we're going to defer number 1 to Dr. Howe.

Debbie?

MEMBER GILLEY: Yes. Could you provide the technical basis for this particular suggestion of leaving attestation in for the grandfathered individuals?

MR. LOHR: I would be glad to speak to

that. I was the project manager that resolved this petition. In resolving the petition, within the NRC, the staff takes their recommendations to a board of senior managers.

And the senior managers then vote whether to accept the recommendations from the working group or not. And then it goes on up to the Office of Operations. And they send it on over to the Registrar.

But during the actual working group deliberations and recommendations to the review board, we established our rationale for why the attestation should be required for individuals to be grandfathered who are not currently in the regulation.

And it goes back to why we grandfathered them to begin with in 2002, in 2005, and the final. And that is that their credentials, those people who are listed on the license, had been reviewed by somebody, an Agreement State of NRC, and placed on license based on that review.

And the second part of that was because they were on a license that meant that they had established an acceptable record of performance. Those are the words that we used.

Using the same criteria, we applied that

to those individuals who were not named on a license in 2005, when subpart J went away, but who had been working in the field. The petitioner had asked for those individuals to be recognized for the modalities that they were performing at that time.

And so we applied that same logic in the suggestion to the review board for accepting this petition in that we said that if they were board-certified by I believe it is ABR or ABMP -- and you guys know these initials far better than I -- that that was like having their credentials reviewed by a licenser person. They passed and they were board-certified.

And then we said, well, to have an acceptance performance just says you were listed on a license, we accepted that in 2005. We would accept an attestation, which basically says that the individual can function in those modalities.

And so that was the rationale that the NRC applied to considering this particular petition and rulemaking. That was accepted by NRC management. And, of course, that's what went out in the Register.

Now, you don't see those finer details in the Register notice, but I wanted to explain that rationale since you asked. And this is why the staff

is now at the point where we are going into rulemaking and now we have this premise that we have put forth or this rationale as to why we should be able to grandfather these individuals who had not done so in 2005.

But it seems to go up against the other piece, if you will, bullet number one, of removing attestation for all board-certified, recognized individuals.

And so if we, the staff, because of the premise of the petition, were to have an attestation to provide that record of acceptance performance, if you will, now we're in a slight dilemma.

And so we wanted to bring this forth to the ACMUI and to the public to get your feedback on that.

Does that help some?

CHAIR MALMUD: Yes. Thank you.

MEMBER GILLEY: Could I just ask a hypothetical to clarify this? Someone who is board-certified as a medical physicist in 2004 as a board certification and they want to commence to be able to do HDRs and they have had proper training, are you going to require an attestation letter from somebody who is board-certified in 2004?

MR. LOHR: If they were not grandfathered in the 2005 T&E, therefore, the NRC does not have a record of performance. And that was the basis, then, for asking for an attestation for that, unlike somebody who was grandfathered in or listed on a license. They had set the record of performance, if you will.

MEMBER GILLEY: But if they were board-certified in 2007, after you recognized the board, there would be no attestation. Is that correct?

MR. LOHR: Under current regulations, there is an attestation, but that is proposed to be removed.

MS. BHALLA: Well, we --

MEMBER GILLEY: No. Go ahead.

CHAIR MALMUD: Sue?

MEMBER LANGHORST: Okay. For RSOs, being grandfathered, you had to be named on a license. And so there were many board-certified individuals, certified health physicists, that couldn't be grandfathered in because they were not named on a license.

Now, my understanding is that that certification board was approved by the NRC with no changes in how it did its certification and its

review. So I find this to be very constraining and not fairly applied to all certified health physicists. I just don't understand why a person who was board-certified at that time would need an attestation at this point in time.

It is not fairly applied. It is going to be very challenging for licensees to track who needs it, who doesn't need it. And that means it is going to be very challenging for NRC and the Agreement States to figure out who needs it, who doesn't need it. It seems very unnecessary and a lot of make work in my opinion.

MR. LOHR: May I address the first part of your comment? The board has recognized that the process is recognized by the NRC currently. And it is retro-ed back past 2005. Then they are not grandfathered. They are recognized by the NRC, as I understand this already.

So if, for example, you were board-certified in 2004 and that board's processes were recognized by the NRC after the 2005 and it was retro-ed back to -- I don't know how far they went back on some of these 2002 -- to 2002, that individual is recognized and would only need what is under the current regulations.

We're speaking to those individuals whose board processes were not recognized and retro-ed back past 2005. And those individuals who -- you're looking puzzled.

MEMBER LANGHORST: Yes. I thought you just said that -- okay -- was before 2002. See, this is very confusing to me.

CHAIR MALMUD: Yes?

VICE CHAIR THOMADSEN: Can you say which boards you're talking about?

MR. LOHR: Donna-Beth would probably be able to mention those boards better than I. They are on our website. It is something that the medical team keeps track of.

And I know that each board has a different date that it is retro-ed back to. And it is based upon their recognition of their processes that was done after the 2005 rulemaking. I do not know which boards go back how far without looking at the website myself.

MEMBER LANGHORST: I know I am speaking about the American Board of Health Physics.

VICE CHAIR THOMADSEN: Health physics.

MEMBER LANGHORST: Right.

VICE CHAIR THOMADSEN: I do know that.

MR. LOHR: That can be looked up. It's on our website. I do not know how far it goes back.

MEMBER LANGHORST: So whatever date it is, so if someone is certified prior to that, which that would be my case because I was initially certified in, oh, '80-something, when I was 9, --

(Laughter.)

MEMBER LANGHORST: -- and if I were never named as an RSO, then this is what would apply to me. If I wanted to become an RSO, I would have to be -- I would have to have an attestation signature. That is what you are saying?

MR. LOHR: That is correct. And that is based on the rationale that the NRC applied when they created the grandfathered clause in the 2002-2005 team leader rulemaking. And that is that if you were named on devices, that was considered you had acceptable performance. Okay? And then, of course, you had your board certification. Those are the two pieces of the puzzle.

When we move forward in time, again, if we used you as an example and let's say you were not named --

MEMBER LANGHORST: Right. Right.

MR. LOHR: I know that you are.

MEMBER LANGHORST: Right.

MR. LOHR: -- if you were not named, then we would say, "Okay. Your board certification serves as a board certification. And then the attestation would serve as your performance," just as we applied it for all of the original folks who were grandfathered.

So we tried to bring that concept forward, rather than to create something new. That is what the NRC applied as the logic, if you will or the rationale when they did the grandfathering clause to begin with.

VICE CHAIR THOMADSEN: Thank you.

Dr. Zanzonico?

MEMBER ZANZONICO: Well, I have a question and a comment. This really strikes me as kind of bureaucratic tail wagging the dog. I mean, if people are board-certified by a recognized board whenever that recognition was given, to me that is the professional recognition of competence to perform the duties of that certification.

So why don't they just end the need, regardless of the time frame, to now require additional attestation because of some arbitrary point in time, you know, when that recognition was given?

The other issue I have is for states like

New York, where medical physicists are licensed. How does that play into it? If a person has been licensed and is practicing in New York State and several other states as a licensed medical physicist, would they be required to have attestation if they didn't happen to fall within the appropriate time frame? I mean, it just raises a logical and practical consistency.

The other issue, of course, is that the people qualified to provide attestation will no longer be allowed at this point, you know, retired or deceased or moved on. And so who is going to provide that attestation? Someone who was there after the person is really certified, so to speak, had to have been there and practicing. They wouldn't be qualified other than in some legal sense.

So there are a lot of issues and inconsistencies which this raises.

VICE CHAIR THOMADSEN: Would you care to address Dr. --

MR. LOHR: I can address this first comment, I believe. And that is when the NRC decided in 2002 in the rulemaking to have all the boards to have their processes recognized -- all the boards, across the board, so to speak, had to resubmit their processes to the NRC for recognition.

During 2002 to 2005, we retained subpart J. So you had an option. You could go the new route if your board's processes were recognized or if you could go the old route where it was just listed in regulations.

In 2005, the subpart J expired. All those boards who had their processes recognized by the NRC did so by submitting things to the medical team. And they reviewed them, and they set dates. They were not arbitrary. They were based upon the data that was provided by the boards themselves based on the criterion for recognition by the NRC.

So a board that was recognized prior to 2005, if you will, since the grandfathered was still in effect had to have its processes recognized by the NRC for the board to be considered now for their certification plus the attestation, for it to be listed on a license.

So I understand your comment about once you are board-certified and what that represents, but that was across the board for all boards, not just one specific one, picking on one of the boards.

The idea -- I was not part of it, but from reading everything, the idea was that they wanted to put all the boards on the same level again for

recognition. And there were some T&E issues.

I believe anybody who has been around during the 2002 rulemaking knows the T&E issues were the biggest, most complex issue that we dealt with during that rulemaking.

So, although your comment is -- and I don't disagree with necessarily -- board-certified shows that you have a lot more professionalism than you can throw on those things. The NRC did not recognize that after 2005 unless the processes had been submitted and then board recertified I guess is the best word. But that's not what they called it. They just called the process being recognized.

During that time, as I said earlier, we had to keep a community function. So the NRC, in its rationale, decided to own the license. That means that you were performing. And if you were board-certified, no problem. We grandfathered you in.

But that left people, then, after 2005, such as you pointed out, Sue, who were RSOs, if you will, but had never been listed on a license function in those rules, so the petition addressed that issue to the NRC.

This is our proposal to go back out to be able to recognize those certifications, you know,

those board certifications and those individuals for the modalities as we said they were working under to bring them forward with the rest of the group to grandfather them in.

To do that, though, the NRC felt like it was always petitioned that we needed to have something that showed that they had an established acceptance of performance, just as we brought the other folks grandfathered in to have the safe criteria applied.

So, again, we're trying to bring that same criteria and apply it forward in fairness to all people who are board-certified. So that is our attempt. Now, I am not going to say we are perfect at it. And this is why we bring this forward because if, indeed, it is decided not to have attestations for board-certified individuals in the future, then that brings the petition into question on how we resolved it.

Does that rationale now apply? Do we have to redo the petition? It brings up a whole bunch of different questions. And so we wanted to put that out here for discussion.

We, as has been said here many times, are here to listen. I'm just trying to explain the rationale of how we got where we're at. I'm not

trying to express an opinion.

MEMBER ZANZONICO: But can you address the situation with the licensed individuals in certain states? It makes it sound like they have gone through an additional round of certification by states. And now there could be cohort of individuals, who were certified, licensed by the state, may be unemployed in '05, and now have another round of competence review required.

MR. LOHR: I don't believe the NRC recognized state licensures of any profession as a criterion for being an authorized user. Is that correct, Mike? I don't believe that is the case.

MR. FULLER: Probably not. With Chairman Malmud's permission, I would like to kind of maybe move this discussion just a little bit to a different place.

As we stated yesterday and we stated today, we are early in the process of developing proposed rules for the 28 items and so forth that came up.

I know this one is very complicated and complex. And it has been discussed and debated at previous ACMUI meetings and so forth. I am a little concerned that the NRC staff is doing a lot of

talking.

And what I would like to do is unless there are specific questions that someone has that we could add just to try to clarify, I would like to request that you provide us with your concerns and your comments and your interests. And let us get back into the listening mode and take those comments and concerns and consider them as we move forward in the working group, as opposed to trying to solve the problems right here and have the staff, you know, try to explain what we were trying to do.

We are early in the process. We can adjust. We can accommodate. But I would like for us to try to get back into the listening mode if at all possible.

MEMBER MATTMULLER: Yes. The --

CHAIR MALMUD: Excuse me. I think Debbie Gilley was next.

MEMBER GILLEY: I just come from a state that has medical physicist licensing. And we have run into some problems with the certification process for medical physicists.

One is they have to be board-certified to be licensed in the State of Florida. So there is no alternative pathway, even though we were required to

put that alternative pathway language into our regulation. It is a moot point. You can't use it at all.

Second, if you are board-certified, licensed in Florida, it is a right-to-work state. So we have issues with not putting people on the license who are state licensed medical physicists that went through the board certification process prior to 2006. We have already run into some problems with that in my state that does have medical physics licensure.

CHAIR MALMUD: That is one example of one state. There may be other arrangements or mal-arrangements of the same kinds of processes.

MS. BHALLA: I know the staff is not supposed to be talking, but just this is a dialogue here. I just wanted to ask them, are they named on a license?

MEMBER GILLEY: They are now named on a license. They were not named on a license prior to 2005. We did not name our medical physicists on the license except for cobalt teletherapy and Gamma Knives.

MS. BHALLA: Okay.

CHAIR MALMUD: There was another. Sue?

MEMBER LANGHORST: Yes, Sue Langhorst.

Logistically I would like to see how you all would think for a radiation safety officer who was grandfathered in and got attestation to -- or who was not -- well, however you're applying this with an attestation and has a license with HDR and then a Gamma Knife, they want to have a Gamma Knife come in.

Would that RSO then have to get another attestation in order to have that type? I mean, would that be a continuing thing that we would have to track RSOs who were board-certified and didn't need an attestation and now when you have to track them, they're board-certified but don't need an attestation?

I am confused. I am confused as to how that would be applied.

MR. LUEHMAN: I think the question, Neelam, is, did we have -- is that any license or is it a license modality specific license? In other words, if you were named on a license for an HDR and then you were going to go and be on a license with the Gamma Knife, were you named --?

MEMBER LANGHORST: Yes, I think --

CHAIR MALMUD: Is a license a license or is it modalities?

MS. BHALLA: I think, our regs, the way they are now, you have to be for that, the know-how in

that particular thing. It's in the modality that --

MEMBER SUH: So if I am an RSO that needs that attestation all the time, I'm not sure where I get it because I'm just now applying for a Gamma Knife license. How do I get attestation from an RSO when I'm an RSO already and -- I mean, I just don't understand how it is supposed to work other than the manufacturer signs off a statement that says, "Yeah. She's trained. Good luck."

CHAIR MALMUD: As you can tell, there is considerable ambiguity and confusion among the members of the Committee as to what the standards are currently. Would it be helpful if we waited for Dr. Howe's presentation? Because I don't know of anyone who is more knowledgeable about the intricacies of these than Dr. Howe.

And perhaps you can present us with those data and then we can understand questions that we have, the possible answers to the questions that we have. Would that be helpful?

MR. FULLER: It would be. And, just to kind of reflect a little bit, what I'm hearing is that this is extremely complex and it is complicated and confusing. And for me, that is the most important message that we are receiving today so far. And that

is what I wanted to state.

You know, again, we are early in the process. And we need to make sure that we are aware of just how complex and how many layers have been laid on this issue with regard to training and experience. And that is the message I am taking away.

CHAIR MALMUD: I think that that is the message that we wanted you to hear because we discussed this in this Committee, not necessarily with the current members, but this has been an ongoing discussion for years. And there is not clarity. And it is obvious that it is the goal to try to bring some clarity to it. And hopefully we will be able to accomplish that.

I think, though, that it would be useful if perhaps we heard from Dr. Howe. If I may ask a question first? How many individuals -- do we have any idea of how many individuals per 10,000 are eligible for grandfathering?

MS. BHALLA: Let's see. Technically, they all would be, but in the data, the health physicist was about 800-some number those who would be needing that. The ABMP, it is 148 individuals. For the ABR, that is where the largest number came out to be. And it's almost 8,000 radiologists.

That's the one we believe that they had sometimes in the future. Suppose he's a radiologist diagnostic just reading x-rays. Maybe, you know, we plan to do some nuc med at some time in the future. So that's a pretty big number here.

And then because this is ABR board-certified physicists is 415, so we believe that the petition came for the RSOs and the physicists. So that number is about 1,500 or so.

CHAIR MALMUD: Fifteen hundred.

MS. BHALLA: I am just doing a very rough -- so one would think about 1,500 or so.

CHAIR MALMUD: Thank you.

MEMBER GUIBERTEAU: A question. Since this is titled a Ritenour petition rulemaking issue and since you have suddenly narrowed this to RSOs and medical physicists, is there not a consideration here also to deal with the diagnostic portion of this in terms of diagnostic radiologists, radiation oncologists?

MS. BHALLA: That is when the petition came in, the petitioner asked for basically RSOs and the physicists. And these are medical physicists.

It is NRC's initiative that we believe that we resolved the petition, that all of those

individuals may have been inadvertently affected by our rulemaking. And, therefore, this was NRC's initiative to go and survey all the rules.

MEMBER GUIBERTEAU: But you are looking for a solution that will service all of these disadvantaged individuals, not just the original petition.

MS. BHALLA: That's right.

MEMBER GUIBERTEAU: Okay. Thank you.

MEMBER SUH: I have one more.

CHAIR MALMUD: Suh?

MEMBER SUH: So because of the way you resolved the petition, if you do something different than what you recommended and decided upon to resolve the petition, does that delay the Part 35 rulemaking because you have to go back and fix how you resolved the petition?

MR. LOHR: I do not believe it would affect the rulemaking timelines.

MEMBER SUH: Okay.

MR. LOHR: It is something that we have to resolve within the NRC because when we do a rulemaking, it is based on what we call technical basis. The technical basis for this rulemaking is the petition resolution.

So if we no longer have a technical basis that is valid, we have to seek another rationale or something, but it should not affect the timeline on the rulemaking. It is something that we do as part of the process.

MEMBER SUH: Okay. Thank you.

MS. BHALLA: Yes. And that is what we want to hear, that how do you establish for the modalities that you practiced many years ago. We would like to hear that.

Maybe licensure could be an alternative. And these are the things we do here, that what would it be that it is going to establish that a certain individual was good to go. Let's say in the year 2000. So how would we establish that as to what you practiced, the modality you have practiced, or your credentials minus or absent the attestation?

Attestation is what we have in our regulations right now, but we are open to -- and that is the whole idea, is to gather this information to what else do you think would work for us to establish that this individual practiced the modality many years ago?

CHAIR MALMUD: I'm sorry. Yes?

MEMBER GILLEY: There is a recentness of

training requirement in the regulation. So not only do we have board certification. We have documentation of recentness of training in the modality they wish to use within the last seven years.

And that should be sufficient for someone who is board-certified and considered to practice in the profession during that period of time that may not be listed on a license at today's date. That is one way you can overcome this without a letter of attestation is to use that, then.

As Sue was suggesting over there, someone who takes on a new technology, such as a Gamma Knife, that is a board-certified radiation oncologist, there is a recentness of training requirement in that modality called training by to use the Gamma Knife that shows that they at least understand in their proficiency in that without going back to getting an attestation letter from a university or medical school that they went to many years ago.

We see this happening a lot. A lot of physicians, medical physicists are reaching out to new technology. And those technologies are material based. And they may have done nothing but linear accelerators for 20 years, but they see now see the need to take on HDR or Gamma Knife. And it is an issue if they are

not on the license, and they wouldn't be on the license for linear accelerators, wouldn't be on them. But they have been practicing in the profession for 20 years.

CHAIR MALMUD: A member of the public.

MS. FAIROBENT: Thank you, Dr. Malmud.

Lynne Fairobent with AAPM. A couple of things. Since I wrote the Ritenour petition, maybe to clarify when we did submit the petition because physicians are not part of the AAPM member base, we were not able at the time to request resolution or relief for the diagnostic radiologists, but in the background statements on the petition, we did discuss the fact that we felt that it should be expanded to all categories. And NRC did agree when they looked at it.

Neelam or Ed, I believe the survey -- correct me if I am wrong, but the decision to grant the petition was before you went out and surveyed the boards. So I'm not sure that your statement that the survey results was the justification or part of the technical basis but granting the petition is quite accurate in the timeline.

And, you know, since we filed this back in 2006 and asked for expeditious resolution -- and my

memory could be faulty at this point because I don't think five years later we have expeditiously resolved anything.

MR. LUEHMAN: I guess I will comment on that. I think that that may have been a -- I think that the hurdle that the staff is trying to get over in the technical basis is while it may be advantageous that these people get certification, one of the things that we have to do in the rulemaking space is establish not only a technical basis but a safety basis for making the rule change and the point there being that the rules in 2005 may have excluded some people. That may be unfortunate. I don't know that it's a safety issue.

And so what we were trying to do is trying to establish and trying to collect data on is in some way the people that were disadvantaged by the 2005 rule. Was there an actual effect on the community besides a group of people who were not grandfathered? In other words, were there hospitals that were not being served because these individuals could not be certified except through the alternative pathway, which would take too long, because, again, while it was an unfortunate for some of the disadvantaged individuals, if those individuals were not allowed to

practice on NRC licenses, what was the potential? What was the potential safety effect?

If there were enough qualified physicists that were already named on licenses and were coming through schools and in the future would be available, then was there a safety basis to say, you know, we need to do rulemaking to include these other people because not having these other people somehow reduces the level of safety in the availability of these professionals.

I mean, we don't just do rulemaking to include or not include individuals. At the end of the day, our technical basis not only has to be technically sound as to how we get the people in there, but it also has to overcome the hurdle that this is a needed changed, not just a desired change, but this is a needed change to the regulations. So that is one of the reasons that the surveys were done.

MS. FAIROBENT: Dr. Malmud, may I follow up?

CHAIR MALMUD: Yes, please?

MS. FAIROBENT: I would request, then, that staff, when they are developing the new proposed rule changes and also in preparation for the public workshops, that you present where in the 2002

rulemaking there was a safety analysis showing that individuals who had existing board certifications should not have their boards to continue to be recognized because I don't believe it was in the rulemaking.

MR. LUEHMAN: I am not sure I understand the question.

MS. FAIROBENT: Individuals who were board-certified as of 2002 or October 25th, 2004 who may not have been on the license but had been board-certified have been disenfranchised. And that was the basis of the petition.

And you just said that you don't add individuals back unless there is some sort of a safety significance as well. And I'm saying you have already taken individuals off. It would be helpful for the community to understand what the safety basis was to not continue to recognize individuals with board certifications as of the effective date of the new rule.

MR. LUEHMAN: I still don't understand, but I'll just slide.

CHAIR MALMUD: I think that Ms. Fairobent is challenging the basis for the decisions that were made in 2004, 2005 with respect to people who had been

certified in 2002.

Sue, did you? You had your hand up.

MEMBER LANGHORST: Yes. Yes. I think one of the lessons that I think we should all learn from how we got to this point, the language in 35.57, which is all the grandfathering, as I remember, first appeared in the final rule. And it was not in a proposed language in the final form that it showed up in the final rule.

And I would urge the NRC staff to make sure that the language you proposed for that gets out in the proposed rule and that this curve -- it was really a curveball to all of us when that showed up in the final rule the way it did because we saw problems with it immediately.

So that's what I would advise, that you be very careful in what changes get made from proposed rule to final rule, that the community really has time to give you its feedback on it before it's presented so greatly different in the final rule.

CHAIR MALMUD: Other comments? Mr. Lohr?

MR. LOHR: If I may, to answer your question, Lynne, on our safety concerns, I believe what Jim was trying to say -- and this is in rulemaking space -- is how to prioritize petitions and

rulemaking. And I'm not saying this was not important because I felt like it was important. I actually chaired this, if you will.

But in the scheme of things in the NRC, health and safety come very close to the top. And so those rules and petitions are dealt with first and foremost. And then we deal with all others, such as this, as we have resources and such.

I actually believe we brought this forward. Probably our process made it a little more priority than it justified within our own structure because we felt like it was important to the community.

We cannot address what occurred in the past. I don't believe any of us were; most of us were here for that or part of that. We can only go forward with the processes we have now.

CHAIR MALMUD: Thank you.

And Doctor?

MEMBER ZANZONICO: Pat Zanzonico.

I think there was a safety issue that apparently was neglected. It's not a zero sum game. In other words, whether intended or not, there seemed to be an implicit advantage to newcomers to the field, for lack of a better term, people who may have been

board-certified later than '05. So that means people less experienced, et cetera. And the individuals who were disenfranchised, to use Lynne's terms, may have included, likely included, all the more experienced individuals.

So I don't think the fact that you have a sufficient number of warm bodies who are qualified to provide you service means that an equivalent level of safety and competence has been achieved. That is just a comment.

CHAIR MALMUD: Yes?

MR. LUEHMAN: The only thing I would say to that, I have no disagreement with that. I think all we were saying is that we're not sure where the -- I mean, when we went out and surveyed the board and asked the questions, I think the real thing we're trying to find out is okay. These people are out there. They technically fall into these groups, but of these people, how many of them actually have an intent? I mean, maybe they have gone into research. Maybe they are no longer in the field. They have gone on to something else.

So I don't disagree with you that they offer. They would offer a level of experience. The real question was, the real question, we were trying

to get some basis, as Ed said, to, is, were these individuals actually trying to be dissuaded or in some way because they had to go get an alternate path? They would say, "Hey, I would have -- I would be working in the field, but after I looked at that alternate pathway, I said, 'Forget about it'"?

I mean, that's what we were trying to get a feeling for. Was the process as it was setting up actually discouraging qualified people who have been done or was this just a number of people that technically met the qualifications but the vast majority of them had gone on to do other things and really had no intent to get licensed in this area? We were just trying to get an understanding of that.

CHAIR MALMUD: May I ask if you have an understanding of how many people have petitioned or complained that they have been disenfranchised as a result of the change? Is there any knowledge of the number? That's what I was trying to drive at --

MR. LUEHMAN: Right.

CHAIR MALMUD: -- when I asked how many of the 10,000 would be affected or were affected because the majority is board-certified and has other means of achieving their goals. We don't know of that number. We don't know what that number is, but we do know that

there at least is one because we have had a petition from at least one or on behalf of at least one.

MR. LUEHMAN: And we have heard anecdotal statements that this potentially -- I wish that Dr. Zelac was here, but, I mean, I think we have heard statements that in under-served rural communities, that this would potentially be a problem.

I know I asked Ron on a number of occasions, can we produce a small hospital or a couple of small hospitals that have actually run into that problem because they were going to have to use the longer alternate pathway to get somebody named on their license. And that actually provided a challenge to them.

MS. FAIROBENT: Dr. Malmud?

CHAIR MALMUD: Yes?

MS. FAIROBENT: Lynne Fairobent, AAPM.

I can tell you that there are several -- I can't give you an exact number, but I know of many instances where not only medical physicists who would be listed on the license under 35.51, but radiation oncologists and nuclear medicine physicians have not been able to be named as RSOs on the license for several months and, therefore, not being able to practice while the RSO for that facility has jumped

through all the hoops that they can to get them recognized under the alternate pathway.

So, rather than it taking simply maybe a week to put someone on a license, I do know of cases where it has been 6 to 10 to 12 months before an individual has been added to a license.

CHAIR MALMUD: May I ask you, in those instances, was there another RSO who was supervising them so that the work could continue or did the work just stop?

MS. FAIROBENT: Well, first off, these weren't necessarily RSO -- well, RSO positions; they hired a consultant RSO to cover the license to continue operation in several cases. Where this may have been an individual who then -- although we have no limit as to how many licenses an individual can be named an RSO on, we all know that at some point the effectiveness of being an RSO does diminish as perhaps the number of licenses go up that you are the RSO on depending on the complexity of the license.

As far as the physicians that I have gotten calls from the RSOs on how to proceed or how do they handle this, they have to work under the supervision in some cases of individuals. In others, they did not take the job. They went and hired

somebody else that could be added to the license.

So I do think that there is a whole gamut of these cases, but because the RSOs had been diligent and hung in there to get somebody on the license, it's hard to give that quantification of the exact data.

CHAIR MALMUD: Thank you.

Other comments?

(No response.)

CHAIR MALMUD: Those are the comments that we have at this moment. I think we will hear more comments after we hear the next presentation. And those comments will relate to both presentations.

So we would ask you -- I am sure you are going to be here anyway, but we would ask you to stay for that. Don't go too far.

MS. BHALLA: No, we are here.

CHAIR MALMUD: It was valuable. Thank you.

We have an option of either taking a break or moving on with the next presentation. Break? All right. We will take a short break. It is now a few minutes after 9:00, and we will resume at 9:30. Is that okay? 9:30 resumption. Thank you.

(Whereupon, the foregoing matter went off the record at 9:08 a.m. and went back on the record at

9:30 a.m.)

CHAIR MALMUD: Ladies and gentlemen, if we can resume our seats, we will move on with the next item on the agenda.

Dr. Howe, you're on.

DR. HOWE: Let the fun begin. My topic is Training and Experience Attestations. And I wanted you to be aware that I'm talking, specifically, about amending the attestation requirements, which is Item 11. But we had, as we heard this morning, we had some other attestation questions that one was with the Ritenour petition, which is Item 10. Item 8 is the no attestation for experienced RSO only completing training. Number 6, not requiring preceptor RSO attestations for AUs, ANPs and AMPs. And then also down in Item 24, which is correct, the attestation requirements for AUs. So, there are some satellite places in the regs in addition to what I'll be talking about.

How did we get to where we are now? Okay. Actually, before 2002 in the proposed rule, even prior to that, NRC has always had preceptor statements from physicians to show the training and experience they've had with different clinical uses. And then in the proposed rule for our 2002 rule, NRC switched and

brought preceptor statements into the regulation. And part of what NRC did at that point is they equated competency with safety. And they also had a requirement for a training exam, so the Board certification pathway was the Board had to have all of the training and experience that was in the alternate pathway, they had -- someone had to give an exam, so it could be the Board giving the exam. And then there was an attestation that was required before you could be board-certified.

In that case, it wasn't an attestation, it was a certification. Okay? So, in 2002, we introduced statements for all pathways certifying completion of training and experience, and that individuals were competent to function independently as Authorized Users. Now, keep in mind that the competency here was for radiation safety purposes, and the Commission equated competency with safety. So, almost as soon as the 2002 rule is published, we have the ACMUI very concerned about the Board certification pathway.

So, NRC started working on the Board certification pathway, and passed another rule in 2005, which retained the statements for all pathways, but removed the certification requirement from needed

before you could be board-certified, to needed afterwards, or --

MR. LUEHMAN: As part.

DR. HOWE: Not as part of the Board certification process. The certification wasn't even a certification that you were board-certified, it was a certification that you had the training requirements that we looked to the Board for. Okay?

And almost immediately after the 2005 rule is published, the ACMUI had one of its yearly meetings with the Commission, and one of the items on the agenda was the training and experience, and this certification process.

Now, in 2005, we did revise the certification, because that was a word that was causing a great deal of conflict with the medical community to attestation. So, let's see what we had in 2005.

Each attestation was it required each individual to have a written attestation signed by a preceptor authorized whatever the individual was, that the individual had satisfactorily completed the Board or alternate training T&E requirements, not through board-certified, just you finished the training and experience requirements, and achieved a level of

competency sufficient to function independently as an authorized whatever.

Okay. So, the ACMUI's concerns were does each individual have to have a written attestation? ACMUI believed that the Board certification people did not need a written attestation. Does each attestation have to be signed by a preceptor authorized individual who meets certain training and experience requirements?

The question the ACMUI brought up was, we've got people that are getting their training and experience through residency programs, and can we have someone in the residency program, like the Director of the residency program, issue the attestation, but that person that's in charge of the residency program may not meet the qualifications for the preceptor authorized individual.

And the next part that the ACMUI brought up was, does the attestation have to say achieved a level of competency sufficient to function independently? And the word here was "competency," because competency is many times read by the medical community as clinical competency when the Commission has always meant radiation safety competency. And is looking for the ability to function independently.

So, as a result of the Commission briefing from the ACMUI, the Commission sent us a meeting SRM, M080429, that asked the staff to coordinate with the ACMUI and the Agreement States to amend preceptor requirements in 10 CFR Part 35. As a consequence of that, the staff wrote a SECY paper, proposing changes to the attestation statements, and that was SECY-08-0197 in November 2008.

The Commission voted on the SECY paper, and came back with a Staff Requirements Memorandum of 08-179 that approved the staff's recommendations. So, let's look at conceptually what the staff was recommending; to eliminate the written attestation for Board certification pathway, and that would be across the board for all modalities; to revise the attestation statement to say "has demonstrated the ability to function independently to fulfill the radiation safety-related duties required by the licensee," so that's clearly shifting it from competency, which can be confused with clinical to radiation safety duties. And the third main issue was that residency programs may be able to sign attestations under certain conditions. And some of those conditions are that there at least be one authorized individual in the residency program, and

that it can be a group decision, but the authorized individual shouldn't be a negative vote. In other words, the authorized individual would still have a say in whether the person could -- had demonstrated an ability to function independently.

And that brings us to the discussion that I would like to see you have among yourselves, and to give us input, and have you comment on our conceptual direction. It's not enough to say you just like something, you need to tell us why, you need to tell us things you don't like, that you don't want to see. And it's really important for you to give us indications of unintended consequences.

The certification programs today may not adequately cover NRC regulated modalities. We saw yesterday that there's statistics that show that the number of prostate brachytherapies may have decreased by 50 percent, so will all the residency programs in radiation oncology have prostate brachytherapy in their training program? So, think about -- and do all of them have Gamma Knives? Do all of them have HDRs, do all of them have teletherapy, whatever our modality is. So, that's an important thing for you to discuss and let us know.

And perceived relaxation of safety

requirements, because as I said, the Commission equated competency in the attestation statement with safety. So, there are some that perceive that if you take this important safety statement off of the certification, you have somehow maybe diminished the safety on that side. I'm not saying you have, but I'd like to have you give your thoughts, and give us some information back, because we're going to have to do a good job of selling this. So, I turn it over to you, Dr. Malmud.

CHAIR MALMUD: Thank you, Dr. Howe. Are there any questions for Dr. Howe?

MEMBER ZANZONICO: I just have a --

CHAIR MALMUD: DR. Zanzonico.

MEMBER ZANZONICO: On Slide 7, I mean, maybe I'm not quite getting it, but it seems like the first two bullets are incompatible. I mean, one says eliminate written attestations, and the second bullet says revise attestations.

DR. HOWE: If you remember Neelam and Ed's presentation, there are three pathways to becoming an authorized user, one is the Board certification pathway, one is the alternate pathway, and the third is if you're already --

MEMBER ZANZONICO: Okay. So, this is

post-'05.

DR. HOWE: So, what we're looking at is eliminating the attestation for the Board certification pathway, keeping it for the alternate pathway.

MEMBER ZANZONICO: Right, but just post-'05.

DR. HOWE: Right. I mean, from whenever we amend the regulations forward.

MEMBER ZANZONICO: Okay.

DR. HOWE: So, it would be post probably 2012, because the regulations are still the regulations. When you amend a regulation, that's when it takes effect, so it's going to be two to three years.

MEMBER ZANZONICO: But at the current time, people who were boarded before the Boards were recognized will still need the attestation statement.

DR. HOWE: People that are boarded while the Boards are recognized still need the attestation. The attestation is part of the Board certification pathway now. In 2005, the ACMUI took the certification or the attestation, didn't make it part of our recognizing the Board, but if you were board-certified, you still needed an attestation.

MEMBER ZANZONICO: For the NRC.

DR. HOWE: For the NRC, and the Agreement States because it's a very high compatibility.

MEMBER GUIBERTEAU: I think this is an important issue in the fact that, for instance, at the American Board of Radiology, we do collect an attestation from the Program Director, and in terms of the case work, the work experience for 392 and 394 signed by the appropriate preceptors. All of them are, of course, authorized users. And there may be multiple ones over -- I mean, most training programs have more than one AU. But in that process, we take this very seriously, and we collect all these items. And then our Diplomates go out with their certificates to become AUs, and they're asked to resubmit this. And they call us or their program and say well, can you dig out this paperwork because I need it, and it seems like there's a lot of paperwork here that doesn't need to take place. And I think eliminating the attestation, and whether or not you keep it part of the recognition process, we're happy with that. But what's happening is our Diplomates are saying well, it seems like I'm really going through the alternate pathway, because they're asking me for that. They're asking me for the case work that you've

already collected from me signed by my authorized users, and the certificate only says that I've had the training. And I could get a letter from -- I could get all of this from my program. I don't really need the Board to do that.

I think we need to make a decision here whether Board certification really have the value that the NRC wants it to have. And if it does, then I think you really should only have to complete these attestations, and these authorized user preceptor statements once, and submit them somewhere, but not do it in multiple locations.

And I can tell you that each state has something a little bit different. And since we have people working in all the territories, and all the states we're inundated with questions saying well, tell us what to do. And we can't possibly keep up with every state. It's very confusing to them. And many of them move around. They go to a fellowship; they want to become an AU there. And if they do, then they move this to another state, and it isn't always the case where they say well, you know, that's okay, but we want you to resubmit your case work. So, the implementation of this program to make it somewhat more uniform would be welcome, but the basic issue is

what does Board certification get you in terms of becoming an AU, who's going to collect this data, and we shouldn't be doing it more than once.

CHAIR MALMUD: Is that a question, or a statement?

MEMBER GUIBERTEAU: Well, I believe it was a statement, because they want to listen to us, is what I understood, so I brought a soapbox with me.

(Laughter.)

MEMBER GUIBERTEAU: No, it is a complex issue, and everybody -- we all vote for safety here. But it's a matter of making some sense of this, so the Diplomates will say there is a reason for me to want to go through the Board certification part of this that has to do with radioisotopic safety. Because what we don't want to happen is for this to get lost in our training programs.

So, we will continue to provide it, but it is an extra burden for everyone to keep collecting this information in both the programs and the boards, only to have calls, and we get lots of these calls, for people who want to be AUs, to provide all of the basic information that we've already used to implement our certificates.

CHAIR MALMUD: Other comments? Sue.

MEMBER LANGHORST: I will say I have had many of those calls, and they also want to know if the preceptor is an authorized user on our broad scope license, and in good standing. And it seems like a lot of work that keeps going over and over again. So, I'm concerned of the amount of time that takes away from my safety role, and the amount of time it takes for NRC staff who do the same thing, and their role, and Agreement State regulators, it takes them away from their job of radiation safety, because they're tracking all this paperwork.

And my point is on the grandfathering that we were just talking about, if you have a board-certified person, now I'm going to have to figure out okay, so they were before this date, so I have to have paperwork on them, but not on this Board cert. I'm not sure it will add to any safety. I'm afraid it will take away from safety aspects, because people will be trying to figure out what paperwork they have to follow for any given board-certified individual.

CHAIR MALMUD: Thank you. Dr. Zanzonico.

MEMBER ZANZONICO: Just apropos of that point, when they implemented the Medical Physics licensure in New York State where I work, they required a preceptor attestation statement. The person

who as qualified to do that in my case had died, Dr. Becker, God bless him. So, the person who wound up signing it said well, you've been here. I guess you're qualified to do it. I'll sign it, the new Chief. So, again, apropos what Sue said, it doesn't enhance safety in any way. It's someone just willing to sign a piece of paper to get you out of their office.

(Laughter.)

MEMBER GILLEY: Oops.

MEMBER ZANZONICO: So, I just don't think the attestation in this sense has the value intended. Now, there are instances where it certainly does. Dr. Malmud mentioned during the break where for clinical privileges, the Service Chief or the Department Chairs have to attest to the hospital that a person is qualified to perform clinical procedures. And that's a real attestation, which has serious implications for all parties. But I just don't think the attestation requirement if an individual has otherwise met professional competency standards, meaning Board certification, has the intended consequences. And my position would be eliminate all attestation requirements as far as the NRC is concerned in lieu of Board certification as the ultimate professional

standard, regardless of the time a person -- an individual was board-certified.

MEMBER GILLEY: Is that a motion?

MEMBER ZANZONICO: I would be happy to make it a motion. I don't think we're at that stage.

CHAIR MALMUD: We can make it a motion, or we can continue the discussion at this moment. I'd like to bring something up that you just raised, and that is that in seeking privileges at a hospital, or a health care organization, someone must certify that the individual who is going to provide a specific service is qualified to do so in the eyes of the Director of the program. So, if it's the Department Chair, we are required as Department Chairs to certify that Dr. X or Dr. Y is competent to do whatever procedures we recognize that person is competent to do. And that's a personal responsibility of the Chair to say well, he's competent in the nuclear, but he's not competent in MRI, even though technically he's a board-certified radiologist. He didn't have experience in MRI; I'm not going to certify him at it until he takes some additional training. And he can do that while he's still working for me, but not MRI at the moment or theoretically not nuclear medicine at the moment, what have you, or not nuclear medicine

therapy, but nuclear medicine diagnosis is okay, but not therapy. And that's a responsibility which is assumed by the immediate supervisor, and has the most meaning, because it has the most significance in terms of assuming responsibility and liability in the event that something goes wrong.

And I can understand how that works well. And, quite frankly, it's a matter of hospital privileging, and I think its significance overrides everything that we do, whether it's Board certification or NRC certification, because we now have a responsible party who says I certify that this person is capable of doing this.

The gap in my understanding is what happens when there's a freestanding radiotherapy unit, a privately owned freestanding radiotherapy unit, who would certify that the radiotherapist is competent in that situation? What governing body overrides that, is that the JCAHO, or is that -- how does it work? I don't know.

DR. HOWE: Dr. Malmud, you just pointed out one of our major concerns. As members of the ACMUI, you are normally at large institutions with well controlled structures for who's authorized to do things. Many of our licensees are not at large

institutions. We have a significant number that are private practice, so there is no governing body for them. And I think that's something that you as ACMUI members need to keep in mind, that we have another group, and a very significant group that doesn't have these groups.

CHAIR MALMUD: How do the states deal with this? Debbie, are you --

MEMBER GILLEY: We have lots of freestanding facilities, so we have lots of those. We require them to get Board certification in that particular aspect you talked about, for Gamma Knife they're board-certified.

CHAIR MALMUD: So, the individual states, at least in --

MEMBER GILLEY: Provide specific training.

CHAIR MALMUD: Requires Board certification. Would that accept alternate pathway?

MEMBER GILLEY: Probably not. We have not accepted any alternate pathway for radiation therapy, the Gamma Knife, HDR, because it's very difficult for them to complete a residency program which is a requirement. We have accepted alternate pathway for nuclear cardiologists prior to implementation of our current rules that recognizes their Board.

CHAIR MALMUD: Mickey, what about your familiarity with it in your state?

MEMBER GUIBERTEAU: Well, before I get to the state, the CMS has taken a huge interest in this, and in the recent legislation. There is a requirement in order to be a provider for CMS that advanced imaging facilities, especially those that are not associated with an institution, will need to become accredited. And that's coming -- that's been in the rule for quite a while, but the deadlines are coming pretty quickly. And they have deemed three organizations as accreditors, and these are the Joint Commission and the International Accreditors, and the ACR.

And within these accreditation programs, they not only look at the equipment, the procedures in terms of the technical aspects, but they also look at the personnel, the medical personnel including physicians, and their certifications. And private payers are picking this up, as well, in terms of accreditation. So, it's coming pretty quickly that we're bringing everyone into the fold and having the same sort -- whichever of these organizations you decide to use, you have some standard by which these organizations -- your imaging facility will be gauged.

In Texas, to be honest, it's not -- certainly not as strict as this, but there is some consideration, in fact, the Texas legislature is meeting right now, and there are several bills in the works to require accreditation, the same as what I'm talking about, for these facilities within Texas. But, currently, we don't have that yet.

CHAIR MALMUD: From your understanding, if an individual were a radiotherapist and wishes to open a freestanding radiotherapy unit not associated with a major hospital or university, and then wanted to hire a physicist, the radiotherapist is board-certified, but needs a physicist, who would certify that the physicist is competent to do that which is necessary to run the freestanding radiotherapy unit?

MEMBER GILLEY: It couldn't happen in Florida, have to be board-certified medical physicist.

CHAIR MALMUD: In Florida it's required a board-certified medical physicist. In other states, we're not sure, so there --

VICE CHAIR THOMADSEN: In Wisconsin, it's not.

CHAIR MALMUD: In Wisconsin?

VICE CHAIR THOMADSEN: It's not required.

CHAIR MALMUD: Dr. Thomadsen says in

Wisconsin it's not necessary. So, therefore, it is in theory possible that a competent, well-trained radiation oncologist could hire a physicist who is not well-suited to that position.

VICE CHAIR THOMADSEN: No, is not board-certified.

CHAIR MALMUD: Not board-certified. Who would assume the responsibility for that individual's competency, the owner of the facility?

VICE CHAIR THOMADSEN: They would have to go through the alternate pathway.

CHAIR MALMUD: Yes, that takes us back to the NRC, rather than through practice guidelines through JCAHO. All right. So, you've really answered the first part of my question, that there is need for the NRC to be involved in this. That's a very basic question. Why do we really need the NRC to do it, when, in fact, we have hospital privileging? And the answer is it's quite clear, that in freestanding units the NRC, at least the NRC has to be involved in the absence of standard hospital privileging procedures, which are under JCAHO, and generally will require that these individuals be competent to do their job, or trained and experienced. They'll have the T&E to do the job.

I'm sorry. Dr. Howe, you want to say something.

DR. HOWE: And how do you know if a person is board-certified, that they've got training and experience in the specific modality?

MEMBER GILLEY: Debbie?

MEMBER GILLEY: They submit a certificate showing they've completed that training.

DR. HOWE: So, in addition to being board-certified, you require some additional information to demonstrate that they have experience in the modality. So, the Board certification alone is not sufficient.

MEMBER GILLEY: For medical therapy, we want to see -- if they're going to be put on an HDR license, we want to see recentness of training from Nucletron, Varian, or whatever. They send a certificate in if it's their first time being on a license. If they're currently already on a license and they want a new modality, such as they want to do Gamma Knife, we would expect to see recentness of training within the last seven years in that device, so we would want to be seeing that to add them to that license. We wouldn't require board-certification again, nor attestation if they're already on a license. We'd just be looking for the device-specific

training within the last seven years.

CHAIR MALMUD: Thank you.

MEMBER LANGHORST: Can I follow-up on that?

CHAIR MALMUD: Yes.

MEMBER LANGHORST: So, does NRC require currently an attestation if a new modality is happening for the RSO for -- like if an HDR is being added to a current license, and does the RSO need a new preceptor statement for that modality?

DR. HOWE: The modality training is included in the attestation. For new modalities, because we understand that at some point there is the first, and there is the second, and the third, and there aren't enough people there to give attestations, and the population is not large enough. So, what we've done with the Perfexion was to say you don't need attestations until so many years out where we thought we'd have enough population. And then we -- I think we put a criteria that you had to document the training in the modality, but if you were board-certified and on another license, you didn't have to get another attestation. But if you were brand new, you had to have an attestation. So, we've handled it in emerging technologies in various ways knowing that

in the beginning you don't have people to attest.

MEMBER LANGHORST: Right. But let's say -- my question was it is not brand new. HDR is well established, but it's new to the license, and an RSO is covering it. So, does that RSO -- is it adequate to get training in HDR, or does that RSO have to go out someplace and get an attestation --

DR. HOWE: Our current requirements --

MEMBER LANGHORST: -- specific for HDR then?

DR. HOWE: -- in 35.50 includes attestation for Paragraph E. And E is, "Has training in radiation safety regulatory issues, emergency procedures for the types of use which the licensee seeks approval." And that training can come from another RSO, an authorized medical physicist, authorized nuclear pharmacist, authorized user with specific type of use.

MEMBER LANGHORST: Okay.

DR. HOWE: Technically, you've got to get that additional training.

MEMBER LANGHORST: No argument there.

DR. HOWE: And, technically, it comes under the, has a written attestation.

MEMBER LANGHORST: Okay. So, then you do

have to get an attestation for that.

DR. HOWE: That's what our current requirements are.

MEMBER LANGHORST: That's very difficult, because -- does that mean you have to work for a year under that RSO in that unit?

DR. HOWE: No. No. You're not getting an attestation for the -- if you're an RSO, you're not getting the attestation for -- to be an RSO. You're getting an attestation that you completed that training.

MEMBER LANGHORST: Okay. So, then you get that from the manufacturer, essentially.

DR. HOWE: Well, the attestation has to come from an RSO.

MEMBER LANGHORST: Yes. So, the manufacturer is RSO.

DR. HOWE: The manufacturer is RSO could do it, if they're on the license.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: So, if somebody has training adequate to be an RSO, but they don't experience with a particular form of therapy, they, basically, just need to get some training on that form of therapy. Is that correct? It's just like we do

with Part 1000, when something new comes out, you have to have some training in that modality. And it's assumed that you're competent as a radiation safety person, regardless of which role you are playing. Your safety aspects are taken care of by your Board certification for the most part. Would that be correct?

DR. HOWE: The basic radiation safety -- the modality stuff I believe would still come outside of the certification, unless you could show that your certification included it.

VICE CHAIR THOMADSEN: Yes. So, it would seem that for anybody who was board-certified, that the attestation to the effect that they understand radiation safety is not particularly useful. But if they were to begin a modality in which they have never been trained, they just need to get training in that modality. Would that be the case?

DR. HOWE: Under the current rule or that's what you would like to --

VICE CHAIR THOMADSEN: Let's just say practicality, it seems that general principles in radiation safety don't vary by modality. The specific applications for a given modality would, in which case the general principles, which is what you would

basically be getting the attestation in, would be covered by the Boards. But you would have to just make sure that for a given modality, that you have particular training in that modality.

For example, most people trained in this country have never worked on a cobalt machine. And I assume that the NRC would insist that they were board-certified, and they were going to get a cobalt machine in their department, that they would need to get training on the cobalt machine. Is that not the case?

DR. HOWE: That is the case.

VICE CHAIR THOMADSEN: Yes. So, it doesn't seem that the attestations themselves have very much value for somebody who's board-certified, if you then would have to have the certification and training in the given modality.

DR. HOWE: I hope you're directing that to your fellow ACMUI members.

VICE CHAIR THOMADSEN: Right. That was my answer to the question that you posed.

MEMBER ZANZONICO: Agreed. Attestation does not have much value.

MEMBER GILLEY: I agree.

DR. HOWE: But be careful when you're making these statements that you're qualified, because

what you're really talking about is attestation for board-certified people.

MEMBER ZANZONICO: Yes.

DR. HOWE: When you make that statement attestations are not -- without any qualifier, that's across the board.

MEMBER ZANZONICO: Agreed.

DR. HOWE: Okay.

CHAIR MALMUD: Yes, Sue.

MEMBER LANGHORST: But we have to be careful because they might be grandfathered board-certified people, and then we have to track them with preceptor statements, which I think is unnecessary. That just adds to the level of confusion, and I don't think adds any safety factor.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: That would be covered under my previous statement.

MEMBER LANGHORST: Right. I agree. It just -- in answer to our previous discussion, I think that is a layer of complexity that adds nothing to safety.

CHAIR MALMUD: Dr. Zanzonico.

MEMBER ZANZONICO: There's another scenario. I mean, and this is with respect to

physicists, many of whom work in, unlike us, like most of us in smaller hospitals, and so forth, where they're the only physics person there, and have been for many years. It's especially true of a number of old-timers, so the question is who provides in those instances the attestation? There really is no -- the presumption is these are board-certified individuals, and we'll assume that's the case in all instances. But then who provides their attestation? And there really is no one who is qualified in the sense of promoting safety and so forth, because the only professionals that you work with would be physicians, and so forth. And attestation should be provided by one's peers in all cases. But in a number of these instances, there is not a peer professional who can provide that sort of attestation, so that just strikes me as another problem beyond the professional rule, which would be board-certification.

DR. HOWE: When NRC designed the preceptor, they made sure that they included verifies, so you don't have to provide the training, you don't have to supervise the training to be the preceptor. You just have to verify, so that -- in our mind, in NRC's mind that said you can go to someone -- if you got trained 20 years ago and that person died, you can go to

someone that's alive now, and have them verify. And whatever it is that they do to verify, they talk to you, they find out what your capabilities are by talking to you, what your knowledge is, and they can verify.

MEMBER ZANZONICO: That's more effectively done by Board certification. Again, I'm taking very much to heart the NRC's position that this is done, primarily, for safety purposes. And I think that's most effectively done again by one's professional peers, and meaning board-certification and having another individual speak to you formally or informally who is not a member of that profession, and really is not in a position to judge your competency, frankly; that it's much better done by one's professional peers. And, again, that amounts to Board certification. You've done all of that verification in advance of you being eligible and sitting for Board certification. So, that's why I think in terms of attestation, promoting patient safety and so forth, it's really a very hollow way of approaching it. And that if an individual is board-certified, that should be the first and final metric of professional competency, and safety.

CHAIR MALMUD: Dr. Zanzonico, are you

suggesting that only ones who should be permitted to practice are those who are board-certified?

MEMBER ZANZONICO: No. I wouldn't eliminate the alternate pathway.

CHAIR MALMUD: All right.

MEMBER ZANZONICO: All I'm saying is that for board-certified individuals, requirement for attestation is not particularly helpful.

CHAIR MALMUD: What if it's a board-certified individual who is being recruited to another institution to do the Gamma Knife therapy, and has had no experience in Gamma Knife that was included in his board-certification, wouldn't he need an attestation that he was trained in Gamma Knife?

MEMBER ZANZONICO: I wouldn't think -- not in my opinion to be an NRC authorized user, or whatever the correct term is. But that whoever would be hiring that individual would make that a condition of their employment. I'm just -- I guess I'm just objecting to the NRC through the attestation mechanism being the arbiter of whether an individual is qualified for a procedure, new or otherwise, as opposed to an individual's professional colleagues, professional peers, and so forth.

CHAIR MALMUD: Thank you. That's,

essentially, an analogous point to the one that I was making, which is that when I, as a Chairman, certify that someone is competent to perform a procedure in my department, I am the one who is most at risk after that individual. And, therefore, it's my responsibility to make sure that he or she was adequately trained for the procedures that they'll be doing. And that's a much closer responsibility, and much more important responsibility than certification, which may or may not -- which will carry some weight on paper, but may not really reflect the ability of the individual to perform the duties for which they're being hired.

I guess the question we're kind of tossing around is, is this really an NRC issue with respect to specific responsibilities and competencies? We've always entrusted the Boards to certify that each of us in his or her program has had adequate training. And I think that the public relies upon that, and the NRC itself relies upon it for certain elements of our ability to achieve licensure at authorized user status.

The other option is, of course, the alternate pathway. It's another option to achieve the Boards. So, I have the feeling that the majority of

this Committee feels that board-certification should be adequate in itself to judge competence. Is that what I'm hearing from the members of the Committee?

MEMBER ZANZONICO: Yes.

MEMBER GUIBERTEAU: I think as a corollary to that, that it is -- it really is necessary to revise the attestation. I mean, these are linked, but let's suppose we don't eliminate the written attestation on the certification pathway, my feeling is we do need, regardless of that item, and I'm in favor of that, that we revise the attestation because in the parlance of our profession, competency is equated with Board certification. We do have preceptors who refuse to sign statements, so that their folks, even though they're trained, cannot become AUs, because they don’t -- they say the Board tests for competency. I cannot sign an attestation even to the ABR that this person is competent, because that's your job. So, we have them attest to the fact that they have been given the necessary training and experience. But I do think that that can become a catch-22, that they can't take the Board because they're not qualified, they didn't go through that pathway, but they can't get -- go through the alternate pathway because they can't take the Board,

and no one wants to sign something that says that they're competent, because that is a Board -- that's believed to be a Board issue. And in some instances, some people interpret that as having legal responsibility for that person, because the Boards certainly do, because we make that claim that that's what we're there for.

DR. HOWE: So, what I'm hearing you say is that the word "competency" and "competent," is really a red flag.

MEMBER GUIBERTEAU: Yes.

DR. HOWE: And we have a potential here that says: "Demonstrate the ability to function independently to fulfill the radiation safety-related." Does that get to more what you believe other people could attest to?

MEMBER GUIBERTEAU: I think it's closer. I can't speak for everyone. But, certainly -- and I think the word "competency," or "competence" should be taken out of it, because this is an attestation that I think -- I don't think the -- an attestation cannot take the place of board-certification, but it can add to the NRC's confidence in the performance abilities in a safe manner of the person being proffered for Authorized Usership. So, yes, I mean, I'm agreeing

with that.

CHAIR MALMUD: I'm agreeing with it, but wondering if there's a better way of expressing it, in that the individual has received the necessary -- the requisite, the training and experience in order to perform a function, rather than has demonstrated the ability to function independently. I'm not certain -- - do we certify that our residents have demonstrated the ability to function independently?

MEMBER GUIBERTEAU: Do we --

CHAIR MALMUD: As residency training program directors, do we really certify that the residents are able to function independently, since technically the residents are always functioning under the direction of an attending physician?

MEMBER GUIBERTEAU: No, we don't. And, two, it's confusing when we say certify, because really when we talk about certification, it's not privileging, it's not credentialing, it's not accreditation, it is certification. And that really means Board certification in our community, in our profession. So, I don't think anybody in a training program, a program director would certify, but they would attest that the person has received the training and experience. And that's what we ask for, in the

hours that the NRC requires, that's what the ABR requires of the programs before they can sit to demonstrate their competence in radiation safety, radioisotopic safety by taking our radioisotope examination.

CHAIR MALMUD: And I'm agreeing with you, and I'm questioning this wording, because this wording says that the attestation should be revised to say that the individual has demonstrated the ability to function independently to fulfill the radiation safety-related duties. I think that the individual has received the requisite training and experience in order to function independently.

DR. HOWE: I will point out that there are three dots there, and the three dots is that we weren't really looking to change the part that they have successfully completed the training and experience requirements in certain paragraphs. So, this is the second part of the attestation we're focusing on.

CHAIR MALMUD: So, that's in there.

DR. HOWE: Yes, that's in there.

CHAIR MALMUD: Okay. Then we're in agreement then.

DR. HOWE: Yes.

CHAIR MALMUD: At least you and I are in agreement on it.

VICE CHAIR THOMADSEN: You're in agreement that that's the wording?

CHAIR MALMUD: No. Dr. Howe said that the words missing in there are -- why don't you -- if you would find the exact words.

DR. HOWE: Yes. They're the same in any section.

CHAIR MALMUD: We've gone over this before; it would be useful to hear it again.

DR. HOWE: "The individual has satisfactorily completed the requirements of Paragraph" whatever, and there may be several paragraphs of this section, "and has demonstrated the ability to function independently," would be the new wording. Right now, it says -- I better take something other than that, because that one is slightly different. Right now it says, "And has achieved a level of competency sufficient to function independently as an authorized individual." That's what the rules currently say. You completed the training and experience in certain paragraphs, and you have -- what did I say here?

MEMBER GUIBERTEAU: I think, I mean --

DR. HOWE: And achieved a level of competency.

MEMBER GUIBERTEAU: I agree with DR. Malmud here. One, I'm very uncomfortable with competency, and I know if Doug Eggli were still here, he would not sign any of these statements. And I know there are numerous other authorized users and preceptors who won't do this. But I also think that it's difficult when you are giving monitored training and experience sufficient enough to satisfy the current regulations, and then to say the person has demonstrated the ability to function independently, because really almost the full time they were functioning under observation. So, we don't know what they would function like if they went off. I mean, even the best students, so I think there will be some who have difficulty with this. They would say under my supervision, I provided the training and experience, and this person seemed to absorb it, but to perform independently of my observation, I don't know. So, I mean, when I said I thought this was closer, I was going to bring this up, and I'm bringing it up now, because I think that also might be a barrier to some people getting an attestation to become an AU.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: I would agree with what DR. Guiberteau was saying wholeheartedly, that the modification you have there is really just a substitute of words for the offensive word "competency." And that is a synonym that I think many of us recognize as simply a different way of saying the same thing.

My suggestion would be to leave it as the individual has received the training and education, rather than go on to say that we also acknowledge this person's competence, or that we -- that this person has demonstrated the ability to function independently, because that part is nebulous for the reasons Dr. Guiberteau has outlined.

CHAIR MALMUD: Might bullet 2 be changed to say, instead of has demonstrated the ability, has received the requisite training and experience necessary to function?

DR. HOWE: I will tell you that one of the concerns of previous Commissioners was that we were seeing a number of enforcement actions with single physician practices. They didn't appear to know the NRC requirements, and they sat through the training classes, and they wanted to have a positive statement

that said these people could function, not that they had just sat through the training class, or they signed their name on the training class, but that they could function. So, that was important to our previous Commissioners.

CHAIR MALMUD: The word "function" would remain. With my suggestion, it would be that they received the requisite training and experience necessary to function, but that they haven't demonstrated it independently. And the reason is that when we certify a resident's activities for purposes of reimbursement under Medicare and Medicaid, it is specifically under the supervision of an attending physician. And if they're functioning independently, we cannot bill for them, because that's included in the basic -- direct and indirect doctor/patient support, so this would be contrary to that which we've already certified, namely, that they have been functioning under our supervision, not independently, never independently.

MEMBER ZANZONICO: Can I ask a question?

CHAIR MALMUD: Dr. Zanzonico.

MEMBER ZANZONICO: Don't all -- regardless of this, don't all residency or fellowship programs provide the equivalent of a diploma when a --

CHAIR MALMUD: Yes.

MEMBER ZANZONICO: -- when the trainee has successfully completed the program?

CHAIR MALMUD: Yes.

MEMBER ZANZONICO: So, that would seem to represent the institution and the program director's documentation that they received this minimum training, and so the requirement for an additional attestation seems superfluous.

CHAIR MALMUD: I agree with you, except that I believe that the concern here is that they have received the component of the education which relates to radiation safety procedures. And, therefore, the concern of the NRC on this, it's not -- the NRC should not be, to the best of my knowledge, is not interfering with the practice of medicine, but with the radiation component of it. And that's what we've been discussing for several years now, and the word "competency" is absolutely abhorrent to every training program director in the United States, some of whom just refuse to sign.

DR. HOWE: And the other point is not everybody goes through a residency program. Only certain ones that are authorized users or medical physicists need to go through a residency program.

CHAIR MALMUD: I hear another voice?

MS. FAIROBENT: Lynne Fairobent. I bet that would change, all medical physicists will have to go through a residency program beginning in 2014, Bruce. Would you address that?

VICE CHAIR THOMADSEN: No, that's only if they want to become board-certified. They will not have to become board-certified to function. There is the alternative pathway.

MS. FAIROBENT: That under NRC may be correct, but we are working with the Agreement States to, hopefully, close the door, and if the Care legislation gets through, in order to practice clinical medical physics, AAPM's Board position, as well as the American College of Medical Physics Board position is that one must have a graduate degree and be board-certified in the subspecialty of practice.

CHAIR MALMUD: Thank you. Dr. Welsh, did you have your hand up?

MEMBER WELSH: Yes, I did. Two quick points. One, Dr. Zanzonico's point about the diploma is relevant to the question that Dr. Howe brought up earlier, which is how does the NRC know what modalities an individual who's board-certified has been trained in? That diploma could provide the

answer. It may not state it explicitly, but the individual institution that grants that diploma would have a list of all the modalities at that institution at that time. And HDR is there, Gamma Knife is there, et cetera, and the individual gets the diploma, in addition to his board-certification, we know that that individual has received those, so that possibly can answer that question.

The other point that I wanted to bring up was in relationship to Dr. Malmud's suggested amendment to that statement. I would add, perhaps, the words "should allow", rather than just say "has demonstrated the ability to function independently to fulfill," I don't agree with that terminology. I believe he came up with another alternative phraseology, and I would add the words "that should allow," rather than apply with.

CHAIR MALMUD: Should allow is a softer statement. I'm not -- we'll entertain that at the appropriate time to see if we want to alter the statement that's up on the slide currently. Dr. Guiberteau.

MEMBER GUIBERTEAU: I just want to point out that the diplomas that you get for completing a residency are suitable for framing.

(Laughter.)

MEMBER GUIBERTEAU: They are based on the program requirements that you need from the ACGME and the RRCs in order to complete that program. You must complete all of those training requirements to take the Board certification examinations. So, built in -- - anyone who -- now, this doesn't count for non-certified persons, but those who have Board certifications will inevitably have this diploma, because even when they take our examination at the end of their residency, if that residency doesn't write us back two weeks later, let's say they take it in June, June 30th, if we don't start getting those letters, they do not get a certificate from us, because they have not completed the program. So, any -- if someone -- if you want to go back and really look at what the training was, all you need is the date of certification and look what the residency program requirements were at that time, and that's the training that they must have gotten. So, all I'm saying is these diplomas are nice, but they really don't have a lot of cachet in terms of -- other than saying that the person was here for four years.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: But I would argue that the

diploma might not specifically state something of that sort, but it would say something, for example, the Cleveland Clinic, and that -- an individual who completes the Cleveland Clinic residency training program in radiation oncology more likely than not will have Gamma Knife experience, because Cleveland Clinic is renowned for its Gamma Knife program, and the Gamma Knife is there. Whereas, my previous institution, somebody will have a diploma, somebody will have Board certification, but will not have Gamma Knife training. How does the NRC know if one person has Board certification, and another person has Board certification, but one person has a diploma from this place, and another person has a diploma from that place? NRC will know, because they know where the Gamma Knife training could be --

MEMBER GUIBERTEAU: I understand that, but the diploma itself does not list the training requirements, or the training completed by that person. And when you said if they have a diploma, it's more likely than not. Well, that's yes or no. And that's not on the diploma. So, I mean, if we're talking about program requirements, and you've completed a residency at this date, you must have had all the training in those program requirements, or you

don't get the diploma, and you don't get board-certified. But if it's an evolving technology that has not yet made it into the program requirements, for instance, you would have to go to the program and ask them for some verification, because it would not be reflected in the program requirements.

CHAIR MALMUD: You are correct, Dr. Guiberteau. I could demonstrate an example of a diploma from the distinguished medical institution in the United States, which indicates that the person received training in the department in which he was not even present, but the person was there for the requisite number of years, and because of the internal politics of the institution at that time, they refused to use the name of the specialty, instead used another specialty instead. So, the diploma is not reflective of the accomplishment, the certification is.

But getting back to this statement, if we may. We've jumped away from it. Let's stay focused on that second bullet. Clearly, in many years of discussion, we know that the word "competence" is anathema to all of the members of the Committee, and to all the department chairs, if not, the vast majority of department chairs in the United States. So, we're looking for alternative wording.

My concern about this wording is that it's in conflict with what we certify for -- what we correctly certify for Medicare and Medicaid reimbursement. So, I would suggest that we simply state instead that the individual has received the requisite training and experience necessary in order to fulfill the -- in order to function in fulfillment of the radiation safety-related duties required by the licensee. That would not be in conflict with the other statements that we certify with respect to reimbursement for Medicare and Medicaid. And I think to achieve the goal that's necessary on behalf of the NRC's concern with respect to our trainee's ability to deal with radiation.

Now, so we see that Board certification is one pathway. The alternate pathway is a second pathway. Specific modality training is a third pathway for limited specific modality. And then the other requirement is the recency of training, which is -- does not require actual intensive years of training, but just the fact that the training has been refreshed, if you will, in some manner to the satisfaction of the director of the program in terms of its recency. So, those are the four means. Are there any other means that need to be looked at for

status as either an AU or an RSO?

MEMBER LANGHORST: I have a question.

CHAIR MALMUD: Dr. Langhorst.

MEMBER LANGHORST: One question I have, and it might get back to Donna-Beth's question on smaller clinics, freestanding clinics, is the Item 6 on our list about not to require preceptor RSO attestation for AUs, AMPs, and ANPs. And I just wanted to put that on the table for discussion as far as the Board certification. I think some of them have a route that they could go which has RSO-eligible. Is that -- am I correct in understanding that?

DR. HOWE: If you get a board-certification that says RSO-eligible that means that that individual meets all the requirements for NRC to recognize the Board, and that particular board-certification. The individual that doesn't have RSO-eligible means that there's something in their qualifications that did not meet the NRC requirements.

MEMBER LANGHORST: For them to be eligible to be an RSO?

DR. HOWE: Yes. So, it's -- the RSO-eligible is just a designation that you meet NRC requirements for us to recognize that particular certificate as meeting our requirements. That's our

recognition of the Board.

CHAIR MALMUD: Does that clarify the issue?

MEMBER LANGHORST: I'll ask the Committee if that clarifies the issue.

CHAIR MALMUD: Does that clarify the issue for the members of the Committee?

MEMBER GILLEY: What Board does RSO eligibility? Any current Board that's accepted by NRC does that designation?

DR. HOWE: Yes, I think we do. I passed out a list of boards.

CHAIR MALMUD: It's this document.

DR. HOWE: Yes. And so, the American Board of Radiology, and if you look at that, it says, the second bullet -- yes, the second and third bullet part, "Special needs for Diplomates who have been issued certificates before or after that date with the words RSO-eligible appearing on the ABR certificate." There is something in our requirements that the individual did not meet that would prevent them from getting the RSO eligible.

VICE CHAIR THOMADSEN: Could you just refresh my memory? It's been a long time since we've covered that. What is it that they didn't meet, just

before that?

DR. HOWE: Well, there's also in the American Board of Medical Physics. Generally, it is a degree training. In other words, we specify what degrees would be acceptable. Let's say for the medical physics, a Master's or Doctor's degree in physics, medical physics, or other physical science, engineering, applied mathematics from accredited college or university." And that individual may not have that degree. Maybe their degree is in English, maybe their degree is in History. It could be in anything, and then they got on-the-job training to meet other criteria.

And what we try to tell the Boards is, we're not telling you who takes your exam. We're just saying you need to let us know who meets the requirements for us to recognize your certificate. And if they put a designation on the certificate, we can recognize the certificate with that designation.

CHAIR MALMUD: Does that answer your question?

VICE CHAIR THOMADSEN: That does.

CHAIR MALMUD: Thank you.

VICE CHAIR THOMADSEN: Thank you.

MEMBER LANGHORST: I guess one additional

question I have --

CHAIR MALMUD: Sue.

MEMBER LANGHORST: -- on that is if, I guess there would be no grandfathering applied. I mean, all AUs, ANPs, and AMPs would have to understand that their Board certification has to have RSO eligible in order to serve as the RSO on a license.

MEMBER GILLEY: For their modality.

MEMBER LANGHORST: For?

MEMBER GILLEY: For their specific modalities.

MEMBER LANGHORST: Well, there's only one RSO right now.

MEMBER GILLEY: Well, I suggest that if you're American Board of Radiology RSO eligible, you could do the procedures that you are trained in. Diagnostic, yes. You couldn't go over to therapeutic without additional training.

DR. HOWE: Currently, in the Board certification pathway, you are certified by a Board that's recognized by the NRC. The recognized Boards are up on the website. And you meet the requirements in (d) and (e); (d) is the attestation; (e) is you have radiation safety training in the modalities for which the license is seeking authorization. So,

board-certification does not stand as the only thing. Right now there are three things. If we take the attestation out, we may be left with two things, because board-certification does not guarantee that you've got the modalities.

CHAIR MALMUD: That's correct.

MS. FAIROBENT: Dr. Malmud.

CHAIR MALMUD: Yes?

MS. FAIROBENT: May I ask Dr. Guiberteau a question, please?

CHAIR MALMUD: Please.

MS. FAIROBENT: Lynne Fairobent, AAPM. Mickey, in reading what Donna-Beth just handed out, and I guess it gets back to your question on the grandfathering provision for AUs, and also for AMPs now under 35.51. It says ABR certification process from June 2007 forward for the specialties listed who have a certificate before and after that date with the words RSO eligible. Has ABR then, therefore, gone back to all previous certificates prior to 2007 and added RSO eligible?

MEMBER GUIBERTEAU: No.

MS. FAIROBENT: So, should this say before and after, or what's -- I guess my impression was that when ABR agreed to this, it was after the date in 2007

the RSO eligible. It wouldn't appear on certificates before that examination year date.

MEMBER GUIBERTEAU: I can't tell you what -- maybe Donna-Beth can, the negotiations in terms of how ABR worked this out with NRC, because I was not privy to this, nor is it in my area as a diagnostic radiology nuclear medicine physician. But I do know that they were careful that if they asked for this language to be included, there was a reason for it. But we do not -- I mean, our general policy is not to go back and reissue certificates, and put something on them that wasn't present in the certification process at that time.

MS. FAIROBENT: My concern I think goes to — I think was it Sue that said then, I'm not sure there is a grandfathering option then for anybody for these Boards now given the way this language appears.

DR. HOWE: I can't answer for the American Board of Radiology for the health physics part, but I can answer for the American Board of Nuclear Medicine. They decided that most of their board-certified people were authorized users. And, therefore, on a very rare occasion, they would have an individual that was board-certified, had not been listed on a license as an authorized user, but met the NRC requirements. So,

in those cases, they would go back and put the designated words on the certificate, so that's what it means for the American Board of Nuclear Medicine, and I believe it's the same thing for the American Board of Radiology, that they don't expect to go back and do all of them, but if they have a request, and the person does meet our requirements, then they may.

MEMBER GUIBERTEAU: That may be the case. I don't know whether it's being done for individuals, but I know we don't just blanketly redo certificates.

MS. FAIROBENT: I guess my question, as staff prepares for the public workshops, I think that that's an issue in discussing the resolution on the Ritenour petition, because with the before and afterwards now, and the need to have RSO-eligible on the certificates, I'm not sure how this now would fit in with the Ritenour Petition, which was originally filed before this sort of agreement was reached. It may just be a paperwork catch-up for the Boards, but I'm not -- I think that this should be discussed, or thought about, and then discussed and presented when you're putting together the workshop presentations.

CHAIR MALMUD: Thank you.

MEMBER GILLEY: I would also like to know how many certificates don't have RSO-eligible on them?

Is that a large population? Are the majority of people RSO eligible?

DR. HOWE: I know in some cases there's just a few people. In some cases, it's -- we have requirements in -- the Board has to meet the requirements of the alternate pathway, especially in the nuclear medicine. And there's a requirement that there be supervision under an authorized user. The authorized user has to be someone that's an authorized user by our definition. So, the Canadian folks that are not trained under an authorized user are -- can take the examination, but they won't meet our qualifications, so they don't get whatever the designation is, because that designation just says this particular certificate guarantees that the person that has it met the criteria for us to recognize that certificate.

VICE CHAIR THOMADSEN: Can I ask --?

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: I realize this is sort of going back to the previous discussion, rather than this one, except it came up here. So, if you have somebody who had a degree in English, but had been board-certified by the ABR prior to 2004, those people could not be grandfathered then? Is that the

case?

DR. HOWE: That is the case right now.

CHAIR MALMUD: Do you have --

VICE CHAIR THOMADSEN: No.

CHAIR MALMUD: Your question was answered.

VICE CHAIR THOMADSEN: The question was answered. I just have to contemplate --

CHAIR MALMUD: Sue, you were next, and then Jim.

MEMBER LANGHORST: And that just made me think of another question. We had -- it was pretty easy to have everybody grandfathered when NRC took over accelerator-produced radioactive materials. Does anything that we're doing here impact that population? And I have not looked at that in that light, but that's a question I have for myself even. So, I'll have to look at that.

CHAIR MALMUD: That's a question we haven't considered until now, which is probably worth considering, because of --

DR. HOWE: What we did with the NARM rule is we said anyone that was working with the materials, we understood that certain states licensed NARM material. We understood certain states registered NARM material, and we recognized that certain states

did nothing. So, we did not grandfather people that were listed on licenses, because not all states had licenses. We didn't grandfather people that were registered, because not all states register. So, we said if you are using the new byproduct material covered by the NARM rule, you are using it, you need to come in for an amendment, or a license, and if you file your amendment or your license within the period of time, you could continue to use that material until NRC takes its final action. So, that's how we grandfathered those folks, because we recognized we could not depend on a license, we could not depend on a permit.

MEMBER LANGHORST: I'll have to think on that some more just to make sure.

CHAIR MALMUD: Thank you.

MEMBER WELSH: I have a question regarding Dr. Thomadsen's question and Dr. Howe's answer. If I understood correctly, you were asking if somebody was a history or literature major, and then became board-certified, if that individual could be an RSO, and the answer is no. But I guess --

DR. HOWE: Under the board-certification pathway. If they came the alternate pathway?

MEMBER WELSH: But it would seem impossible

to become board-certified, if they didn't have the 20 credits, or whatever minimum is required during their graduate education.

DR. HOWE: Well, there is a different one for that. The health physics one is a Bachelor's or graduate degree from an accredited college or university in physical science or engineering, or biological science with a minimum of 20 college credits in physical science. But I believe there are some individuals that may have a degree that were going for the health physics board-certification, and there were some that did not have physical science, engineering, biological science, or 20 college credits, because they came through from 20 years of work experience type of --

MEMBER WELSH: I just don't think I can understand how somebody would want to get board-certified in physics if you don't have education in physics.

VICE CHAIR THOMADSEN: Actually, that is a very good point. I remember when I got in the field in 1970, in order to get ABR certified I needed to have an advanced degree in one of those. I mean, there was no possibility with an English degree to get an ABR certification at the time, so I can't believe that

there was, that there existed an English major who was board-certified by ABR.

DR. HOWE: I used that as an example just because it would be obvious.

VICE CHAIR THOMADSEN: Right. But I didn't think that there --

DR. HOWE: But the Board had its -- the Board's requirements that were posted for people to take the Board essentially may have listed all of these, and said or equivalent. And the or-equivalent is not included in our regulations, so we gave the Boards the -- we said if you want someone to sit for your Board, that's fine. But for us to recognize a particular certificate, we need to insure that all the people have what's in here. The or-equivalent may or may not be equivalent in NRC's eyes. We don't have that option.

CHAIR MALMUD: May I ask a question, and that is, does the NRC believe that any current AU or RSO should be eliminated from practice, even though they have experience?

DR. HOWE: Repeat that one more time.

CHAIR MALMUD: Does the NRC believe that any currently certified AU or RSO should be denied the continued privilege?

DR. HOWE: Well, you said continued privilege.

CHAIR MALMUD: Any currently practicing RSO or AU.

DR. HOWE: Practicing RSO or AU?

CHAIR MALMUD: Yes.

DR. HOWE: Which means they would be on a license, or a permit?

CHAIR MALMUD: Yes.

DR. HOWE: No, because if they're on a license, or a permit, that makes you, by definition, an AUNP.

CHAIR MALMUD: So, can we agree that whatever rules are changed, that they are grandfathered, since we don't feel that they should be denied the ability to continue to practice?

DR. HOWE: When we change our rules, we don't always word it right, but the idea is that when we change the training and experience requirements, if you're already one of those individuals, you're already listed on a license, you are, by definition, an authorized user, RSO, ANP, you get to continue to do that. You don't have to meet the new requirements that gave you that authorization.

Now, if you want to be that authorized

individual for a new modality, that's another question.

CHAIR MALMUD: Different story.

DR. HOWE: But you get to continue to be an authorized user, authorized medical physicist, pharmacist, RSO. That's part of the grandfathering. And that's always been part of the grandfathering.

CHAIR MALMUD: So, that in these discussions that we're having, we are not discussing eliminating the privileging of any currently practicing AU or RSO. Is that a fair statement that I made, or is there an exception to my statement?

DR. HOWE: That's a fair statement. For a while there, we had practicing people in Agreement States that weren't listed on licenses. There may still be a few that aren't listed on licenses. That's the only exception I can think of right now, because if you weren't authorized and you're on a license, you get to continue. I think Lynne Fairobent has --

MS. FAIROBENT: Dr. Malmud, Lynne Fairobent with AAPM. For authorized medical physicists prior to this current Part 35, there was no category of ANP, so there were very instances where that individual would have been on a license. So, you couldn't simply -- because they weren't listed on licenses, that's where

we ran into the problems when the Board dates were put prospective with effective dates, because by virtue of the Boards, they couldn't simply come under the new Board pathway to be an ANP. That still continues to be a problem for those individuals who had not done Part 600 uses, but are board-certified in therapy physics.

CHAIR MALMUD: Have you any idea how many people are affected by that?

MS. FAIROBENT: I'm not sure we have good hard numbers, because we are six years out from all the --

CHAIR MALMUD: Order of magnitude, 10, 100, 1,000?

MS. FAIROBENT: Hundreds, potentially.

CHAIR MALMUD: Hundreds plural?

MS. FAIROBENT: Sure, because a lot of therapy physicists may only currently do Part 400 use, which an ANP is not listed -- is not required to be listed on the license for manual brachytherapy. An ANP only is listed on a license for Part 600 uses, HDR, Gamma Knife, and cobalt teletherapy.

DR. HOWE: And strontium-90.

MS. FAIROBENT: Yes, strontium-90. Thank you.

CHAIR MALMUD: Thank you. My question is answered. Any other questions or comments?

MEMBER SUH: I have a question.

CHAIR MALMUD: Please do.

MEMBER SUH: Does the NRC have a definition of what's considered required training and experience? Like for instance, the Gamma Knife, is there something that's written that says you have to do -- see X number of cases, or be -- is there a certain language that is --

DR. HOWE: We have for 35.1000 use, the Gamma Knife is actually in our regulations, so the requirements for an authorized user are in 35.690. For the Perfexion, which is a 35.1000 use, we've got what we believe are adequate training and experience criteria on our website. For the other modalities, like the yttrium-90 microspheres, the gliasite, the Novoste intravascular brachytherapy, and seeds being used as markers, we've got that guidance up on our website. And if you go to the medical toolkit, you'll find a lot of very helpful information for medical use licensees, and individual physicians. And we try to keep that up to date. Does that answer your question?

MEMBER SUH: Yes.

CHAIR MALMUD: Debbie.

MEMBER GILLEY: I just wanted to comment on Donna-Beth's remarks. It is guidance; it is not regulation, so you may see some variation in the states from what you see as NRC guidance.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: But I don't think that anything in the 35.690 specifically says anything about number of cases.

DR. HOWE: No, it does not. It has a residency training program, which we're assuming you'll get case work in the residency training program. But it also does not say anything about the individual modalities that are in 600.

VICE CHAIR THOMADSEN: I'm sorry. What was the last thing you said? I couldn't hear.

DR. HOWE: It doesn't say anything about number of cases, because we're assuming that in your residency training program, you will be treating patients. It also does not say anything about the specific modalities, and that's why we have a paragraph after the attestation that talks about training and experience in those modalities.

MEMBER WELSH: So, this gets back to the point that was raised earlier about how does NRC know whether or not somebody has had Gamma training during

their residency training program? Relatively few training programs offer Gamma Knife training and experience. So, the question becomes a practical one, for the majority of radiation oncologists who have not received Gamma Knife training during their residency training program, what is the minimum requirement to allow that person to now become a Gamma Knife user? We know about the vendor-specific training, but how about an authorized user at the institution that has Gamma Knife saying I have supervised and trained this individual, and he or she can now do Gamma Knife independently at my institution. There's nothing that allows for that explicitly enough to satisfy most institutions.

DR. HOWE: It's not prescriptive, but it says you have to receive training in device operation, safety procedures, and clinical use for the types of use for which the authorization is sought. The training may be satisfied by, one is vendor, two is receive training supervised by an authorized user, or authorized medical physicist, as appropriate, who is authorized for the type of use which the individual is seeking authorization. So, we do have the physician pathway for the training in a facility that's got a Gamma Knife. And then we have vendor training for the

facility that's just getting a Gamma Knife.

MEMBER WELSH: And nothing as far as number of cases.

DR. HOWE: No, we're not that prescriptive.

CHAIR MALMUD: Would you wish the NRC to -

DR. HOWE: Do you want us to put number of cases?

MEMBER WELSH: Well, I can just say that my institution interpreted this a little bit differently, and insisted that I go elsewhere for the training at considerable expense. So, perhaps that's a single institution --

CHAIR MALMUD: That, Dr. Welsh, reinforces my earlier comment, which is the director of your training program or your program really is the one who bears the responsibility for certifying your competence, and required you to do that.

MEMBER WELSH: Yes.

CHAIR MALMUD: Right at the home base, not at a distance from the NRC. That's extremely effective, and the NRC's guidelines are very well written to allow for that to occur in their current state. I've got a member of the public who wanted to say something. Is that what --?

DR. MOWER: Herb Mower with AAPM. I

actually have two questions. As somebody who was a radiation safety officer a couple of years before the new regulations went in, training a person who came along with a Master's in medical physics and whatnot, who took over in that role, am I qualified to serve again as a radiation safety officer because at the time of the conversion to the new I was not on a license, but had been on the license previously? I've heard both interpretations on that. An authorized user would probably be continuing to function as an authorized user through that time frame, but if I were to go to another institution, and one of the things they now wanted me to do was to be an authorized user again, could I do that not actually being on a license on the date of the cross-over to the new regulations?

CHAIR MALMUD: I will allow that question to be addressed to Dr. Howe.

DR. HOWE: Yes. And you're talking about being an authorized medical physicist?

DR. MOWER: No, I'm talking about being a radiation safety officer.

DR. HOWE: Being a radiation safety officer.

DR. MOWER: As a medical physicist, I am continuing to do that.

DR. HOWE: Because you're definitely not authorized to be an authorized user, because that's physicians, dentists, and podiatrists. So, unless you're a physician, dentist, or podiatrist -- but the other one says you're not listed on a license, so then you would go to the 35.57 --

DR. MOWER: Well, but I was listed on a license prior to the date of conversion, but not on the date of conversion.

DR. HOWE: If you were listed on October 24th of 2002, then you're grandfathered.

DR. MOWER: Okay. If they were on the license October 23rd of that year, but not on October 24, would I be eligible to be an RSO again without going through a lot of red tape?

DR. HOWE: It says if you were listed on a license of broad scope before October 24th of 2002 you need not comply with the new requirements. And then you've got requirements that changed again, and you go back into April 2005.

DR. MOWER: I'm sorry, I don't hear as well as I used to. Could you speak up a little bit, please?

DR. HOWE: The regulations say that if you were listed on a license before October 24th, then you

need not comply. But your specific case would be reviewed by, if you were in an NRC state, by the NRC Regional License reviewers. And they would give you an exact answer. And if you're in an Agreement State, it would be answered by the Agreement State people. So, I could not answer your question in this part of the meeting without seeing other information.

DR. MOWER: Okay. My other question is relative to an RSO. What things governed by the NRC which may be at a particular institution, does the RSO have to have had extensive training in or personally to be the RSO, in order to serve as RSO for that institution. In other words, if somebody is an authorized user as a radiation oncologist, as a nuclear medicine person, and has something on their certificate which says they're eligible, but they had never done radiation therapy, and that institution does I-125 prostate seed implants, what does -- does that person have to go through something else relative to that, since basic principles of radiation safety are pretty much the same for everything?

DR. HOWE: For an authorized user to become an RSO at a facility, they have to have training and experience with similar types of use for which the license is asking authorization for.

DR. MOWER: So, somebody who was trained in therapy would then have to go and get some kind of training in nuclear medicine and things, procedures and whatnot.

DR. HOWE: And then you would fall down to the other category, you have training in radiation safety, regulatory issues, and emergency procedures for the type of use for which the licensee seeks approval. So, the authorized individual has to have experience with radiation safety aspects of similar types of use, a byproduct material for which the individual has radiation safety officer responsibilities.

DR. MOWER: Okay. That ends up being a rather large menu.

DR. HOWE: It's very flexible.

DR. MOWER: And I'm sure -- I think the Commission should take a look at that and see relative to what are radiation safety aspects of something, what is the overlap, and are they being overly prescriptive in what's being required of this. And I would suggest that this be one of the things that you gentlemen look at as you go out to the workshops.

CHAIR MALMUD: Thank you. Other comments or questions at this point? Dr. Guiberteau.

MEMBER GUIBERTEAU: I just wanted to point out again that a number of these items that may seem disconnected are not, and to encourage in the workshops inclusion of some of these other items, such as Number 12, to allow Assistant RSOs to be named on a license, because with the difficulty we seem to be having and the confusion regarding who does, and who does not qualify, that these may be in some institutions the only way that they can provide these services with a competent RSO, or a well trained, or appropriately trained RSO. So, again, I'm not -- I don't, necessarily, think you need to physically put these together, but I do think that the items in the discussion of certain topics should include those that impinge upon a shortage of RSOs.

CHAIR MALMUD: Thank you. May we have a motion with respect to Bullet 2 currently before us with regard to recommendation for changing some of the wording there?

MEMBER ZANZONICO: Could we have a motion to eliminate the requirement?

DR. HOWE: For all pathways.

MEMBER ZANZONICO: For Board -- the requirement for attestation for board-certified individuals.

CHAIR MALMUD: That's bullet what?

DR. HOWE: That's bullet 1.

MEMBER ZANZONICO: But then that makes bullet 2 --

CHAIR MALMUD: You are recommending that we eliminate the attestation for Board certification pathway. That's a motion. Is there a second?

MEMBER GUIBERTEAU: Second.

CHAIR MALMUD: Seconded by Dr. Guiberteau. Any further discussion of that motion?

MEMBER GILLEY: But that's only for Boards that have been recognized since 2005. Correct? That Board certification pathway is only for Boards that have been recognized by NRC since 2005. That is not anybody that passed a board-certification prior to the date that the Boards were recognized by NRC.

DR. HOWE: You would have to meet the A Part of the training and experience, which is you're board-certified by a Board recognized by the NRC.

MEMBER ZANZONICO: But the timing of the recognition by the NRC, is that relevant?

DR. HOWE: Is in the recognition.

MEMBER ZANZONICO: Right.

DR. HOWE: I gave you a printout of --

MEMBER GILLEY: So, anybody who was board-

certified before that date, that won't apply. That attestation will still be required.

MEMBER ZANZONICO: Well, my motion would be to eliminate the attestation for board-certification, the board-certified individuals regardless of their date of certification.

MEMBER GILLEY: I will second that.

CHAIR MALMUD: It's been seconded by Dr. Guiberteau, and any further discussion of it? All in favor of that motion?

(Show of hands.)

CHAIR MALMUD: Any abstentions? Any opposed? It carries unanimously. This recommendation carries unanimously to eliminate the written attestation for board-certification pathway.

MEMBER ZANZONICO: Regardless of date of--

CHAIR MALMUD: Regardless of the date of the certification.

DR. HOWE: Thank you.

CHAIR MALMUD: That, therefore, addresses Bullet 2, does it not?

MEMBER GILLEY: No.

DR. HOWE: Bullet 2 is the alternate pathway.

MEMBER GILLEY: Without board-

certification.

CHAIR MALMUD: Okay. So, now we're up to Bullet 2, which is we need a recommendation for altering the wording there, if you wish to.

MEMBER LANGHORST: And could we hear the proposed wording again?

CHAIR MALMUD: It would say, "Revise the attestation to say dot, dot, dot, has received the requisite training and experience necessary to fulfill the radiation safety-related duties required by the licensee.

MEMBER LANGHORST: So moved.

CHAIR MALMUD: And seconded by Dr. Thomadsen. Any further discussion of that motion?

MS. HOLIDAY: Dr. Malmud, this is Sophie. Could you please repeat that motion for me?

CHAIR MALMUD: Certainly. Bullet 2 would be changed to say, "Revise the attestation to say," and then there are some dots there for missing words, "has received the requisite training and experience in order to fulfill the radiation safety-related duties required by the licensee."

MS. HOLIDAY: Thank you.

CHAIR MALMUD: Thank you. Any further discussion of that motion? The motion was made by Dr.

Langhorst, and seconded by Dr. Thomadsen. All in favor?

(Show of hands.)

CHAIR MALMUD: Any opposed? Any abstentions? It's unanimous. The third bullet doesn't require action, does it?

DR. HOWE: We have several SRMs, et cetera, that you could vote on, if you want.

CHAIR MALMUD: I'm sorry, I couldn't hear you.

DR. HOWE: We have Commission papers and SRMs you could vote on it, if you want. It doesn't have all the language there, but it essentially says residency programs can sign attestations if certain conditions are met. We're not sure exactly what all those conditions are met, but the concept right now is that there be at least one authorized user in the residency training, and that that authorized user agrees that the person meets the attestation.

CHAIR MALMUD: Is that acceptable?

VICE CHAIR THOMADSEN: That sounds good.

CHAIR MALMUD: Would you wish to make a motion?

VICE CHAIR THOMADSEN: I would make a motion to support the language which isn't shown

there, but has been read into the record by Dr. Howe.

CHAIR MALMUD: It's been moved. Is there a second to the motion?

MEMBER WELSH: Second.

CHAIR MALMUD: Second by Dr. Welsh. Discussion?

MEMBER FISHER: Yes, Darrell Fisher. Just is this essential and important?

DR. HOWE: Is this essential?

MEMBER FISHER: The third bullet, is it essential and important to define the conditions under which a residency program director can sign an attestation letter, or is it merely satisfactory that that residency program signs a letter?

DR. HOWE: I think the staff's concept is that it would like to have the training associated with an authorized user, or an authorized medical physicist, because we have residency training in both. And that if that authorized user, or authorized medical physicist didn't believe the person was qualified, that that would be an important statement.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: I would say that it most likely is a very important component of what we're looking for. Think back to the question Dr. Howe

raised a while ago now about how does NRC know if an individual has received training in a specific modality during their residency training program, if all we have is board-certification? I brought up the term diploma, which I meant to use loosely. I understand that the diploma itself is really nothing more than just a pretty piece of paper, but this residency program attestation is the real meat of the act, the real meat. And this attestation, or this statement, the residency program director says during the previous four years, this individual received training in HDR, brachytherapy, prostate seed implantation, Gamma Knife, and signs off, that indicates to the NRC that this individual came from a training program that provided those modalities, and in addition to that board-certification, should supply NRC with everything that they're looking for. Without something of this sort NRC will always be scratching their heads about well, there's board-certification, but is Gamma Knife included or not? Does this person have to go and take the specialized training course? Is this person an authorized user for prostate seeds, or not? So, I think that is --

CHAIR MALMUD: Thank you. Dr. Guiberteau.

MEMBER GUIBERTEAU: I agree with Dr.

Welsh. I think this is a key part of this revision. In residency programs, the residency director is responsible overall for the education and all of the requirements of the RRC, and of the ABR in order to take -- become board-certified and to complete their residency successfully. No one else in the program has responsibility for this.

In terms of the NRC training, there are multiple AUs. And, for instance, in the ABR Diagnostic Radiology certificate with the words AU-eligible affixed above the seal, this means three areas of the rule. So, it's not infrequent that the case experience and the training has been provided by a number of preceptors who are AUs, and to have each one sign separately would not be -- would be, one, sometimes impossible to do because the three may not be there at the time you might need an attestation for somebody who's going through the alternate pathway, and has had this training in a program, for instance. So, I think from just an efficiency point of view, from a responsibility point of view, and from a practical point of view that I think we have to have that in terms of making sense of this whole revision.

CHAIR MALMUD: Thank you. Debbie.

MEMBER GILLEY: Yes, I just have a

logistics question. Is there a list of residency program directors that I, as someone who's reviewing this attestation, can verify that this is a residency program director that signed off on this attestation?

MEMBER GUIBERTEAU: Yes.

CHAIR MALMUD: Yes.

MEMBER GUIBERTEAU: You can go to the ACGME website under the individual programs.

MEMBER GILLEY: Okay.

MEMBER GUIBERTEAU: And it will tell you who the program director is currently.

MEMBER GILLEY: But not past.

MEMBER GUIBERTEAU: No, but that program director has access to all of the records, some of which are peer review protected, and so that person can, if there's a new program director, can go back and look through the records to see exactly what - that person had all their paperwork. So, that's the way that works.

MEMBER GILLEY: Thank you.

CHAIR MALMUD: And I believe we have a motion on the table?

MEMBER ZANZONICO: Could someone repeat the motion?

VICE CHAIR THOMADSEN: I think it was

mine.

CHAIR MALMUD: Yes, it was.

VICE CHAIR THOMADSEN: And it was that we support the language, not all of which was on the slide, but presented by Dr. Howe and is in the transcript on the residency program director signing attestations.

MEMBER ZANZONICO: Would you repeat your language again?

DR. HOWE: I may not get it exactly. Yes, this is a little more than I had said, but it's essentially -- except the attestations from residency program directors representing consensus of residency program facilities as long as at least one member of the residency program faculty is an authorized individual. And in the same category, that the designated by the applicant seeking authorized status, and there was another one that that authorized individual did not vote against.

VICE CHAIR THOMADSEN: Right.

CHAIR MALMUD: Thank you. All in favor of the motion?

(Show of hands.)

CHAIR MALMUD: Any opposed? Any abstentions? The motion carries unanimously, Dr.

Howe.

DR. HOWE: Thank you.

CHAIR MALMUD: I believe that completes the business of this session.

MR. LOHR: Dr. Malmud.

CHAIR MALMUD: Oh, I'm sorry. Excuse me.

MR. LOHR: Ed Lohr. I understand Dr. Welsh's comments how the NRC would be -- have the opportunity to see what the modalities were for the alternate pathway. On board-certification training, I'm still a little unclear and would like to hear the ACMUI's views on how the NRC should collect the data or information, if you will, on a board-certified individual, so we would know what modalities that individual was trained in.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: I would reply that anything that applies to the alternate pathway, essentially, would be the same for board-certified individuals, and that you can't become board-certified if you haven't gone through the residency training program. And, therefore, the residency training program director could have a statement that lists the modalities at that institution's training program. Does that answer your question?

MR. LOHR: Well, it's not a question that I went looking for a direct answer. I was looking for views of how the NRC should go about getting this information, such as the attestation for the alternate pathway as you suggested would list the modalities. But in the Board certification pathway, we would not have an attestation under your motion. Therefore, I was asking what the Board thought for the -- that perhaps we should do for collecting information or being able to have access to information.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: I don't think that Dr. Welsh was talking about the attestation. He was talking about the certification, not certification, the statement of the residency director as to what modalities the resident saw as a resident. So, it would be from the residency program.

MR. LOHR: Correct, but does that not -- in the discussion was that not for the alternate pathway for that attestation?

VICE CHAIR THOMADSEN: The resident needs to have that statement to go to the Board to take the Boards, so they would have to supply that -- right, they would need to supply that information to the NRC when applying for a given modality. There is no other

way to know what modality they've trained in.

CHAIR MALMUD: So, a copy of the document would be available to be submitted to the NRC?

VICE CHAIR THOMADSEN: Yes. Right.

CHAIR MALMUD: Thank you.

VICE CHAIR THOMADSEN: They need that document.

CHAIR MALMUD: That being the case, we'll break for lunch, and resume on schedule at 1:00. Thank you all.

(Whereupon, the proceedings went off the record at 11:25 a.m., and went back on the record at 1:05 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:05 p.m.)

CHAIR MALMUD: Okay. Ladies and gentlemen, if you would care to join us at the table, we can get started.

The next item is Item 13 on the agenda, and that is Public Dose Limits for Released Patients: Is There a Need for Rulemaking? Mr. Luehman will initiate the discussion.

MR. LUEHMAN: Okay. Thank you, Mr. Chairman. I guess, as the title says, it is patient public dose limits per annum/per episode. This has been an issue for some time. It last came up in the public meeting with the Commission last October.

I guess what the staff is seeking from the Committee is their views on this issue as well as their views on the significance of this issue. And what I mean by that second part is right now this is not in the collective 28 items that are in the expanded rulemaking.

And I guess the staff would like to get some sense if the Committee believes this is something that needs to be dealt with, what kind of priority it should have, given that we have a lot of issues already trying -- probably have a full rulemaking as it is. So those are the two points I want to make on

that slide.

Let's see. Background -- right now, if you read the regulations, the current regulation is silent on the issue of per annum/per episode. I was asked at the Commission meeting by one of the Commissioners how that happened, and I told him I wasn't there, but I opined that the drafters of the rule felt, you know, just that they knew what they were talking about, and so that's what got written down, what everybody assumed everybody understood. And as it turns out, I think that some people left that believing that it was per annum and others believing it was per episode.

And maybe there was another group, given that at the time there wasn't -- there weren't that many treatments, there weren't that many members of -- excuse me, patients that were giving -- being given multiple doses that really per annum and per episode really didn't make any difference, because patients were typically treated once with -- the isotope, obviously, of most use is iodine-131, but people were going to be treated with one fairly large therapeutic dose. And, therefore, whether it was per annum or per episode really didn't make any difference, because they were going to be treated once.

Again, I wasn't there, but the fact is that the regulations presently are silent. In 2008, March 2008, the NRC stated that, "We intend to pursue rulemaking to clarify this limit," but that at least based -- in this RIS that we were interpreting it as an annual rather than a per release limit.

The statement's consideration -- there was an extensive review of the statements of consideration done, and they appear to support that it was written as an intended dose limit on the annual limit. Then, following the October meeting, at the January 2011 meeting, this Committee recommended that the NRC pursue a rulemaking to clarify the criteria, and the Committee endorsed a per episode limit.

And my understanding that the Committee's -- one of the Committee's concerns with an annual limit was that it created a -- it would create a fairly large administrative nightmare if -- you know, with people moving around, changing hospitals, that there would be some kind of requirement to track these doses as -- in order to comply with an annual limit.

And given that the patient could only be released if the maximum exposure to a member of the public was 500 millirem, that the potential safety significance of an additional exposure was not -- it

clearly didn't justify the administrative burden that would be put on licensee's if they -- in order to track this.

And so, really, what is open to discussion is there a solution that appropriately balances ACMUI's recommendation with the NRC's current position? And that is kind of where I will leave it. I mean, I don't want to -- I think I have my opinions, but I will turn it back to the Committee and get your advice.

Again, the other discussion item I would like is some -- what the Committee views as the priority of this given all of the other things that we have in the rulemaking area.

CHAIR MALMUD: Thank you for introducing the topic. Does anyone wish to make a statement? Sue?

MEMBER LANGHORST: I do have a few slides that I put together to help explain the Subcommittee's, and then hopefully the full Committee's, opinion that the current regulations are based on a per release limit.

CHAIR MALMUD: Thank you. And we'll put them up there.

MEMBER LANGHORST: Would you like me to go

up there, or can I sit here?

CHAIR MALMUD: Wherever you're more comfortable.

MEMBER LANGHORST: Okay.

MR. LUEHMAN: Do you want to change the slides or --

MEMBER LANGHORST: I'll have Sophie change them.

MR. LUEHMAN: Okay.

MEMBER LANGHORST: Okay? So if you'll go to the first one, this is from the proposed rule, and I just put up here what was in that proposed rule, June 15, 1994. And I will let you read that for yourself, but you can see the criteria was not likely to exceed five millisieverts or 500 millirem in any one year.

And if you'd go to the next slide, Sophie, this is Part (b) of that where if it was likely to exceed one millisievert in a year from a single administration; upon release they would provide written instructions. And the final part of that -- maintain that record for three years.

So that was the proposed rule published in the Federal Register in '94.

Then, to the next slide please, in the

final rule publication, there was a statement made in the section under activity-based versus dose-based release limit that the NRC is establishing a dose limit of five millisieverts or 500 millirem total effective dose equivalent to an individual from exposure to the release patient for each patient release.

Next slide. Under the discussion of the text of the final rule -- and this was under a paragraph where it was talking about recordkeeping requirements -- each patient release is to be treated as a separate event, and the licensee knowledge of previous administrations is unnecessary.

So next slide, Sophie, please. This is our final criteria, as published in 1997. And the per year, which was in there before, has been dropped.

And then, Sophie, the final slide, the same thing is in place for the written instructions. I did not finish the final part of that paragraph, which then deals with instructions concerning breastfeeding.

I would like to say that in our report on patient release, the ACMUI agreed that we believe this regulation, based on these criteria, is on a per release basis. We think that adequate safety is

provided by that current regulation, and we would not recommend that this be changed.

CHAIR MALMUD: Thank you. Comments from other members of the Committee?

MEMBER ZANZONICO: Pat Zanzonico. Certainly, I endorse the Subcommittee's recommendation that it remain a per release dose limit.

The other issues that this raises, among the other issues this raises is the following. If a per year dose limit were implemented, not only does one have the paperwork issue of patients potentially treated at many institutions, but at least the theoretical possibility of now incorporating diagnostic exposures -- I mean, exposures to individuals around a patient undergoing a diagnostic nuclear medicine procedure -- myocardial perfusion, whatever the case may be -- have a very small but finite dose to individuals around the patient, so it would seem illogical that if you impose an annual limit, why should not those be summed into the total exposure to individuals around the patient. And there, the logistical complications grow exponentially to the point it really does become unwieldy.

The other consideration -- and this hawks back to the days of the 30 millicurie rule where some

physicians were specifically treating patients or ablating the thyroid with I-131 doses of 29.9 millicuries, not because it was in the best interest of the patient medically, but specifically because it avoided hospitalization.

And so that was a situation where, at least implicitly, physicians were treating or managing patients suboptimally purely for regulatory reasons. And I can imagine that if an annual dose limit were imposed, physicians may likewise delay a second treatment in the same calendar year to avoid having to hospitalize a patient for that second treatment.

That doesn't speak to the soundness of the rule, but it is a reality I think that has to be taken into consideration. But I think, as the Subcommittee has said, based on practical as well as safety considerations, the .5 rem per episode limit is sound, is protective of public safety, and is consistent with optimum clinical management of the patients who would receive such treatments.

CHAIR MALMUD: Thank you, Dr. Zanzonico. Other comments?

(No response.)

If I may, as someone who is still engaged in the treatment of patients with radioiodine, I would

second Dr. Zanzonico's comments, in that I believe that optimal patient care would result from adhering to the per exposure rather than -- the per treatment rather than the per year limit.

It would constrain that which is in the best interest of the patient in terms of therapy, and would not really achieve much in the way of protection of members of the public compared to an annual limit for precisely the reasons that both members of the Committee have already stated.

It is not a significant issue in most instances either, because it is not common for a patient to be treated twice within a year, though it's possible. But the main issue is the quality of patient care would be limited by using an annual dose rather than a per treatment.

MR. LUEHMAN: We have a public comment on that.

CHAIR MALMUD: Excuse me. Oh, please.

MR. MOWER: Thank you, Mr. Chair. Herb Mower from the AAPM. And I support the standing of the ACMUI on this, and would ask the -- take back to the Commission and what not, we have -- Patient A, we have John Q, Public X. And what we seem to be worried about here is Patient A getting two exposures with

John Q X.

If you're really worried about what the public is receiving in a year, what happens to John Q X who encounters Patient A, Patient B, Patient C, none of which in this scenario would be realized because you are only looking at Patient A and how they intercept with John Q X but not Patient B, Patient C.

And in this more broader scope of worrying about that member of the general public, I don't see any way, with today's technology and following things, that we would ever be able to know all of the people that John Q X came in contact with who might have a radioactive body burden.

CHAIR MALMUD: Thank you. Other comments? Dr. Thomadsen?

VICE CHAIR THOMADSEN: If we make the assumption that the effect of the radiation is following the linear no-threshold model, it really makes no difference to the people who are being exposed from the patients whether they get exposed in one year or separated by a year. The biological effect is -- has to be the same. You might as well then optimize for the patient treatment.

CHAIR MALMUD: Thank you. Other comments?

MEMBER FISHER: Darrell Fisher. I think the arguments have been well stated by the different members of this Committee, so I won't try to duplicate anything already said.

But in looking at this, I considered one thing, and that is of what advantage to the regulators, or what advantage to the hospital, or to the patient, could be found in a per -- in a dose per year rule relative to a per release rule? Is there any advantage; is there any benefit, in regulating exposures to the non-patient general public from patient -- from released patient exposures?

In a very pure sense, if the risks were high, if the doses were high, I can see some justification. But through our analysis, we found that the -- through calculations that the doses to the general public in the vicinity of released patients is really very trivial. And the practicality of a hospital, trying to track doses to the -- to people beyond its control is really very limited.

I can't find any advantage to the NRC, to the patient, or to the hospital in trying to track doses to the general public on an annual basis. In a pure sense, yes, it makes -- we track doses to nuclear power plant workers, to hospital personnel with

dosimeters. They are always wearing dosimeters. There is a justifiable reason for an annual dose limit to radiation workers.

But I can't find any added benefit to either the regulator, to the patient, or the offsite general public, from an annualized limit. So I would, therefore, concur with the statements of the other Committee members on this issue, and recommend that the NRC clarify this during the process of revising the rules.

CHAIR MALMUD: Thank you, Dr. Fisher. Dr. Suleiman?

MEMBER SULEIMAN: I, for one, was pretty conflicted with the discussion the entire time. And my perspective is if you look on this as a regulatory limit, a dose limit to be enforced, adding a one-time event limit and ignoring the annual limit doesn't make any regulatory sense.

If I throw the regulatory dose limit, with enforcement and compliance aside, and look on this as a constraint -- I hate to use that word, but a speed bump, because this is a low probability scenario, we are not talking about an unsafe amount of radiation. This is clearly very, very, very low. And as people follow this, it is very, very unlikely that these

individuals may get multiple exposures during the course of the year. Even if they did, it wouldn't amount to much.

And if you look -- we don't go monitoring each and every individual member of the public to maintain their annual limit. It is just sort of a level at which we say we need to pay more attention to it. Then, I think it is perfectly adequate.

So if you're looking at it from a regulatory enforcement point of view, I have problems without having an annual limit. But if you're looking at it as sort of a guideline for people to follow -- and we are dealing with, as I said, a speed bump, a very low level here -- I'm pretty comfortable with it as it is. It really depends on how the NRC is going to pursue this.

CHAIR MALMUD: Any other comments from members of the Committee or the public?

MEMBER MATTMULLER: Yes. Again, I am in complete agreement with Sue's comments, except I would almost like to take it one step further -- and I know we will have a motion coming up on this -- but to also recommend that the NRC doesn't really need to follow up on this anymore, that there is no need for additional rulemaking to clarify this. I don't

believe so.

I think what Sue has highlighted in the Federal Register is more than adequate to support our position and subsequent motion that I'm sure will be coming that any rulemaking activities on this issue further will only take valuable staff and time away from other issues that we know are on their plate to consider.

CHAIR MALMUD: Thank you. Other comments? Member of the public?

MS. FAIROBENT: Thank you, Dr. Malmud. Lynne Fairobent with AAPM. Just follow up a little bit from Steve's comment, slightly different, and I would ask NRC in that I believe this is one of the topics for the upcoming workshops -- if when you publish the information that is going to be discussed at the workshop, if there is clear citations that could be provided from the statements of consideration of either the proposed rule or the final rule on this, that the staff base their decision on that it seems to be contrary to the sections that Sue has projected on slides, it would be helpful for the community to know where to look in the Statements of Consideration, considering this is a 1994/1997 regulation that we are talking about.

So if staff could lay out where their logic and their flow from their read of the Statements of Consideration, I think it would help to promote perhaps more intelligent discussion at the workshops on this.

CHAIR MALMUD: Thank you. Other comments? Does anyone wish to make a summary statement on behalf of the Committee to the NRC with regard to this issue? Sue?

MEMBER LANGHORST: I think I'll make that summary statement in the form of a motion.

CHAIR MALMUD: Thank you.

MEMBER LANGHORST: That the ACMUI continues to assert that the current regulations are based on a per release limit, and that we do not recommend any change in that regulation, and do not recommend that the NRC consider this at this time in this rulemaking process.

CHAIR MALMUD: Thank you. Do you want to include in that statement a reason for the statement, such as that there is no advantage to the patient or the public from --

MEMBER LANGHORST: As we have discussed, that there is no -- I'm sorry, I don't --

CHAIR MALMUD: No clinical advantage?

MEMBER LANGHORST: There is no clinical advantage and --

CHAIR MALMUD: And no advantage to the members of the public in using an annual rather than a per release limit.

MEMBER LANGHORST: Thank you for that addition.

CHAIR MALMUD: Thank you. That's a motion. Is there a second to the motion?

MEMBER WELSH: Second.

CHAIR MALMUD: Dr. Welsh seconds the motion. Any further discussion of the motion?

(No response.)

All in favor of the motion?

(A show of hands.)

Any opposed? Any abstentions? It's unanimous. So you have both the feeling of the Committee and the reason for the feeling of the Committee that there is no advantage to either -- in fact, there is a disadvantage to the patient to make it annual, and a disadvantage to the cost centers to make it annual, with no obvious advantage in doing so.

MR. LUEHMAN: Okay.

CHAIR MALMUD: Now, the second -- the issue about -- is this an issue, the final criteria,

up on the board now?

MEMBER LANGHORST: No. I just wanted to complete both the -- when the limit is and also when the written instructions were required.

CHAIR MALMUD: Now, the Committee -- I should state on behalf of the Committee, the Committee does recognize the public concern about this issue, particularly as it has been portrayed in some news reports. And the Committee is not ignorant of the concern, nor is it callous with regard to the concern. But the concern is not felt to be based in science and is not one which can be effectively addressed administratively.

MR. LUEHMAN: We appreciate that. Appreciate the Committee's views. And I guess the real -- the second part of the request was -- I think I heard Dr. Langhorst say that we don't need to address it.

Well, I mean, we can just leave it as it is, but I think that if you go to the regulation as it is it is -- right now, you can read it in, but in the -- I don't have the regulation in front of me, but in the section it is -- it's just -- it doesn't specify either, and so, I mean, I think the optimal solution would be to put -- not to be -- to make it clear for

all time is --

CHAIR MALMUD: We recognize the current ambiguity.

MR. LUEHMAN: Right.

CHAIR MALMUD: And it's our recommendation that it be interpreted as per release, not per year, and we feel -- the Committee feels unanimously and strongly about it.

MR. LUEHMAN: And you could live with the ambiguity, I mean, at least as it's written.

VICE CHAIR THOMADSEN: As long as it's enforced.

CHAIR MALMUD: As long as it's enforced on a per release basis, not a per annum basis.

MR. LUEHMAN: No, I appreciate that.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Would you feel better if there were something written in guidance documents about that?

MR. LUEHMAN: No, no, I was just getting the Committee's sense of the regulation and the necessity to actually make that abundantly clear in the regulation or simply interpret it that way going forward.

MEMBER LANGHORST: Sue Langhorst. Let me

clarify, I do not think it is something that should be pursued in this rulemaking that then can delay the rest of the rulemaking process.

MR. LUEHMAN: I appreciate that. Okay.

CHAIR MALMUD: Dr. Howe?

DR. HOWE: The ACMUI believes it is per release. But if the NRC looks at all of its materials and continues to conclude that it is per annum, does the Committee want to make a motion for rulemaking?

CHAIR MALMUD: What were the last two words you said?

DR. HOWE: Do you want to make a motion that you would or wouldn't support rulemaking?

CHAIR MALMUD: The Committee -- I think I am speaking for the Committee when I say that the Committee would not support an annual limit. The Committee is not supportive of the annual limit, of the interpretation as an annual limit. Does that answer the question as you have posed it? I'm not sure that I have answered the question as you posed it.

DR. HOWE: Your premise of not pursuing rulemaking was based on an interpretation of it being per release. But if NRC goes back and says it's -- "We thought it was per annum, and we still think it's

per annum," perhaps you might want to consider what you do in that case.

CHAIR MALMUD: Any suggestions what we would do next? Dr. Suleiman?

MEMBER SULEIMAN: Well, again, I felt all along that having a per release and a per annual limit being the same number was problematic. So my thinking would be is if you had to have an annual limit, I would increase it and allow multiple -- if you want an annual limit, I would not restrict it to the per event release.

I would allow somebody to be exposed to more than one event, because I think it's such a low number it would be constraining. If that's -- but I think having a per event and having it equal to an annual limit is basically limiting it to a per event.

CHAIR MALMUD: If I may, my concern about an annual limit is that there really is no way of monitoring it. The way patients are treated today, thanks to the insurance industry, a patient may be sent to Hospital A for an X-ray, Hospital B for an ultrasound, Hospital C for a diagnostic study with isotopes, and back to Hospital A for the treatment with isotopes, all depending upon which hospital has a contract with that particular insurer for the

provision of that service at the lowest price available. And we see that daily now in our own city, and I'm certain that the same issue exists elsewhere.

So that would mean the patient would have to keep a running record with them of their radiation exposure, not to mention occasional X-ray exposure for a variety of other treatments. So that it is impractical. It's just not -- it's not enforceable.

And unless everyone is to wear a badge, if we were all to be issued badges as patients, and turn them in perhaps annually rather than monthly, it might be tracked. But that's highly -- it's very expensive, and it's impractical.

So I think that the Committee's feelings are both -- on behalf of the patient who would be convenienced, the public, which doesn't really -- which isn't exposed to any significant risk from this, and the expense would be extraordinary in implementing something which is totally unnecessary. And the amount of radiation that we are discussing with respect to exposure is trivial.

And, furthermore, the difference between the two is dependent upon patient behavior. For example, if a patient who was on an annual limit decides to have intercourse with another individual

immediately after therapy, the radiation exposure there will be dependent upon the proximity, which is very close, and the time, which is a variable.

(Laughter.)

But, nevertheless, it's not brief.

(Laughter.)

Under the best of circumstances.

(Laughter.)

So that to monitor human behavior on this scale is just impractical. And we are not cats or dogs. We don't generally urinate in the street. So the concern about the effluent of the radiation for animals is different from that for humans. Humans generally use toilet facilities, and the effluent is diluted immediately, so that these are very different issues from the ones that have been highlighted in the newspaper.

And I don't think that we should be obligated to respond to -- on behalf of the public, on behalf of the budget, on behalf of the patients, we shouldn't be responding to issues that are trivial in terms of the amount of radiation exposure.

Do I sum up what the Committee feels in general?

(Several responses in the affirmative.)

So how would we respond if they said they want it annualized anyway? Dr. Welsh?

MEMBER WELSH: So if I understood what Dr. Howe was asking of us, I wonder if it might be appropriate to amend Dr. Langhorst's motion to state that if NRC continues to interpret this as a per annum rule that we then would say rulemaking may be appropriate, just so that the language is no longer ambiguous? Because we are all in unanimous consensus that we feel this way. But if somebody could read the rule and still say that it's unclear enough that it's per year instead of per release, then we have -- we'll have the same discussion next year.

CHAIR MALMUD: May I ask, Dr. Howe, was that the purpose of your question?

DR. HOWE: That was the purpose.

CHAIR MALMUD: And Dr. Welsh has captured the purpose of your question better than I have. Dr. Langhorst?

MEMBER LANGHORST: In the IRS -- excuse me, RIS --

(Laughter.)

Excuse me, slip of the tongue there. And I can't remember the number -- I don't have that right in front of me -- that was the annual versus --

MR. FULLER: It should be 08-007, March 2008.

MEMBER LANGHORST: I believe in that RIS that NRC voiced that their opinion was they wanted it -- they had meant it to be per year, that there was confusion, and that in order to move forward in making it an annual limit, they would have to pursue rulemaking, and said that NRC intends to pursue rulemaking with this.

I think that the Committee is concerned that if you pursue this rulemaking on this topic, with this current rulemaking process, we are concerned about it slowing up the progress with the rest of the rulemaking. And so we would recommend it not be included in this rulemaking process.

CHAIR MALMUD: Is that a motion, Dr. Langhorst?

MEMBER LANGHORST: I will make it so.

CHAIR MALMUD: Is there a second to the motion, and then discussion?

MEMBER ZANZONICO: Second.

CHAIR MALMUD: Second by Dr. Zanzonico. And Dr. Thomadsen?

VICE CHAIR THOMADSEN: How long would you expect the rulemaking to be held up if you were just

to be inserting, as appropriate, per release into the regulation?

MR. LUEHMAN: Well, I don't think that the change -- I don't think that the change itself would be extensive. I think that what you have to keep in mind is there are likely to be other stakeholders that have different views on this.

And, therefore, even if we -- or the Committee, or even -- whether we take the per annum or per release and have to choose one in a rulemaking, this may -- this always has, any time you go to rulemaking, it has the possibility of being the relatively small or piece of the puzzle that holds up the whole -- you know, the whole thing from moving forward, in that it gets extensive comments, in that, you know, there is -- I mean, all the way to somebody challenging the NRC -- I'm not saying this is going to happen, but, you know -- on this, but, hypothetically speaking, somebody challenging that requirement or that proposed requirement before it went final in a lawsuit.

So, I mean, any time -- I guess the point I'm making, Dr. Thomadsen, is I don't think that the mechanics of inserting it into a rulemaking and going forward are that extensive. But the issue may in fact

be one of some controversy from some set of stakeholders, and it could in fact slow down the process simply because there is much debate, much concern, about that provision.

So that is -- you know, that's -- I mean, I would make it analogous to when they do -- you know, when our -- when Congress goes through their budget process. At the end, it always seems like it's some small -- relatively small detail that holds up an agreement. And could this be that?

I know that there are stakeholders that would feel strongly on both sides, so, I mean, I'm not saying that it would be. It may go through and everybody may accept whichever one is chosen, but there always is the potential when you know that there are stakeholders on -- that have different views of the issue, whereas many I think of the other issues, of the 28 that we didn't discuss in detail, the few that we did spend some time on, obviously we chose those because they elicit a lot of different views.

But many of the other probably 20 of the others are, I would say, updates, conforming changes, non-controversial changes, things that just need to be updated that we are probably not likely to get very much comment on.

If I thought this was going to be one of those, I would -- you know, I think it would be relatively easy, but I think that our experiences in the area of patient release any time we -- we change something in 35.75, or discuss something in 35.75, we get some pretty strong stakeholder comments on both sides, both from the medical side, the stakeholders such as yourselves, and the professional societies, as well as people -- you know, members of the public.

So that would be my perspective on it, that the -- I don't think the rulemaking preparation would be extraordinary, but it may be a -- I think it's a requirement or adding it as part of a rulemaking package, may turn out to be -- lengthen the process just because of the nature of the item.

CHAIR MALMUD: Thank you. Dr. Guiberteau?

MEMBER GUIBERTEAU: I agree with those comments. I would like to speak in favor of Dr. Langhorst's motion by saying that I think if we look at this from a point of view of the stakeholders in the medical community and their patients, that the risk of a significant distraction that delays, you know, any further progress on these will impact that group, including patients and practitioners using radiopharmaceuticals and radioisotopes, far more than

trying to change something that we believe is already in the rule.

I can tell you that I don't believe that practitioners using -- using a therapy are confused at all, because the literature is clear, the guidance from non-regulatory agencies in the literature is clear. The formulas that we use to calculate release are based on the dose to the public on that release.

And my feeling is there is no need to clarify that from the point of view of the standards in the community, because that is the way it is being practiced. So I don't see an urgency for making any change to the rule, and I see a real down side on this issue, not to mention perhaps getting more -- you know, getting confusion in an area that seems to be one of the few places where it's clear. You know, we give the patient dose, we make the calculations. If it fits, the patient can go home, can be released, based on what we know about the patient.

So, I mean, to me it might be more disruptive to do this when it's already clear. I don't think that any further movement in terms of rulemaking on this issue should be initiated at the present time.

CHAIR MALMUD: Thank you, Dr. Guiberteau.

Dr. Welsh, you had something to say?

MEMBER WELSH: Yes. I understand and appreciate what Dr. Guiberteau has just stated. However, I would ask, what are we going to do when this problem is discussed again at the next meeting and the meeting afterwards? Because NRC continues to interpret the wording in a fashion that is different from what we are stating would be most appropriate.

And from what I gather, NRC is telling us that they are going to continue to interpret it as per annum rather than per release. So I'm just wondering if we have an opportunity to address this, and perhaps put some closure to this rather than leave it so open-ended like we risk doing presently.

CHAIR MALMUD: Thank you. I think we had a member of the public.

MS. FAIROBENT: Thank you, Dr. Malmud. Lynne Fairobent, AAPM. From my perspective, I would not like to see this included in this expanded rulemaking for the same reasons that have been expressed. However, I do have a different issue.

If NRC is interpreting it from their perspective on a per annual basis and not a per episode or a per release limit, how are they implementing this in enforcement authority? What is

their guidance to their inspectors when they are out looking at this? And are licensees being cited based on NRC's current interpretation versus what may be in the regulatory language?

And I think that that's something that I would ask the staff to -- if they are going to continue this issue as part of the public workshops to also factor in, in their discussion piece on this to address how it is being handled in enforcement and how NRC intends to handle it in enforcement until they meet their statement that they intend to pursue rulemaking on this basis.

CHAIR MALMUD: Thank you. We take that as a question to NRC staff.

MR. LUEHMAN: And I think that -- yes, I think that the last time this came up Rob Lewis answered this question, and I guess I will answer it again, maybe slightly differently. But the fact is that the regulation right now, as it's written, you know, where -- is, as we stated, the language -- whether you believe the interpretation -- is ambiguous.

And I don't think that presently because it's viewed -- the language is viewed as ambiguous, and at least the staff's position is that way because

we put out the RIS, that we are taking it -- we are enforcing that, because I think that if we enforced it, the only thing we have is the RIS, we may be able to rely on the regulatory -- you know, the basis.

But we don't think that the regulation right now is clear enough that we are instructing anybody to even look at this area. So, I mean, our inspectors are not looking at whether this should be per year or per episode.

So, I mean, it is kind of an odd situation to be in, and I think that is why I got asked the question by one of the Commissioners at the Commission meeting -- how did we get here where we don't have -- where it isn't clear right specifically in the rule language, and I told them honestly, "Well, I don't know."

But the reality is because it's that way, and because there are these -- the diversity of the opinions, we do find ourselves in a situation where we are not attempting to look at this, because I think that if we went to Dr. Langhorst's facility, she would say, "Go ahead, cite me," and we would, and then there would be a big argument and neither of us could point at the regulation and say, "See, right here it says it's per year or per episode."

And I think that given that situation, we are not -- we, from the regulatory clarity standpoint, are not in a good position with the regulation as it is. So the practical effect of that is, if you want to use a baseball analogy, is tie goes to the licensee. And we are not, you know, presently -- you know, we are not presently trying to enforce our interpretation.

We put out in a RIS that we think that that is the best -- per annum is the best interpretation, if, as I believe Dr. Guiberteau said that the community -- and we believe that the community is interpreting it and it has interpreted it as per episode, that is going to continue.

The fact is, we believe that whether it's interpreted as per year or per episode, given the very small number of patients that are actually treated in, you know, consecutive years or consecutively in the same year, that the safety significance, the potential safety significance of that is so low that -- and so infrequent that -- I hate to say this as a regulator, but we have lived with the ambiguity, and I guess we could continue to live with the ambiguity, though I think ultimately we do think that it should be clarified at some point.

CHAIR MALMUD: Thank you. Sue?

MEMBER LANGHORST: I will clarify on the point you make about your inspectors, they do look at our release analysis and how we document it. So they are not ignoring --

MR. LUEHMAN: No, no, no, no.

MEMBER LANGHORST: -- it, but, I mean, they are looking at how we document that we are within the limit, and we do it on a per release basis.

MR. LUEHMAN: And I didn't mean to imply that -- you know, inspectors are looking --

MEMBER LANGHORST: I just wanted to clarify that.

MR. LUEHMAN: Right, yes. Thank you for the correction. Our inspectors are looking at release and whether the calculations that are done to release patients or whether a patient stays hospitalized, are done and done properly. The only issue that I -- that the inspectors are not raising -- and in that regard, if there is an issue, is this interpretation of whether that is done on a per annum or per release basis.

So I think that -- to summarize, I think that the NRC finds itself in kind of an ambiguous situation itself. It has an unclear regulation, as

stated by -- basically, admitted by the RIS. At some point, we think that it ought to be clarified. We stated a position, the Committee stated a position, and at some point we will have to clarify it.

But the Committee has recommended, at least what I've heard today, has today, "Don't tie up the resources on all these other long-awaited rulemaking issues that we want to get out, to delve back into this one." So --

CHAIR MALMUD: That is the correct interpretation --

MR. LUEHMAN: Okay.

CHAIR MALMUD: -- of the Committee's feelings.

MR. LUEHMAN: Thank you.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: Yes. I was just going to reiterate or reword what you have just stated, and so I have no further comments on that. The ambiguity exists, and perhaps it is best to remain ambiguous rather than waste valuable time and resources on changing one word here, if it's going to take so much effort and time to change that one word.

We have lived with this ambiguity without too much consequence, from what I'm gathering. We're

devoting an awful lot of effort and attention and argument about this one word. Is it really worth any further attention, discussion, or should we just continue to leave it as is?

CHAIR MALMUD: Dr. Zanzonico?

MEMBER ZANZONICO: I just have a question, and maybe Debbie -- how did this impact -- this ambiguity impact the Agreement States? I mean, are some states interpreting it differently than others, this per year versus per episode?

MEMBER GILLEY: That is possible, that the Agreement States could be interpreting it different, because I don't know if it's a Compatibility B or we could have more restrictive or different language. I will have to go back and look at the compatibility. Does anybody know? I don't have my little cheat sheet that tells me which sections are compatible and which ones are not compatible. So you may find variations from Agreement State to Agreement State.

CHAIR MALMUD: Is anyone aware of anyone tracking this for a year for a patient?

MEMBER GILLEY: I'm going to go back and look at it -- at Florida's. I don't believe we have it in there, but I won't be 100 percent sure until I verify it.

CHAIR MALMUD: Thank you. Does that deal with the issue that you've --?

MR. LUEHMAN: I appreciate the Committee's input.

MEMBER MATTMULLER: Was there a motion on the table?

MEMBER LANGHORST: I think there's a motion.

CHAIR MALMUD: Oh. I thought we passed the motion. I'm sorry.

MEMBER LANGHORST: And the motion --

MS. HOLIDAY: Actually, Dr. Malmud -- this is Sophie -- I think the motion that you guys are getting ready to discuss has already been voted on. If I'm not mistaken, that Sue had made the motion, and Dr. Welsh had seconded, when you said that ACMUI continues to assert that the current regulations are based on a per release limit, and ACMUI does not recommend any change to the regulation and does not recommend that the NRC consider this topic during the current rulemaking process.

MEMBER LANGHORST: That was my first motion, and I think I --

VICE CHAIR THOMADSEN: Dr. Howe raised the question about --

MEMBER LANGHORST: Right. And I reiterated that last part of that motion, so I guess we did pass that one.

CHAIR MALMUD: Then that was passed, okay. Thank you, Sophie.

MS. HOLIDAY: Thank you.

CHAIR MALMUD: We may want to move on?

MR. LUEHMAN: Yes.

CHAIR MALMUD: Unless you and Mike have something else --

MR. LUEHMAN: No.

CHAIR MALMUD: -- on this particular item. All right. We hope you've clarified that.

We now are a little early for a break. Should we move on to the next item? Are we prepared to do that, Jim?

MR. FULLER: We really thought we were going to spend more time talking about these --

CHAIR MALMUD: Yes.

MR. FULLER: It's a good time to take a break now. We have some administrative things that we can do later on. Of course, if there are any issues or comments that you would like to provide us on the other 28 items, we left some -- we had said that time -- time allowed, we would, you know, love to hear on

other issues, although yesterday we had some opportunity and didn't seem to have any.

So it's probably a good time for a break, and then come back and do the administrative stuff.

CHAIR MALMUD: Fifteen minutes. That would be 2:15. Does that sound good? Thank you, all.

(Whereupon, the proceedings in the foregoing matter went off the record at 1:59 p.m. and went back on the record at 2:22 p.m.)

CHAIR MALMUD: Ladies and gentlemen, if we may, we'll resume, so we will be able to perhaps leave a little bit early today.

Mike, is this item or your Sophie's item next?

MR. FULLER: Sophie is going to -- there's one thing we wanted to ask the ACMUI their views on, back to the ASTRO position from yesterday, just for some clarity.

CHAIR MALMUD: Okay. We have one more business item that was on the agenda that we will come back to just for a moment, and that is going to be handled by Mr. Fuller.

MR. FULLER: Yes. Believe it or not, we have actually had some sidebar discussions over the last day or so. And one of the issues that we

discussed is in the event -- and I guess it's page 3, the third paragraph down where it says ASTRO -- I'm sorry, in the ASTRO letter -- I'm sorry, I should have made that clear, or the ASTRO statement I should say -- on page 3, the second full paragraph, or the third paragraph down I guess where it says, "ASTRO acknowledges one scenario."

And what is being discussed here is that there are situations or circumstances where some of the target may be overdosed, and some of the target may be underdosed. So what we have in the past referred to as the bunching of sources. And it says, "To address this rare event, ASTRO recommends that the authorized user be required to affirm in writing, on the written directive, after the implant is completed, that the distribution of the sources within the treatment site was as intended per the pre-implant written directive."

Now, I feel certain somewhere along the line someone is going to point out to us that this means that the physician could simply affirm a mistake, and there would be no other QA or no other check on that. So what we would like to hear, if at all possible, is some discussion, or the views or comments, about this particular provision in the ASTRO

statement, and see if there is any -- if anyone shares any of our unease I guess with that situation.

CHAIR MALMUD: I am still reading. I'm sorry. Dr. Welsh, why don't you comment?

MEMBER WELSH: I'll start off the discussion by saying that I think it's quite unlikely that that would happen, but I think we must all acknowledge that it's certainly not impossible.

One way that a physician would certainly be dissuaded from ever doing something like that is simply the fact that if they have a written directive, and that written directive calls for, say, 145 gray, and that 145 gray to the perimeter of our target volume, treatment site, is done on a computerized plan, as they all are now, the physician is putting his or her name to a piece of paper that says that, "I put these seeds in accordance to that plan on the computer."

And then, if what you see on the ultrasound or the follow-up CT during post-implant dosimetry is very, very far off from that idealized seed distribution, you would know that the physician has committed fraud. So, I think that the physician would be very unlikely to sign something saying that, "I put the seeds in accordance to this plan" when

there is proof that the seeds were supposed to be in a certain way.

I don't think that it's likely to be -- to actually happen. So I will start the conversation off with that statement. I know that several members here, including myself and Dr. Thomadsen, probably would have additional comments to follow.

CHAIR MALMUD: Thank you. Who else had a comment on this?

MEMBER SULEIMAN: I have a question.

CHAIR MALMUD: A question from Dr. Suleiman.

MEMBER SULEIMAN: That still doesn't change what the original written directive was, so there is documentation of what the dose was before and after, right?

MR. LUEHMAN: But I think that what our concern is -- I think the answer is yes, but the concern that it does is it places the regulator, the inspector, or whomever, now to essentially make -- since this isn't being evaluated against a criteria, it's being evaluated against a judgment, it now places the inspector or the regulator that is looking at this and saying, "I think this situation is unusual," but the physician has said he thinks it's adequate.

Now I'm going to question his medical judgment that this isn't what the -- what he proposed in the plan, although it would appear to me from the written directive that -- I'm no doctor, but I think he missed by a lot, but he's saying that he didn't miss by a lot.

And that's all that the proposal says is that if he certifies it is, basically sort of the game is over. He did it, he did what, you know, he said the proposal was, and, therefore, even if we don't believe that, what is the -- you know, what is the recourse? It seems since you are not evaluating it against a criteria of some kind, just his judgment, that's -- you know, that's not, from a regulatory perspective, really that inspectable or scrutable or -- I think that's our concern.

MR. FULLER: And keep in mind, Dr. Suleiman that we are not talking about a dose here. We are talking about activity and where it is clear to everyone who looks at it, based upon the way it's presented here, that we don't have a medical event based upon 20 percent of the activity being outside the intended treatment site or volume.

So we are talking about a situation here where all of -- or adequate activity, at least 80

percent of the activity is within the volume, but it comes down to the question of the distribution and the -- and if the distribution -- and whether or not the distribution is in accordance with the intentions of the authorized user. So --

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: And I think it is true that while there is a plan that the physician has approved, at least in most cases, or they use a nomogram that gives an inherent distribution, the sources do not always go exactly where they are intended, and you probably will have cases where there is an ambiguity as to whether or not the plan was actually what was executed. So I think you are probably going to end up in places where you have that type of discussion between the inspector and the practitioner.

CHAIR MALMUD: Other comments? Dr. Welsh?

MEMBER WELSH: So this particular question is uncannily timely given that in our medical events report from yesterday I was astounded to see a case -- and we have mentioned this before -- wherein 39 out of 41 seeds were all placed in a single location. They were bunched together, just like our hypothetical situation that we have all said that could never

happen. Well, it seems that it did happen.

At first I thought it was some kind of a joke or a setup that somebody put this in to test if I was actually reading what was in the NMED site. But apparently it is real, and the way the new ASTRO proposed definition would address that is the physician would then have to sign something saying that these seeds are all in the position that they are -- that we intended to implant the seeds -- in positions that I intended to implant them into, understanding what Dr. Thomadsen has just said about seeds can migrate a little bit as you move your needles out.

But the physician would have to sign something saying that, "I have placed these seeds in accordance to my pre-plan." I can't see how a physician could sign something to state that when something like this could happen -- when this situation is happening.

So the ASTRO definition should flag that as a medical event.

CHAIR MALMUD: If I understand you correctly, you're saying that the ASTRO definition would flag this as a medical event, whereas the previous one would not flag it as a medical event.

MEMBER WELSH: That's correct. In fact, this is not labeled as a medical event. Even though 39 out of 40 seeds are all within a few millimeters of each other, they are all within the target, and, therefore, the current definition did not capture it as a medical event. But clearly, it's not what is good for the patient, and clearly it is probably not what the physician intended.

CHAIR MALMUD: Whereas the ASTRO document holds the physician up to a higher standard.

MEMBER WELSH: Yes.

CHAIR MALMUD: Thank you.

MR. FULLER: Just so I'm clear, I'm thinking that the current rule must have flagged it, because otherwise we wouldn't have seen it as a medical event reported in NMED. So --

MEMBER WELSH: Well, the D-90 was one percent.

MR. FULLER: Right. So if that licensee was using a dose-based criteria for identifying -- or for their written directives, and so forth, then it got reported.

MEMBER WELSH: So this case illustrates the bizarre one-in-a-million scenario wherein the dose would have identified this as a misadministration

medical event, whereas the activity does not. So it illustrates that the proposed definition that the Subcommittee put together a few years ago had its limitations, and those limitations, which were dismissed by many of us as something that could never happen, really can happen, and it did happen.

And this is not listed as a medical event by any of the -- by the current definition, and it would not have been listed as a medical event by our proposed definition in 2008. But I think it would be flagged as such by the ASTRO definition.

CHAIR MALMUD: Thank you. Is that -- actually, we have -- please.

MS. BHALLA: I think, going back to the ASTRO report, on page 4, going to the third paragraph it says, "Accordingly, ASTRO recommends that the written directive refer to the total source strength implanted after administration but before the patient leaves," and so on.

So I think staff just would like to have that clarification that, how would we know that, indeed, if the physician has made an error in implanting the seeds, and then is doing this written directive and is saying, "Yes, the way I have planted is what I wanted to do."

So we would just like a little bit of clarification on that, because for an inspector it may be very difficult to go and look at an implant. And if the written directive is done after the implant, and it says everything is okay, is there another party who is going to look at it? Is the hospital's Radiation Safety Committee look at -- is looking at these implants? JCAHO?

And so I guess because the -- when Jim started this discussion yesterday, we wanted to have in our regs some process where this error would be identified. And from this approach, it seems like we may not be able to detect that error. So the question is: how would that kind of an error be detected?

CHAIR MALMUD: That's a question to one of our radiation oncology physicists or radiation oncologists. Sue?

MEMBER LANGHORST: I have a question that may be -- I don't know if it would, but in your proposed definition you have something that tries to address that. Would that be a way to quantify that?

MEMBER WELSH: Are you talking about the ASTRO or --

MEMBER LANGHORST: The ones that you and Dr. Thomadsen put together, the less than five percent

of sources occupy any octant of the PTV? Would that address this?

VICE CHAIR THOMADSEN: Sure.

CHAIR MALMUD: Dr. Thomadsen says sure. Dr. Welsh?

MEMBER WELSH: So basically, the question we just heard is: how does this definition reel in the unethical physician? Because, basically, I think you are asking if ASTRO's definition is saying that the physician must assert that the seeds were placed in accordance to the plan, and then the post-implant written directive is perhaps modified to say, "Whoa, you know, I really did want to do that. Yes, that's what I wanted to do, sign this." How would NRC ever catch that?

So basically, you're asking, how do you catch an unethical radiation oncologist? To me, that's very difficult to --

MR. LUEHMAN: That's a contradiction in terms.

MEMBER WELSH: Yes. I've never heard of such a thing.

(Laughter.)

But I suppose, hypothetically, this is a problem, a possible problem, and I would then say that

the Thomadsen modification of the ASTRO definition would be able to address those concerns objectively, understanding that the ASTRO definition many of us believe is fine, but it does put a lot of faith in the ethical behavior of that physician that could be objectified with the --

MR. LUEHMAN: I don't think that we're saying that -- the staff is not implying that the doctor -- that the doctor would be -- that there is necessarily an unethical physician. It could be a very -- a poorly trained physician that thinks that what he or she performed was adequate enough, whereas I think that if a more experienced physician was to look at it and be the quality check or have done that him or herself, they would have said, "No, I did that," and that was really -- that's pretty unacceptable, because I think that the position -- the discomfort I think that the regulator finds themselves in is that, at the end of the day, in this unusual case -- and we admit it's the unusual case where you have the grouping or bunching of seeds, because 20 percent would -- outside the volume would take care of -- is very objective and would take care of, you know, most of the cases.

But in these few cases where you do get

the bunching, what you're relying on is basically a self-check and/or a self-certification. And in regulatory space, I guess that makes us -- we regulators a little bit uncomfortable.

CHAIR MALMUD: Dr. Howe?

DR. HOWE: It's not a theoretical situation. That was our situation in VA-Philadelphia. The physician put most of the seeds in the bladder, removed the seeds, and because the current regulations were seen to allow you to revise the written directive before completion of the procedure, he wrote that he didn't intend to give all those seeds, he only intended to give half of them.

And then, in one case he said, "Oh, this is only procedure -- it's a two-phase procedure." So this is the first fraction, and I'm going to put the others in, in the second fraction. So it's not theoretical, and this was one of the things that we were trying to fix in the rule.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: If I could reply to that -- I don't want to get bogged down into the minor details, but a simple way of validating or refuting that assertion is just to look at the plan that was used to put those seeds in. And that plan I'm sure

was going to call for 145 gray or something standard, because you know the physician plans to put a bunch of seeds in the bladder and then take them out and give 70 gray to the prostate. So there is a mechanism to verify whether or not that's a voracious statement.

DR. HOWE: But if your requirement is to only look at the written directive after implantation, then you don't have an error.

CHAIR MALMUD: Mr. Fuller?

MR. FULLER: If I might just offer something in clarify, what Neelam -- the passage that Neelam was reading to us is in the section on real-time planning. So now we have kind of gone off assuming that there's a pre-plan and talking about that scenario. So if you read the ASTRO statement, it talks about in terms of -- in situations where you have real-time planning you produce the written directive after the fact.

Based on what we heard yesterday, and what we know about real-time planning, there isn't any other option. You plan as you go. So I think these points are valid for the staff to consider when we're talking about a situation where there is no plan or a pre-plan, but I really don't think we have anything that we need clarification on, if you're talking about

real-time planning. I mean, I don't know how you can expect a written directive prior to implantation if you're doing real-time planning. That's just the way I understand it. So, I mean, unless it's just something that's written very generally.

So, again, I think that the position or the concern is valid for no plan or pre-planned procedures. But for real-time planning, unless someone can enlighten me, I don't know how we could have a written directive before the fact.

CHAIR MALMUD: Dr. Fisher?

MEMBER FISHER: I'm not sure I can answer that question exactly. But in the plans that I have reviewed and do review on an ongoing basis, the treatment plan specifies the seed placement needed to achieve 145 gray from iodine-125 or 125 gray from palladium-103 or 115 gray from cesium-131.

And the physicians that I work with typically will order extra seeds that they can use in a post-treatment planning to ensure that the prostate receives enough seeds in the right places to achieve the dose desired to treat the cancer.

And they don't usually use them, but usually six or eight seeds are available and have been purchased that can be then, if there is a region that

doesn't receive enough seeds, they can then go ahead one by one and insert seeds in the untreated area, and then on the written directive make note of the fact that additional seeds were required to achieve the pre-treatment written directive. And that's how I see it working in practice.

I think it makes sense and it works. The patient achieves the advantage of getting the dose needed, even though the total dose will end up being a bit higher than what was planned. At least the untreated areas are then addressed.

You have probably had this same experience at Memorial Sloan-Kettering. And, again, in Dr. Suh's practice there is probably the same thing. But we see the physician doing the best the physician can do to place the activity that is needed to achieve treatment objectives, and then the written directive is noted -- that that's what was done.

MEMBER ZANZONICO: I have a question.

CHAIR MALMUD: Yes.

MEMBER ZANZONICO: Even if you are doing interactive or real-time planning, it is still to achieve a specified dose of -- specified dose at a target point. So, you know, there does seem to be all self-limits -- limiting there in how fraudulent even

the most unethical physician could be. I mean, they are aiming to achieve a dose at a specific point. If you're off that dose by 90 percent, you know, you are really hard-pressed to say, "Well, I intended that once I got into the procedure." It's not as if it's just an arbitrary distribution.

MR. FULLER: But in this case we're not talking about dose.

MEMBER ZANZONICO: No. But I understand in terms of -- but in terms of a physician affirming that the seed placement they achieved what was they intended, what they intended was a seed placement that is going to give a specified dose as part of the treatment at a target point.

If they are off that dose, that prescribed dose, at that point by more than 90 percent, having nothing to do with reporting of an event, you know, it is going to be obvious to everyone, including colleagues, that this patient -- this physician is not being truthful. I mean, I think there is some self-limitation in there just in the course of routine practice.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: So if I might comment on some of the questions and comments that have been

raised here, to answer your question, Mike, about the pre-plan versus real-time planning, real-time planning is probably a bit of a misnomer. For the most part, what we call real-time planning is intraoperative planning in contrast to pre-planning that is done a couple of weeks ahead of time, for example.

And there are disadvantages to the pre-planning approach. Patient's anatomy might change, the gland could change size and shape, and so the pre-planning strategy is starting to give way to the more appropriate intraoperative planning where you see the anatomy right there and then and generate the plan.

Nonetheless, you still are generating a plan for that particular patient, and that particular prostate size and shape. So there is a plan that is generated, and the physician will attempt to place the seeds in accordance to that plan. So I just wanted to clarify that.

But, therefore, Dr. Howe's point about the distribution of the seeds or what we were talking about earlier, how the physician could then change the written directive or change the -- make an attestation that "I put the seeds in accordance to my plan." I would say that the ASTRO definition might benefit from the addition of a sentence or so saying that, "The

distribution of the -- ASTRO recommends that the authorized user be required to affirm in writing, on the written directive, after the implant is completed, that the distribution of the sources within the treatment site was as intended per the pre-treatment written directive," and then I would say, "and is verifiable by a computerized plan."

Because then, in addition to the written directive that Dr. Howe said, if that's all we're looking at, somebody could just scribble it out or change it. You can't do that as easily with a computerized plan. So the physician should -- I think this should say, "And is verifiable with -- by the -- this statement is verified by the computerized plan." So that's the other comment I wanted to raise.

The final point is that Dr. Fisher said that sometimes we will order a few extra seeds. And as the anatomy changes intraoperatively, you can see where there is going to be a cold spot with the edema that naturally occurs. And sometimes we put in an extra seed, and this is why we don't feel -- and we do this because we don't feel that excess dose to the prostate is as significant an issue as underdose to the prostate, so long as we are not overdosing the rectum and the urethra and the bladder.

And, therefore, once again, the amendment definition is also a very reasonable alternative to the ASTRO definition as written, because that alternative definition does spell these issues out that you have raised.

VICE CHAIR THOMADSEN: Jim?

MR. LUEHMAN: I guess the purpose of us, you know, bringing this up was not -- you know, I appreciate that -- I think all we wanted to point out -- and I -- we would ask the Committee, and specifically the Subcommittee, we think that, you know, ASTRO has put a very powerful proposal together. And I don't want to minimize that.

I just think that we want to express that what we had asked the Committee and the Subcommittee to consider as they come to their final recommendation as we head towards rulemaking -- and maybe even, you know, get -- talk to people as they come to the workshops on this is that our discomfort -- and I think that you hit on it -- is that, you know, for the placement of the seeds, the 20 percent, that is an objective, verifiable standard. And I think that most stakeholders would accept that. You either got the 20 percent outside or you didn't.

The second part of it I think is a little

bit less, you know, from a regulatory standpoint. You know, it doesn't -- may not pass scrutiny with some of the stakeholders simply because it is an objective standard that is being left to the person that did -- whose practice and is not against a verifiable standard. It is just his -- it is the judgment.

Now, I agree with what you said, Dr. Welsh, if that's -- then has to be compared against an image or a computer-generated plan, and that's the basis that he makes -- he or she makes the statement against -- well, that's much more of an, if you will, objective standard that a regulator can evaluate against, rather than just, you know, the doctor's opinion.

And so going forward I think that that's the -- that's the thing that -- that's the issue that we have. To the extent that we can come to some additional clarity or additional rigor or whatever you want -- objective standard in that -- in those cases where you get the seed -- where you get a seed distribution that is -- you know, that may be necessary for, you know, the particular case, that that would be more of an objective standard rather than a statement by the person that, you know, produced it. I think that that would go a long way

towards I think getting general stakeholder approval of that as a standard.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: So then I might ask Dr. Howe if my suggested amendment to the ASTRO definition would satisfy the concerns or answer the questions that you have raised. If we say that, in addition to the physician signing an attestation that he or she has placed the seeds in accordance to the written directive, we should say that this statement is verifiable when compared to the computer plan, would that address your concern?

DR. HOWE: I don't know if I can answer that, but if we go back to the regulations in 35.41, the licensee is supposed to have a written program that will allow him to verify -- he or she verify that the administration was in accordance with the written directive. And so simply attesting is not necessarily verification, but you have added the verifiable by computer plan, and that comes much closer to verifying that the administration is in accordance with the written directive.

MR. LUEHMAN: So that's the -- I think that was the one --

MR. FULLER: Yes, appreciate the feedback.

We wanted to just get a little more -- while we had you here, we just wanted some -- a little bit more insight.

CHAIR MALMUD: Thank you. Sophie, I think you're on.

MS. HOLIDAY: Okay. So I passed out the amended 2011 ACMUI recommendations and actions chart. As you can see, we have quite a number of actions here. So starting at Item Number 7, Dr. Malmud agreed -- or volunteered, rather -- to serve as a reviewer to screen iodine-131 cases for the ACMUI Medical Events Subcommittee. Are there any questions to that?

(No response.)

Okay. Moving to Item Number 8, there was a recommendation to reserve some time at the fall ACMUI meeting for public stakeholders in the event that they were not able to attend the summer sessions to discuss items for the Part 35 public workshops. And this motion was not passed. Are there any questions?

(No response.)

Okay. Moving to Item Number 9, this motion was made by Dr. Welsh and seconded by Dr. Thomadsen, that there be a recommendation that there is a three-month minimum notice for future public

stakeholder meetings. Are there any questions for this? Yes.

CHAIR MALMUD: I have a question. Is the telephone conference considered a public stakeholder meeting?

MR. FULLER: The way we took this was for workshops such as what had currently been planned for June, and -- but we do not consider a normal teleconference with the Committee as a workshop. That's just a public meeting with the Committee.

CHAIR MALMUD: I understand what we meant, and my question was, the way we phrased it, it's not relating to the workshop. It's a public stakeholder meeting, which I believe our telephone conference calls are public stakeholder meetings. So we didn't mean to include telephone conference calls.

MS. HOLIDAY: Okay.

CHAIR MALMUD: And so how -- we just have to word that so that it's clear that we're not handicapping ourselves.

MS. HOLIDAY: All right.

CHAIR MALMUD: Thank you.

MS. HOLIDAY: You're welcome. Okay. So to amend the statement to exclude --

VICE CHAIR THOMADSEN: Actually, if I

might --

MS. HOLIDAY: I'm sorry.

VICE CHAIR THOMADSEN: -- I think that we were even more narrow than that. I think the intention was just dealing with the stakeholder meetings that -- the workshops discussing for the -- these rule changes as opposed to anything more global than that.

CHAIR MALMUD: Thank you, Dr. Thomadsen. So shall we simply have that statement, "ACMUI recommends a three-month minimum notice for future public workshop stakeholder meetings," insert the word "workshop?"

MS. HOLIDAY: Sure.

CHAIR MALMUD: Will that satisfy -- thank you.

VICE CHAIR THOMADSEN: I suppose that's fine. I think this was a very narrow recommendation.

CHAIR MALMUD: Yes.

MS. HOLIDAY: Okay. All right. Moving to Item Number 10, there was a recommendation that we hold our second public stakeholder workshop in August versus June in order to accommodate all public stakeholders, with the caveat that the ACMUI Permanent Implant Brachytherapy Subcommittee report be finalized

in time for the fall ACMUI meeting.

And I have this as partially accepted, because, as NRC staff, we have accepted this request, but we are of course checking to make sure that these dates and times are possible for us to work in.

MR. FULLER: And I will add that we are working to do exactly as it says here, to move one of the workshops to August, and so far we have gotten no -- working both with contracts and management, we have gotten no information that there is any reason why we can't do this. So that's what we are planning to do, and we will be working to do that.

CHAIR MALMUD: Thank you.

MS. HOLIDAY: Okay. Moving to Item Number 11, I have, "ACMUI feels that ASTRO's approach to the permanent implant brachytherapy, as noted in their handout, is the correct approach for patient welfare. ACMUI also recommends that NRC require post-implant dosimetry following brachytherapy treatment, and that ACMUI believes that prostate brachytherapy is a unique set of brachytherapy and should, therefore, require a separate set of rules or regulations from non-prostate brachytherapy."

Are there any questions for this item?

CHAIR MALMUD: I see none.

MS. HOLIDAY: Okay. Moving to Item 12, yesterday we discussed scheduling of the fall ACMUI meeting, and we have our proposed date as September 22nd and 23rd, 2011. Our backup date is October 27th and 28th, and our alternate backup date is October 31st and November 1st. Are there any questions?

CHAIR MALMUD: None.

MS. HOLIDAY: Okay. Moving to Item 13, I have a recommendation to eliminate the written attestation for board certification pathway regardless of the date of certification. The motion was made by Dr. Zanzonico and seconded by Dr. Guiberteau. Are there any questions?

CHAIR MALMUD: I see none.

MS. HOLIDAY: Okay. Moving to Item 14, I have, "ACMUI recommends the attestation be revised to say, 'Has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee.'" Motion was made by Dr. Langhorst and seconded by Dr. Thomadsen. Do I have any questions?

CHAIR MALMUD: I see none.

MS. HOLIDAY: Okay. Moving to Item 15, I have, "ACMUI supports the statement that" -- I believe

this is worded the way you wanted to word it -- "the statement that residency program directors can sign attestation letters representing consensus of residency program faculties, if at least one member of the faculty is an authorized user in the same category as that designated by the applicant seeking authorized status." I have this motion made by Dr. Thomadsen and seconded by Dr. Welsh.

DR. HOWE: There is one more addition on that, and that is that the authorized individual agrees with OGS for the --

MS. HOLIDAY: I'm sorry. Could you repeat that, Dr. Howe?

DR. HOWE: One more part, and that is --

MR. FULLER: Can you speak into the microphone, please?

DR. HOWE: I'm trying to.

MR. FULLER: I think the microphone is not --

THE COURT REPORTER: It's working.

DR. HOWE: Okay. I mean, I can't get it any closer.

MR. FULLER: Okay, sorry.

DR. HOWE: Also, that the AU -- how do I phrase it? The AU votes for the attestation.

MEMBER GUIBERTEAU: When it was stated, I remember your saying that there was a possible detail, and you also said if he did not approve. My feeling is that because the authorized user may not always be around when these are signed, although there usually is some paperwork, my understanding is, as it was phrased during the meeting, was that the AU had a veto effect. That is, if he disagreed with that, then it would not be signed. But he didn't necessarily have to come across and agree.

DR. HOWE: I think we equated both as being equal, but that may not be true.

MEMBER GUIBERTEAU: I'm not sure that they would be necessarily equal in the setting that these are done. That's why I didn't say anything, because I thought the way you phrased it was the way I understood it, originally.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: I agree with that, and I think the wording was something like, "As long as the authorized user did not disagree with the" --

DR. HOWE: I could live with that.

VICE CHAIR THOMADSEN: -- "approval."

MEMBER GUIBERTEAU: Yes.

DR. HOWE: Okay.

VICE CHAIR THOMADSEN: Is that what you --

MEMBER GUIBERTEAU: Yes.

MS. HOLIDAY: Okay. After that statement was made, does anybody else have questions for this item?

CHAIR MALMUD: I see none.

MS. HOLIDAY: Okay. Our last item is Item 16 where ACMUI continues to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the regulation and does not recommend NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit. This motion was made by Dr. Langhorst and seconded by Dr. Welsh.

Are there any questions?

CHAIR MALMUD: I see none.

MS. HOLIDAY: Okay. That will close my recommendations and action items. The rest of our items are purely administrative. I have distributed the Form 148 to each of you for your professional services during this meeting. If you could please fill that out and return it to me before you leave.

I also, during our meeting yesterday, asked that self-evaluation forms be completed and

returned to me. I am still missing a couple, and I have one without a name, if someone would claim this one.

Also, I will be e-mailing your Form 64 for your travel paperwork. If you could have that turned back in to me within a week.

And, lastly, if you could, remove your name tags and leave your table tents, that concludes my portion.

MR. FULLER: I have one other --

CHAIR MALMUD: Thank you. Yes, please.

MR. FULLER: I just wanted to make sure that the Committee is aware that the staff also has two actions that were taken from this meeting in addition to the items that Sophie made note of for the Committee, and that is that we will be grouping the 28 items, you know, of the additional -- I'm sorry, for the rulemaking, the expanded rulemaking, the 28 items, that we will be grouping those items according to topical area.

I think the way they were laid out was in accordance with how they show up in the rules, so they were sort of numerical order.

CHAIR MALMUD: Yes.

MR. FULLER: We are going to redo that

list for purposes of future meetings, so that they are grouped by topic, like for instance all the T&E changes would be grouped together, all the attestation changes would be grouped together, and so forth.

And then, we will also provide a link to the previous ACMUI discussions on the various issues, so -- where we have records, and I'm sure we have records for all of these. Where the ACMUI has provided us either with their recommendations or their position on the various items, we will make sure that there is a link or some way to identify where that is, so members of the public or members of the Committee can go back and refresh their memory on that. So those are two action items that are taking for ourselves.

CHAIR MALMUD: Thank you. Any other items to be covered in today's agenda or additional items?

(No response.)

If not, I would like to thank the members of the Committee, the members of the staff, and members of the public, for having participated in what I think has been a very productive meeting with a lively discussion and a number of conclusions. Your efforts are always appreciated, and it is a pleasure to work with you all.

Thank you all very much. Have a safe trip home.

(Whereupon, at 3:10 p.m., the proceedings in the foregoing matter were concluded.)