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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 TUESDAY,

7 APRIL 12, 2011

8 + + + + +

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

13 MEMBERS PRESENT:

14 LEON S. MALMUD, M.D., Chair

15 BRUCE THOMADSEN, Ph.D., Vice Chair

16 DARRELL FISHER, Ph.D., Member

17 DEBBIE GILLEY, Member

18 MILTON GUIBERTEAU, M.D., Member

19 SUE LANGHORST, Ph.D., Member

20 STEVE MATTMULLER, Member

21 JOHN SUH, M.D., Member

22 ORHAN SULEIMAN, Ph.D., Member

23 WILLIAM VAN DECKER, M.D., Member

24 JAMES WELSH, Ph.D., Member

25 PAT ZANZONICO, Ph.D., Member

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1 MEMBERS ABSENT:

2 CHRISTOPHER PALESTRO, M.D., Member

3  
4 NRC STAFF PRESENT:

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

7 MICHAEL FULLER, Alternate Designated Federal  
8 Officer

9 SOPHIE HOLIDAY, Alternate ACMUI Coordinator

10 NEELAM BHALLA

11 JUNE CAI

12 SUSAN CHIDAKEL

13 SAID DAIBES, Ph.D.

14 SARENEE HAWKINS

15 DONNA-BETH HOWE, Ph.D.

16 ANDREA KOCK

17 VARUGHESE KURIAN

18 ED LOHR

19 JULIE MARBLE, Ph.D.

20 PATRICIA PELKE

21 JOSEPHINE PICCONE, Ph.D.

22 GRETCHEN RIVERA-CAPELLA

23 GLENDA VILLAMAR

24 SHIRLEY XU

25

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1 MEMBERS OF THE PUBLIC PRESENT:

2 KEITH BROWN, University of Pennsylvania

3 WILLIAM DAVIDSON, University of Pennsylvania

4 LYNNE FAIROBENT, American Association of  
5 Physicists in Medicine

6 KAREN LANGLEY, University of Utah

7 RALPH LIETO, St. Joseph Mercy Hospital

8 CANDI MCDOWELL, Georgetown University

9 JANETTE MERILL, Society of Nuclear Medicine

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

12 MIKE PETERS, American College of Radiology

13 AMANDA POTTER, American Association of  
14 Physicists in Medicine

15 JOE RODGERS, Theragenics

16 GLORIA ROMANELLI, American College of Radiology

17 CINDY TOMLINSON, American Society for Radiation  
18 Oncology

19 ANN WARBICK-CERONE, MDS Nordion

20 JENNA M. WILKES, American Society of Nuclear  
21 Cardiology

22 GARY E. WILLIAMS, Veterans Health  
23 Administration

24  
25  
26

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Adjourn	

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

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

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

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

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

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1 and whether or not we need rulemaking in that area.

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

5 CHAIR MALMUD: Thank you.

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

10 11) EXTENDING "GRANDFATHERING" TO

11 CERTAIN CERTIFIED INDIVIDUALS RULEMAKING

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

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

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

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

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

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

25 NRC resolved the petition in May 2008 and

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

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

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

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

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

19 So the petitioner requested to medically  
20 clarify 57, to recognize both 35 medical physicists  
21 for the modalities they practiced as of October 24,  
22 2005 and also to recognize all diplomates for RSOs  
23 providing the appropriate preceptor statement.

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

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

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

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

15 CHAIR MALMUD: Thank you.

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

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

25 CHAIR MALMUD: All right. So, then, just

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1 --

2 DR. HOWE: If you defer it to mine.

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

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

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

14 MR. FULLER: Yes.

15 CHAIR MALMUD: -- rather than discussing  
16 it now?

17 MR. LUEHMAN: Yes

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

25 But what we are presenting here is that

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

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

9 DR. HOWE: I have bullet number 1.

10 CHAIR MALMUD: I'm sorry?

11 DR. HOWE: I have bullet number 1.

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

14 MS. BHALLA: Correct.

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

20 Debbie?

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

25 MR. LOHR: I would be glad to speak to

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

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

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

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

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

25 Using the same criteria, we applied that

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

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

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

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

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

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1 is now at the point where we are going into rulemaking  
2 and now we have this premise that we have put forth or  
3 this rationale as to why we should be able to  
4 grandfather these individuals who had not done so in  
5 2005.

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

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

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

17 Does that help some?

18 CHAIR MALMUD: Yes. Thank you.

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

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

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

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

14 MS. BHALLA: Well, we --

15 MEMBER GILLEY: No. Go ahead.

16 CHAIR MALMUD: Sue?

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

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

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

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

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

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

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

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

8 CHAIR MALMUD: Yes?

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

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

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

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

23 VICE CHAIR THOMADSEN: Health physics.

24 MEMBER LANGHORST: Right.

25 VICE CHAIR THOMADSEN: I do know that.

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

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

7 (Laughter.)

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

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

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

24 MEMBER LANGHORST: Right. Right.

25 MR. LOHR: I know that you are.

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1 MEMBER LANGHORST: Right.

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

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

12 VICE CHAIR THOMADSEN: Thank you.

13 Dr. Zanzonico?

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

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

25 The other issue I have is for states like

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

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

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

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

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

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

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

13                   So a board that was recognized prior to  
14 2005, if you will, since the grandfathered was still  
15 in effect had to have its processes recognized by the  
16 NRC for the board to be considered now for their  
17 certification plus the attestation, for it to be  
18 listed on a license.

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

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

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1 recognition. And there were some T&E issues.

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

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

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

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

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

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

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

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

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

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

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1 trying to express an opinion.

2 MEMBER ZANZONICO: But can you address the  
3 situation with the licensed individuals in certain  
4 states? It makes it sound like they have gone through  
5 an additional round of certification by states. And  
6 now there could be cohort of individuals, who were  
7 certified, licensed by the state, may be unemployed in  
8 '05, and now have another round of competence review  
9 required.

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

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

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

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

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1 talking.

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

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

16 MEMBER MATTMULLER: Yes. The --

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

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

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

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

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

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

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

18 MEMBER GILLEY: They are now named on a  
19 license. They were not named on a license prior to  
20 2005. We did not name our medical physicists on the  
21 license except for cobalt teletherapy and Gamma  
22 Knives.

23 MS. BHALLA: Okay.

24 CHAIR MALMUD: There was another. Sue?

25 MEMBER LANGHORST: Yes, Sue Langhorst.

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

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

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

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

21           MEMBER LANGHORST: Yes, I think --

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

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

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

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

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

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

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

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1 is what I wanted to state.

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

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

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

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

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

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

10           CHAIR MALMUD: Fifteen hundred.

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

13           CHAIR MALMUD: Thank you.

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

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

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

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

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

8 MS. BHALLA: That's right.

9 MEMBER GUIBERTEAU: Okay. Thank you.

10 MEMBER SUH: I have one more.

11 CHAIR MALMUD: Suh?

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

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

20 MEMBER SUH: Okay.

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

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

6           MEMBER SUH: Okay. Thank you.

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

11           Maybe licensure could be an alternative.  
12 And these are the things we do here, that what would  
13 it be that it is going to establish that a certain  
14 individual was good to go. Let's say in the year  
15 2000. So how would we establish that as to what you  
16 practiced, the modality you have practiced, or your  
17 credentials minus or absent the attestation?

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

24           CHAIR MALMUD: I'm sorry. Yes?

25           MEMBER GILLEY: There is a recentness of

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

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

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

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

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

5 CHAIR MALMUD: A member of the public.

6 MS. FAIROBENT: Thank you, Dr. Malmud.

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

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

24 And, you know, since we filed this back in  
25 2006 and asked for expeditious resolution -- and my

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

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

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

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

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

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

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

21 CHAIR MALMUD: Yes, please?

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

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

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

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

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

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

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

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1 certified in 2002.

2 Sue, did you? You had your hand up.

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

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

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

21 CHAIR MALMUD: Other comments? Mr. Lohr?

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

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

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

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

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

18 CHAIR MALMUD: Thank you.

19 And Doctor?

20 MEMBER ZANZONICO: Pat Zanzonico.

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

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

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

11 CHAIR MALMUD: Yes?

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

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

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

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

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

20 MR. LUEHMAN: Right.

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

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

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

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

15 MS. FAIROBENT: Dr. Malmud?

16 CHAIR MALMUD: Yes?

17 MS. FAIROBENT: Lynne Fairobent, AAPM.

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

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

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

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

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

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

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1 somebody else that could be added to the license.

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

6 CHAIR MALMUD: Thank you.

7 Other comments?

8 (No response.)

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

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

16 MS. BHALLA: No, we are here.

17 CHAIR MALMUD: It was valuable. Thank  
18 you.

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

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

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1 9:30 a.m.)

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

5 Dr. Howe, you're on.

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

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

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

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

22 So, NRC started working on the Board  
23 certification pathway, and passed another rule in  
24 2005, which retained the statements for all pathways,  
25 but removed the certification requirement from needed

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

3 MR. LUEHMAN: As part.

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

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

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

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

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1 competency sufficient to function independently as an  
2 authorized whatever.

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

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

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

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1           So, as a result of the Commission briefing  
2 from the ACMUI, the Commission sent us a meeting SRM,  
3 M080429, that asked the staff to coordinate with the  
4 ACMUI and the Agreement States to amend preceptor  
5 requirements in 10 CFR Part 35. As a consequence of  
6 that, the staff wrote a SECY paper, proposing changes  
7 to the attestation statements, and that was SECY-08-  
8 0197 in November 2008.

9           The Commission voted on the SECY paper,  
10 and came back with a Staff Requirements Memorandum of  
11 08-179 that approved the staff's recommendations. So,  
12 let's look at conceptually what the staff was  
13 recommending; to eliminate the written attestation for  
14 Board certification pathway, and that would be across  
15 the board for all modalities; to revise the  
16 attestation statement to say "has demonstrated the  
17 ability to function independently to fulfill the  
18 radiation safety-related duties required by the  
19 licensee," so that's clearly shifting it from  
20 competency, which can be confused with clinical to  
21 radiation safety duties. And the third main issue was  
22 that residency programs may be able to sign  
23 attestations under certain conditions. And some of  
24 those conditions are that there at least be one  
25 authorized individual in the residency program, and

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

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

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

25 And perceived relaxation of safety

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

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

13 MEMBER ZANZONICO: I just have a --

14 CHAIR MALMUD: DR. Zanzonico.

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

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

25 MEMBER ZANZONICO: Okay. So, this is

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1 post-'05.

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

6 MEMBER ZANZONICO: Right, but just post-  
7 '05.

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

10 MEMBER ZANZONICO: Okay.

11 DR. HOWE: So, it would be post probably  
12 2012, because the regulations are still the  
13 regulations. When you amend a regulation, that's when  
14 it takes effect, so it's going to be two to three  
15 years.

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

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

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1 MEMBER ZANZONICO: For the NRC.

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

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

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

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

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

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

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

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

9 (Laughter.)

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

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

25 CHAIR MALMUD: Other comments? Sue.

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

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

21           CHAIR MALMUD: Thank you. Dr. Zanzonico.

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

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

9 (Laughter.)

10 MEMBER GILLEY: Oops.

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

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

3 MEMBER GILLEY: Is that a motion?

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

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

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

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

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

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

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

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

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

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

16 MEMBER GILLEY: Provide specific training.

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

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

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

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

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

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

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

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

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

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

23          CHAIR MALMUD: In Wisconsin?

24          VICE CHAIR THOMADSEN: It's not required.

25          CHAIR MALMUD: Dr. Thomadsen says in

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

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

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

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

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

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

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

6 MEMBER GILLEY: Debbie?

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

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

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

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1 training within the last seven years.

2 CHAIR MALMUD: Thank you.

3 MEMBER LANGHORST: Can I follow-up on  
4 that?

5 CHAIR MALMUD: Yes.

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

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

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

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

8 DR. HOWE: Our current requirements --

9 MEMBER LANGHORST: -- specific for HDR  
10 then?

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

19 MEMBER LANGHORST: Okay.

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

22 MEMBER LANGHORST: No argument there.

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

25 MEMBER LANGHORST: Okay. So, then you do

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1 have to get an attestation for that.

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

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

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

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

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

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

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

20 CHAIR MALMUD: Dr. Thomadsen.

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

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

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

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

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

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

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

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

11 DR. HOWE: That is the case.

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

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

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

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

23 MEMBER GILLEY: I agree.

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

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

3 MEMBER ZANZONICO: Yes.

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

7 MEMBER ZANZONICO: Agreed.

8 DR. HOWE: Okay.

9 CHAIR MALMUD: Yes, Sue.

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

16 CHAIR MALMUD: Dr. Thomadsen.

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

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

23 CHAIR MALMUD: Dr. Zanzonico.

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

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

19 DR. HOWE: When NRC designed the preceptor,  
20 they made sure that they included verifies, so you  
21 don't have to provide the training, you don't have to  
22 supervise the training to be the preceptor. You just  
23 have to verify, so that -- in our mind, in NRC's mind  
24 that said you can go to someone -- if you got trained  
25 20 years ago and that person died, you can go to

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

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

25 CHAIR MALMUD: Dr. Zanzonico, are you

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

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

5 CHAIR MALMUD: All right.

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

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

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

25 CHAIR MALMUD: Thank you. That's,

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

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

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

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

4 MEMBER ZANZONICO: Yes.

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

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

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

11 MEMBER GUIBERTEAU: Yes.

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

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

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1 with that.

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

10 MEMBER GUIBERTEAU: Do we --

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

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

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

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

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

21 CHAIR MALMUD: So, that's in there.

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

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

25 DR. HOWE: Yes.

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

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

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

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

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

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

25 MEMBER GUIBERTEAU: I think, I mean --

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1 DR. HOWE: And achieved a level of  
2 competency.

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

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1 CHAIR MALMUD: Dr. Welsh.

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

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

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

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

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

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

21 MEMBER ZANZONICO: Can I ask a question?

22 CHAIR MALMUD: Dr. Zanzonico.

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

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1 CHAIR MALMUD: Yes.

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

4 CHAIR MALMUD: Yes.

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

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

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

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1 CHAIR MALMUD: I hear another voice?

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

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

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

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

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

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

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

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

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

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1 (Laughter.)

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

24 CHAIR MALMUD: Dr. Welsh.

25 MEMBER WELSH: But I would argue that the

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

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

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

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

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

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

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

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1 status as either an AU or an RSO?

2 MEMBER LANGHORST: I have a question.

3 CHAIR MALMUD: Dr. Langhorst.

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

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

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

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

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1 recognition of the Board.

2 CHAIR MALMUD: Does that clarify the  
3 issue?

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

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

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

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

13 CHAIR MALMUD: It's this document.

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

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

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1 before that?

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

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

20 CHAIR MALMUD: Does that answer your  
21 question?

22 VICE CHAIR THOMADSEN: That does.

23 CHAIR MALMUD: Thank you.

24 VICE CHAIR THOMADSEN: Thank you.

25 MEMBER LANGHORST: I guess one additional

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1 question I have --

2 CHAIR MALMUD: Sue.

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

8 MEMBER GILLEY: For their modality.

9 MEMBER LANGHORST: For?

10 MEMBER GILLEY: For their specific  
11 modalities.

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

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

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

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

6 CHAIR MALMUD: That's correct.

7 MS. FAIROBENT: Dr. Malmud.

8 CHAIR MALMUD: Yes?

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

11 CHAIR MALMUD: Please.

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

22 MEMBER GUIBERTEAU: No.

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

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

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

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

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

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

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

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

23 CHAIR MALMUD: Thank you.

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

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

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

18 VICE CHAIR THOMADSEN: Can I ask --?

19 CHAIR MALMUD: Yes.

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

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1 case?

2 DR. HOWE: That is the case right now.

3 CHAIR MALMUD: Do you have --

4 VICE CHAIR THOMADSEN: No.

5 CHAIR MALMUD: Your question was answered.

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

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

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

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

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

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

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

16 CHAIR MALMUD: Thank you.

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

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

25 MEMBER WELSH: But it would seem impossible

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

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

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

20 VICE CHAIR THOMADSEN: Actually, that is a  
21 very good point. I remember when I got in the field in  
22 1970, in order to get ABR certified I needed to have  
23 an advanced degree in one of those. I mean, there was  
24 no possibility with an English degree to get an ABR  
25 certification at the time, so I can't believe that

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

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

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

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

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

22 DR. HOWE: Repeat that one more time.

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

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1 DR. HOWE: Well, you said continued  
2 privilege.

3 CHAIR MALMUD: Any currently practicing  
4 RSO or AU.

5 DR. HOWE: Practicing RSO or AU?

6 CHAIR MALMUD: Yes.

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

9 CHAIR MALMUD: Yes.

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

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

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

25 Now, if you want to be that authorized

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

3 CHAIR MALMUD: Different story.

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

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

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

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

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

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

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

13 CHAIR MALMUD: Order of magnitude, 10,  
14 100, 1,000?

15 MS. FAIROBENT: Hundreds, potentially.

16 CHAIR MALMUD: Hundreds plural?

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

23 DR. HOWE: And strontium-90.

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

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

3 MEMBER SUH: I have a question.

4 CHAIR MALMUD: Please do.

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

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

24 MEMBER SUH: Yes.

25 CHAIR MALMUD: Debbie.

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

5 CHAIR MALMUD: Dr. Welsh.

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

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

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

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

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

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

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

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1 facility that's just getting a Gamma Knife.

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

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

5 CHAIR MALMUD: Would you wish the NRC to -

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

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

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

18 MEMBER WELSH: Yes.

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

25 DR. MOWER: Herb Mower with AAPM. I

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

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

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

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

22 DR. HOWE: Being a radiation safety  
23 officer.

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

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

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

10 DR. HOWE: If you were listed on October  
11 24<sup>th</sup> of 2002, then you're grandfathered.

12 DR. MOWER: Okay. If they were on the  
13 license October 23<sup>rd</sup> of that year, but not on October  
14 24, would I be eligible to be an RSO again without  
15 going through a lot of red tape?

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

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

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

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

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

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

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

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

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

16 DR. HOWE: It's very flexible.

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

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

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

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

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

22                   DR. HOWE: For all pathways.

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

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1 CHAIR MALMUD: That's bullet what?

2 DR. HOWE: That's bullet 1.

3 MEMBER ZANZONICO: But then that makes  
4 bullet 2 --

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

8 MEMBER GUIBERTEAU: Second.

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

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

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

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

22 DR. HOWE: Is in the recognition.

23 MEMBER ZANZONICO: Right.

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

25 MEMBER GILLEY: So, anybody who was board-

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

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

7 MEMBER GILLEY: I will second that.

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

11 (Show of hands.)

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

16 MEMBER ZANZONICO: Regardless of date of--

17 CHAIR MALMUD: Regardless of the date of  
18 the certification.

19 DR. HOWE: Thank you.

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

22 MEMBER GILLEY: No.

23 DR. HOWE: Bullet 2 is the alternate  
24 pathway.

25 MEMBER GILLEY: Without board-

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1 certification.

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

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

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

12 MEMBER LANGHORST: So moved.

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

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

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

23 MS. HOLIDAY: Thank you.

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

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

3 (Show of hands.)

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

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

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

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

20 CHAIR MALMUD: Is that acceptable?

21 VICE CHAIR THOMADSEN: That sounds good.

22 CHAIR MALMUD: Would you wish to make a  
23 motion?

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

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

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

4 MEMBER WELSH: Second.

5 CHAIR MALMUD: Second by Dr. Welsh.  
6 Discussion?

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

9 DR. HOWE: Is this essential?

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

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

22 CHAIR MALMUD: Dr. Welsh.

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

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

24 CHAIR MALMUD: Thank you. Dr. Guiberteau.

25 MEMBER GUIBERTEAU: I agree with Dr.

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

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

24 CHAIR MALMUD: Thank you. Debbie.

25 MEMBER GILLEY: Yes, I just have a

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

5 MEMBER GUIBERTEAU: Yes.

6 CHAIR MALMUD: Yes.

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

9 MEMBER GILLEY: Okay.

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

12 MEMBER GILLEY: But not past.

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

20 MEMBER GILLEY: Thank you.

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

23 MEMBER ZANZONICO: Could someone repeat  
24 the motion?

25 VICE CHAIR THOMADSEN: I think it was

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1 mine.

2 CHAIR MALMUD: Yes, it was.

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

8 MEMBER ZANZONICO: Would you repeat your  
9 language again?

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

20 VICE CHAIR THOMADSEN: Right.

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

23 (Show of hands.)

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

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1 Howe.

2 DR. HOWE: Thank you.

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

5 MR. LOHR: Dr. Malmud.

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

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

16 CHAIR MALMUD: Dr. Welsh.

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

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

11 CHAIR MALMUD: Dr. Thomadsen.

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

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

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

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1 way to know what modality they've trained in.

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

4 VICE CHAIR THOMADSEN: Yes. Right.

5 CHAIR MALMUD: Thank you.

6 VICE CHAIR THOMADSEN: They need that  
7 document.

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

11 (Whereupon, the proceedings went off the  
12 record at 11:25 a.m., and went back on the record at  
13 1:05 p.m.)

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

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(1:05 p.m.)

1  
2 CHAIR MALMUD: Okay. Ladies and  
3 gentlemen, if you would care to join us at the table,  
4 we can get started.

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

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

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

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

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1 that slide.

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

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

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

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

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

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

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

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

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

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

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

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

25 MEMBER LANGHORST: Would you like me to go

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1 up there, or can I sit here?

2 CHAIR MALMUD: Wherever you're more  
3 comfortable.

4 MEMBER LANGHORST: Okay.

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

7 MEMBER LANGHORST: I'll have Sophie change  
8 them.

9 MR. LUEHMAN: Okay.

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

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

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

25 Then, to the next slide please, in the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (No response.)

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

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

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

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

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

19 CHAIR MALMUD: Excuse me. Oh, please.

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

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1 John Q X.

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

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

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

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

25 CHAIR MALMUD: Thank you. Other comments?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 believe so.

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

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

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

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

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

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

12           CHAIR MALMUD: Thank you.

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

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

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

25           CHAIR MALMUD: No clinical advantage?

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1 MEMBER LANGHORST: There is no clinical  
2 advantage and --

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

6 MEMBER LANGHORST: Thank you for that  
7 addition.

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

10 MEMBER WELSH: Second.

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

13 (No response.)

14 All in favor of the motion?

15 (A show of hands.)

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

23 MR. LUEHMAN: Okay.

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

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1 up on the board now?

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

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

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

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

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1 all time is --

2 CHAIR MALMUD: We recognize the current  
3 ambiguity.

4 MR. LUEHMAN: Right.

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

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

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

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

15 MR. LUEHMAN: No, I appreciate that.

16 CHAIR MALMUD: Dr. Thomadsen?

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

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

25 MEMBER LANGHORST: Sue Langhorst. Let me

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

4 MR. LUEHMAN: I appreciate that. Okay.

5 CHAIR MALMUD: Dr. Howe?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 (Laughter.)

5 But, nevertheless, it's not brief.

6 (Laughter.)

7 Under the best of circumstances.

8 (Laughter.)

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

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

23 Do I sum up what the Committee feels in  
24 general?

25 (Several responses in the affirmative.)

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

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

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

16           DR. HOWE: That was the purpose.

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

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

22           (Laughter.)

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

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1 MR. FULLER: It should be 08-007, March  
2 2008.

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

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

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

18 MEMBER LANGHORST: I will make it so.

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

21 MEMBER ZANZONICO: Second.

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

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

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

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

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

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

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

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

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

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

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

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

16           CHAIR MALMUD: Thank you. Dr. Guiberteau?

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

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

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

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

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

25 CHAIR MALMUD: Thank you, Dr. Guiberteau.

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1 Dr. Welsh, you had something to say?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 CHAIR MALMUD: Thank you. Sue?

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

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

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

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

12 MEMBER LANGHORST: I just wanted to  
13 clarify that.

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

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

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

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

10 CHAIR MALMUD: That is the correct  
11 interpretation --

12 MR. LUEHMAN: Okay.

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

15 MR. LUEHMAN: Thank you.

16 CHAIR MALMUD: Dr. Welsh?

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

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

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

5 CHAIR MALMUD: Dr. Zanzonico?

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

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

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

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

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

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

5 MEMBER MATTMULLER: Was there a motion on  
6 the table?

7 MEMBER LANGHORST: I think there's a  
8 motion.

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

11 MEMBER LANGHORST: And the motion --

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

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

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

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

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

6                   MS. HOLIDAY:   Thank you.

7                   CHAIR MALMUD:   We may want to move on?

8                   MR. LUEHMAN:   Yes.

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

11                   MR. LUEHMAN:   No.

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

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

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

19                   CHAIR MALMUD:   Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 MEMBER SULEIMAN: I have a question.

11 CHAIR MALMUD: A question from Dr.  
12 Suleiman.

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

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

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

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

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

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

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

6 CHAIR MALMUD: Dr. Thomadsen?

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

18 CHAIR MALMUD: Other comments? Dr. Welsh?

19 MEMBER WELSH: So this particular question  
20 is uncannily timely given that in our medical events  
21 report from yesterday I was astounded to see a case --  
22 and we have mentioned this before -- wherein 39 out of  
23 41 seeds were all placed in a single location. They  
24 were bunched together, just like our hypothetical  
25 situation that we have all said that could never

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1 happen. Well, it seems that it did happen.

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

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

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

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

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1 MEMBER WELSH: That's correct. In fact,  
2 this is not labeled as a medical event. Even though  
3 39 out of 40 seeds are all within a few millimeters of  
4 each other, they are all within the target, and,  
5 therefore, the current definition did not capture it  
6 as a medical event. But clearly, it's not what is  
7 good for the patient, and clearly it is probably not  
8 what the physician intended.

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

11 MEMBER WELSH: Yes.

12 CHAIR MALMUD: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 VICE CHAIR THOMADSEN: Sure.

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

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

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

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

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

23 (Laughter.)

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

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

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

25 But in these few cases where you do get

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

5 CHAIR MALMUD: Dr. Howe?

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

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

20 CHAIR MALMUD: Dr. Welsh?

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

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1 was going to call for 145 gray or something standard,  
2 because you know the physician plans to put a bunch of  
3 seeds in the bladder and then take them out and give  
4 70 gray to the prostate. So there is a mechanism to  
5 verify whether or not that's a voracious statement.

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

9 CHAIR MALMUD: Mr. Fuller?

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

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

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

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

11 CHAIR MALMUD: Dr. Fisher?

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

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

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

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

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

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

19 MEMBER ZANZONICO: I have a question.

20 CHAIR MALMUD: Yes.

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

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

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

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

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

23 CHAIR MALMUD: Dr. Welsh?

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

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

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

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

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

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

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

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

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

6           VICE CHAIR THOMADSEN: Jim?

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

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

25           The second part of it I think is a little

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

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

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

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

3 CHAIR MALMUD: Dr. Welsh?

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

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

23 MR. LUEHMAN: So that's the -- I think  
24 that was the one --

25 MR. FULLER: Yes, appreciate the feedback.

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1 We wanted to just get a little more -- while we had  
2 you here, we just wanted some -- a little bit more  
3 insight.

4 CHAIR MALMUD: Thank you. Sophie, I think  
5 you're on.

6 MS. HOLIDAY: Okay. So I passed out the  
7 amended 2011 ACMUI recommendations and actions chart.  
8 As you can see, we have quite a number of actions  
9 here. So starting at Item Number 7, Dr. Malmud agreed  
10 -- or volunteered, rather -- to serve as a reviewer to  
11 screen iodine-131 cases for the ACMUI Medical Events  
12 Subcommittee. Are there any questions to that?

13 (No response.)

14 Okay. Moving to Item Number 8, there was  
15 a recommendation to reserve some time at the fall  
16 ACMUI meeting for public stakeholders in the event  
17 that they were not able to attend the summer sessions  
18 to discuss items for the Part 35 public workshops.  
19 And this motion was not passed. Are there any  
20 questions?

21 (No response.)

22 Okay. Moving to Item Number 9, this  
23 motion was made by Dr. Welsh and seconded by Dr.  
24 Thomadsen, that there be a recommendation that there  
25 is a three-month minimum notice for future public

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1 stakeholder meetings. Are there any questions for  
2 this? Yes.

3 CHAIR MALMUD: I have a question. Is the  
4 telephone conference considered a public stakeholder  
5 meeting?

6 MR. FULLER: The way we took this was for  
7 workshops such as what had currently been planned for  
8 June, and -- but we do not consider a normal  
9 teleconference with the Committee as a workshop.  
10 That's just a public meeting with the Committee.

11 CHAIR MALMUD: I understand what we meant,  
12 and my question was, the way we phrased it, it's not  
13 relating to the workshop. It's a public stakeholder  
14 meeting, which I believe our telephone conference  
15 calls are public stakeholder meetings. So we didn't  
16 mean to include telephone conference calls.

17 MS. HOLIDAY: Okay.

18 CHAIR MALMUD: And so how -- we just have  
19 to word that so that it's clear that we're not  
20 handicapping ourselves.

21 MS. HOLIDAY: All right.

22 CHAIR MALMUD: Thank you.

23 MS. HOLIDAY: You're welcome. Okay. So  
24 to amend the statement to exclude --

25 VICE CHAIR THOMADSEN: Actually, if I

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1 might --

2 MS. HOLIDAY: I'm sorry.

3 VICE CHAIR THOMADSEN: -- I think that we  
4 were even more narrow than that. I think the  
5 intention was just dealing with the stakeholder  
6 meetings that -- the workshops discussing for the --  
7 these rule changes as opposed to anything more global  
8 than that.

9 CHAIR MALMUD: Thank you, Dr. Thomadsen.  
10 So shall we simply have that statement, "ACMUI  
11 recommends a three-month minimum notice for future  
12 public workshop stakeholder meetings," insert the word  
13 "workshop?"

14 MS. HOLIDAY: Sure.

15 CHAIR MALMUD: Will that satisfy -- thank  
16 you.

17 VICE CHAIR THOMADSEN: I suppose that's  
18 fine. I think this was a very narrow recommendation.

19 CHAIR MALMUD: Yes.

20 MS. HOLIDAY: Okay. All right. Moving to  
21 Item Number 10, there was a recommendation that we  
22 hold our second public stakeholder workshop in August  
23 versus June in order to accommodate all public  
24 stakeholders, with the caveat that the ACMUI Permanent  
25 Implant Brachytherapy Subcommittee report be finalized

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1 in time for the fall ACMUI meeting.

2 And I have this as partially accepted,  
3 because, as NRC staff, we have accepted this request,  
4 but we are of course checking to make sure that these  
5 dates and times are possible for us to work in.

6 MR. FULLER: And I will add that we are  
7 working to do exactly as it says here, to move one of  
8 the workshops to August, and so far we have gotten no  
9 -- working both with contracts and management, we have  
10 gotten no information that there is any reason why we  
11 can't do this. So that's what we are planning to do,  
12 and we will be working to do that.

13 CHAIR MALMUD: Thank you.

14 MS. HOLIDAY: Okay. Moving to Item  
15 Number 11, I have, "ACMUI feels that ASTRO's approach  
16 to the permanent implant brachytherapy, as noted in  
17 their handout, is the correct approach for patient  
18 welfare. ACMUI also recommends that NRC require post-  
19 implant dosimetry following brachytherapy treatment,  
20 and that ACMUI believes that prostate brachytherapy is  
21 a unique set of brachytherapy and should, therefore,  
22 require a separate set of rules or regulations from  
23 non-prostate brachytherapy."

24 Are there any questions for this item?

25 CHAIR MALMUD: I see none.

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1 MS. HOLIDAY: Okay. Moving to Item 12,  
2 yesterday we discussed scheduling of the fall ACMUI  
3 meeting, and we have our proposed date as  
4 September 22nd and 23rd, 2011. Our backup date is  
5 October 27th and 28th, and our alternate backup date  
6 is October 31st and November 1st. Are there any  
7 questions?

8 CHAIR MALMUD: None.

9 MS. HOLIDAY: Okay. Moving to Item 13, I  
10 have a recommendation to eliminate the written  
11 attestation for board certification pathway regardless  
12 of the date of certification. The motion was made by  
13 Dr. Zanzonico and seconded by Dr. Guiberteau. Are  
14 there any questions?

15 CHAIR MALMUD: I see none.

16 MS. HOLIDAY: Okay. Moving to Item 14, I  
17 have, "ACMUI recommends the attestation be revised to  
18 say, 'Has received the requisite training and  
19 experience in order to fulfill the radiation safety  
20 duties required by the licensee.'" Motion was made by  
21 Dr. Langhorst and seconded by Dr. Thomadsen. Do I  
22 have any questions?

23 CHAIR MALMUD: I see none.

24 MS. HOLIDAY: Okay. Moving to Item 15, I  
25 have, "ACMUI supports the statement that" -- I believe

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1 this is worded the way you wanted to word it -- "the  
2 statement that residency program directors can sign  
3 attestation letters representing consensus of  
4 residency program faculties, if at least one member of  
5 the faculty is an authorized user in the same category  
6 as that designated by the applicant seeking authorized  
7 status." I have this motion made by Dr. Thomadsen and  
8 seconded by Dr. Welsh.

9 DR. HOWE: There is one more addition on  
10 that, and that is that the authorized individual  
11 agrees with OGS for the --

12 MS. HOLIDAY: I'm sorry. Could you repeat  
13 that, Dr. Howe?

14 DR. HOWE: One more part, and that is --

15 MR. FULLER: Can you speak into the  
16 microphone, please?

17 DR. HOWE: I'm trying to.

18 MR. FULLER: I think the microphone is  
19 not --

20 THE COURT REPORTER: It's working.

21 DR. HOWE: Okay. I mean, I can't get it  
22 any closer.

23 MR. FULLER: Okay, sorry.

24 DR. HOWE: Also, that the AU -- how do I  
25 phrase it? The AU votes for the attestation.

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1           MEMBER GUIBERTEAU:  When it was stated, I  
2 remember your saying that there was a possible detail,  
3 and you also said if he did not approve.  My feeling  
4 is that because the authorized user may not always be  
5 around when these are signed, although there usually  
6 is some paperwork, my understanding is, as it was  
7 phrased during the meeting, was that the AU had a veto  
8 effect.  That is, if he disagreed with that, then it  
9 would not be signed.  But he didn't necessarily have  
10 to come across and agree.

11           DR. HOWE:  I think we equated both as  
12 being equal, but that may not be true.

13           MEMBER GUIBERTEAU:  I'm not sure that they  
14 would be necessarily equal in the setting that these  
15 are done.  That's why I didn't say anything, because I  
16 thought the way you phrased it was the way I  
17 understood it, originally.

18           CHAIR MALMUD:  Dr. Thomadsen?

19           VICE CHAIR THOMADSEN:  I agree with that,  
20 and I think the wording was something like, "As long  
21 as the authorized user did not disagree with the" --

22           DR. HOWE:  I could live with that.

23           VICE CHAIR THOMADSEN:  -- "approval."

24           MEMBER GUIBERTEAU:  Yes.

25           DR. HOWE:  Okay.

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1 VICE CHAIR THOMADSEN: Is that what you --

2 MEMBER GUIBERTEAU: Yes.

3 MS. HOLIDAY: Okay. After that statement  
4 was made, does anybody else have questions for this  
5 item?

6 CHAIR MALMUD: I see none.

7 MS. HOLIDAY: Okay. Our last item is  
8 Item 16 where ACMUI continues to assert that the  
9 current regulations are based on a per release limit.  
10 ACMUI does not recommend any change to the regulation  
11 and does not recommend NRC consider this topic during  
12 the current rulemaking process, as there is no  
13 clinical advantage or advantage to members of the  
14 public for using an annual limit. This motion was  
15 made by Dr. Langhorst and seconded by Dr. Welsh.

16 Are there any questions?

17 CHAIR MALMUD: I see none.

18 MS. HOLIDAY: Okay. That will close my  
19 recommendations and action items. The rest of our  
20 items are purely administrative. I have distributed  
21 the Form 148 to each of you for your professional  
22 services during this meeting. If you could please  
23 fill that out and return it to me before you leave.

24 I also, during our meeting yesterday,  
25 asked that self-evaluation forms be completed and

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1 returned to me. I am still missing a couple, and I  
2 have one without a name, if someone would claim this  
3 one.

4 Also, I will be e-mailing your Form 64 for  
5 your travel paperwork. If you could have that turned  
6 back in to me within a week.

7 And, lastly, if you could, remove your  
8 name tags and leave your table tents, that concludes  
9 my portion.

10 MR. FULLER: I have one other --

11 CHAIR MALMUD: Thank you. Yes, please.

12 MR. FULLER: I just wanted to make sure  
13 that the Committee is aware that the staff also has  
14 two actions that were taken from this meeting in  
15 addition to the items that Sophie made note of for the  
16 Committee, and that is that we will be grouping the 28  
17 items, you know, of the additional -- I'm sorry, for  
18 the rulemaking, the expanded rulemaking, the 28 items,  
19 that we will be grouping those items according to  
20 topical area.

21 I think the way they were laid out was in  
22 accordance with how they show up in the rules, so they  
23 were sort of numerical order.

24 CHAIR MALMUD: Yes.

25 MR. FULLER: We are going to redo that

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1 list for purposes of future meetings, so that they are  
2 grouped by topic, like for instance all the T&E  
3 changes would be grouped together, all the attestation  
4 changes would be grouped together, and so forth.

5 And then, we will also provide a link to  
6 the previous ACMUI discussions on the various issues,  
7 so -- where we have records, and I'm sure we have  
8 records for all of these. Where the ACMUI has  
9 provided us either with their recommendations or their  
10 position on the various items, we will make sure that  
11 there is a link or some way to identify where that is,  
12 so members of the public or members of the Committee  
13 can go back and refresh their memory on that. So  
14 those are two action items that are taking for  
15 ourselves.

16 CHAIR MALMUD: Thank you. Any other items  
17 to be covered in today's agenda or additional items?

18 (No response.)

19 If not, I would like to thank the members  
20 of the Committee, the members of the staff, and  
21 members of the public, for having participated in what  
22 I think has been a very productive meeting with a  
23 lively discussion and a number of conclusions. Your  
24 efforts are always appreciated, and it is a pleasure  
25 to work with you all.

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1 Thank you all very much. Have a safe trip  
2 home.

3 (Whereupon, at 3:10 p.m., the proceedings in the  
4 foregoing matter were concluded.)  
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