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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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THURSDAY,

SEPTEMBER , 2007

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The meeting was convened via teleconference, at
1:00 p.m., Leon S. Malmud, M.D., ACMUI Chairman,
presiding.

MEMBERS PRESENT:

LEON MALMUD, M.D., Chairman

DOUGLAS EGGLI, M.D.

RALPH LIETO

SUBIR NAG, M.D.

JAMES WELSH, M.D.

DARRELL FISHER, Ph.D.

ORHAN SULEIMAN, Ph.D.

BRUCE THOMADSEN, Ph.D.

WILLIAM VANDECKER, M.D.

SALLY SCHWARZ

JEFFREY WILLIAMSON, Ph.D.

1 NRC STAFF PRESENT:

2 DONNA-BETH HOWE, Ph.D.

3 CINDY FLANNERY, ALT. DFO

4 MOHAMMAD SABA

5 ASHLEY TULL

6 SANDRA WASTLER, DFO

7 DUANE WHITE

8 CARLEEN SANDERS

9 RONALD ZELAC, Ph.D.

10 EDWARD LOHR

11 JAMES MONTGOMERY

12 JACKIE COOK

13 JASON RAZO

14 ROBERTO TORRES

15

16 ALSO PRESENT:

17 CHRIS GALLAGHER, ASNC

18 CYNTHIA SANDERS, GA

19 DARICE BAILEY, TX

20 DARLENE METTER, TRAB

21 DAVID WALTER, AL

22 DAWN EDGERTON, CBNC

23 DEAN BROGA, ABMP

24 DEBBIE GILLEY, FL/OAS/CRCPD

25

1 ALSO PRESENT:

2 GERALD WHITE, AAPM

3 GLORIA ROMANELLI, ACR

4 GONZALO PEREZ, CA

5 HENRY ROYAL, ABNM

6 HUGH CANNON, SNM

7 JEAN ST.GERMAIN, ABMP

8 JENNIFER CARLIN YOUNG, AACE

9 JENNIFER ELEE, LA/CRCPD

10 JENNIFER GRANGER, CA

11 KIM GILLAM, VA

12 LYNNE FAIROBENT, AAPM

13 MARION EADDY, NC

14 MELISSA CACIA, AACE

15 MELISSA MARTIN, ACR

16 MICHAEL FORD, TRAB

17 MICHELE BEAUVAIS, William Beaumont Hospitals

18 MIKE PETERS, SNM

19 MIKE STEVENS, FL

20 PHILLIP SCOTT, CA

21 RICHARD MARTIN, ASTRO

22 ROBERT DANSEREAU, NY

23 ROBERT YOUNG, TN

24 SALLY CHEEVER, Physics Consultants, Inc.

25 SANDOR ERDELYI, SIRTEX

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ALSO PRESENT:
SHAWN SEELEY, ME
SUSAN LANGHORST, WUSTL

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A G E N D A

REMAINING DISCUSSION ITEMS: 6

Preceptor not available

Seven year recency of training

Increased complexity vs. additional benefit

P R O C E E D I N G S

(1:03:41 p.m.)

1
2
3 MS. WASTLER: Why don't we go ahead and
4 get started. I would just -- we don't have any
5 interference right now, but just remind folks that if
6 you're listening to please put your phone on mute, and
7 if you don't have a mute button you can use star 6 to
8 mute or unmute your line. From the last experience,
9 we found that mobile phones, and voice-over internet
10 protocol often caused the interference when you have
11 a large number of participants, so if you can call
12 over a land-line it makes it better. So that's just
13 some general information.

14 I am the Designated Federal Official for
15 this meeting, and I'm pleased to welcome you to this
16 teleconference public meeting of the ACMUI. My name
17 is Sandra Wastler. I am Chief of the Medical Safety
18 and Events Assessment Branch, and I have been
19 designated as the Federal Officer for this Advisory
20 Committee in accordance with 10 CFR 7.11. Present
21 today as the Alternate Designated Federal Officer is
22 Cindy Flannery, Team Leader for the Medical Radiation
23 Safety Team.

24 This is an announced meeting of the
25 committee to continue the discussion of training and

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1 experience requirements from the June and August --
2 the June meeting, and the August teleconference
3 meeting of ACMUI. It's being held in accordance with
4 the rules and regulations of the Federal Advisory
5 Committee Act and the Nuclear Regulatory Commission.
6 The meeting was announced in the August 29th, 2007
7 edition of the Federal Register.

8 The function of the Committee is to advise
9 the Staff on issues and questions that arise on the
10 medical use of byproduct materials. The Committee
11 provides counsel to the Staff; however, it does not
12 determine or direct the actual decisions of the Staff
13 or the Commission. The NRC solicits the views of the
14 Committee and values their opinion.

15 I request that whenever possible, we try
16 to reach consensus on various issues that we discuss
17 today. And I also recognize there may be minority or
18 dissenting opinions. If you have such an opinion,
19 please allow them to be read into the record.

20 As part of the preparation for this
21 meeting, I have reviewed the agenda for members and
22 employment interests based on the very general nature
23 of the discussions that we're going to have today. I
24 have not identified any items that would pose a
25 conflict; therefore, I see no need for an individual

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1 member of the Committee to recuse themselves from the
2 Committee's decision making activities. However, if
3 during the course of our business you determine that
4 you have a conflict, please state it for the record,
5 and recuse yourself from that particular aspect of
6 this discussion.

7 At this point, I would like to introduce
8 the members of the Committee, Dr. Leon Malmud.

9 CHAIR MALMUD: Here.

10 MS. WASTLER: Dr. Jeffrey Williamson.

11 DR. WILLIAMSON: Here.

12 MS. WASTLER: Ms. Sally Schwarz.

13 MS. SCHWARZ: Here.

14 MS. WASTLER: Mr. Ralph Lieto.

15 MR. LIETO: Present.

16 MS. WASTLER: Dr. Subir Nag.

17 DR. NAG: Yes.

18 MS. WASTLER: Dr. William Van Decker.

19 DR. VAN DECKER: Present.

20 MS. WASTLER: Dr. Douglas Eggli.

21 DR. EGGLI: Present.

22 MS. WASTLER: Dr. Orhan Suleiman.

23 DR. SULEIMAN: Present.

24 MS. WASTLER: Dr. James Welsh.

25 DR. WELSH: Here.

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1 MS. WASTLER: Dr. Darrell Fisher.

2 DR. FISHER: Present.

3 MS. WASTLER: Dr. Vetter is not with us
4 today, and I believe Dr. Thomadsen will be joining us
5 later. I would ask the NRC staff present to please
6 identify themselves.

7 MR. SABA: Mohammad Saba.

8 MR. LOHR: Mr. Lohr.

9 MR. WHITE: Duane White.

10 MR. RAZO: Jason Razo.

11 MS. SANDERS: Carleen Sanders.

12 MS. WASTLER: Region Four.

13 MR. MONTGOMERY: Jim Montgomery.

14 MS. COOK: Jackie Cook. Roberto, he's
15 coming back. He had to step out a minute.

16 MS. WASTLER: Okay. Do we have Region
17 One? Region Two? Region Three? Cindy?

18 MS. FLANNERY: Here.

19 MS. WASTLER: And our Oklahoma contingent?

20 MS. TULL: I'm here.

21 MS. WASTLER: That's Ashley Tull.

22 MS. WASTLER: Next, I would ask Ashley to
23 call the names of the members of the public who have
24 indicated they would listen or participate in today's
25 meeting. Please let us know if you are on line when

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1 she calls your name.

2 MS. TULL: All right. Chris Gallagher,
3 ASNC. Cynthia Sanders with the State of Georgia.

4 MS. SANDERS: Present.

5 MS. TULL: Darice Bailey with the State of
6 Texas.

7 MS. BAILEY: Present.

8 MS. TULL: Darlene Metter with the Texas
9 Radiation Advisory Board. I believe Darlene said she
10 was on earlier. David Walter of the State of Alabama.

11 MR. WALTER: Here.

12 MS. TULL: Dawn Edgerton with CBNC.

13 MS. EDGERTON: Here.

14 MS. TULL: Dean Broga, ABMP. Debbie
15 Gilley.

16 MS. GILLEY: Here.

17 MS. TULL: Thanks. Gerald White with
18 AAPM. Gloria Romanelli with ACR. I believe Gloria
19 said she was on earlier, as well.

20 MS. WASTLER: Yes, she did.

21 MS. TULL: Henry Royal with ABNM.

22 MR. ROYAL: Here.

23 MS. TULL: Hugh Cannon, SNM. I heard him
24 say hello earlier.

25 MS. WASTLER: Yes, he did.

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1 MS. TULL: Jean St. Germain, ABMP.
2 MS. ST. GERMAIN: Here.
3 MS. TULL: Jennifer Carlin Young, AACE.
4 MS. YOUNG: Here.
5 MS. TULL: Jennifer Elee with the State of
6 Louisiana. Kim Gillam with the State of Virginia.
7 MS. GILLAM: Here.
8 MS. TULL: Lynne Fairobent, AAPM.
9 MS. FAIROBENT: Here.
10 MS. TULL: Marion Eaddy with the State of
11 North Carolina.
12 MR. EADDY: Here.
13 MS. TULL: Melissa Cacia with AACE.
14 MS. CACIA: Here.
15 MS. TULL: Melissa Martin, ACR.
16 MS. MARTIN: Here.
17 MS. TULL: Michael Ford with the Texas
18 Radiation Advisory Board.
19 MR. FORD: Present.
20 MS. TULL: Michele Beauvais with the
21 William Beaumont Hospital.
22 MS. BEAUVAIS: Here.
23 MS. TULL: Thank you. Sorry if I
24 mispronounced your last name.
25 MS. BEAUVAIS: It's okay.

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1 MS. TULL: Mike Peters with SNM.

2 MR. PETERS: Here.

3 MS. TULL: Mike Stevens with the State of
4 Florida.

5 MR. STEVENS: Present.

6 MS. TULL: I have Jennifer Granger sitting
7 in for Phillip Scott with the State of California.

8 MS. GRANGER: Yes, I'm here. Thank you.

9 MS. TULL: Okay. And Richard Martin,
10 ASTRO.

11 MR. MARTIN: Here.

12 MS. TULL: Robert Dansereau with the State
13 of New York.

14 MR. DANSEREAU: Present.

15 MS. TULL: Robert Young with the State of
16 Tennessee.

17 MR. YOUNG: Present.

18 MS. TULL: Salli Cheever with Physics
19 Consultants.

20 MS. CHEEVER: Here.

21 MS. TULL: Sandor Erdelyi with SIRTEX.
22 Shawn Seeley with the State of Maine. William Metzger
23 with NeoVista. Also, I have Gonzalo Perez of the
24 State of California. And Susan Langhorst said she was
25 with Sally.

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1 MS. LANGHORST: I'm here.

2 MS. TULL: Okay. That's all I have.

3 MR. GALLAGHER: I'm Chris Gallagher with
4 ASNC.

5 MS. TULL: Hi.

6 MS. ROMANELLI: Gloria Romanelli with ACR.

7 MS. TULL: Okay.

8 DR. ZELAC: Ronald Zelac, NRC staff.

9 MS. TULL: Hello, Ron.

10 DR. ZELAC: Hello.

11 MS. TULL: Cindy, was Cynthia Flannery out
12 there, or, sorry, Sandy.

13 MS. WASTLER: Yes, she is.

14 MS. TULL: Okay.

15 MS. WASTLER: She just came in.

16 MS. TULL: Thank you.

17 MS. WASTLER: All right. With that. Dr.

18 Malmud, our Chairperson, will conduct today's meeting.

19 Following a discussion of each of the agenda items,

20 the Chair, at his option, may entertain comments or

21 questions from members of the public who are

22 participating today. I would remind you that this

23 meeting is being transcribed, and ask that prior to

24 speaking that you introduce yourselves.

25 Dr. Malmud, with that, I will turn the

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1 meeting over to you. We have three remaining agenda
2 item topics on T&E to cover, and I will turn it to
3 you, sir.

4 CHAIR MALMUD: Thank you. This is Dr.
5 Malmud. The remaining discussion items are issues of
6 the preceptor not being available. The second issue
7 is the seven year recency of training issue. And the
8 third is the increased complexity versus the
9 additional benefit.

10 With your permission, we'll start with
11 Item 1, the preceptorship unavailability. Who would
12 like to address this issue first? Would you like
13 staff to remind you of the issue?

14 DR. NAG: No. The question here, is it
15 that the preceptor -- that no preceptor is available
16 to preceptor that person, or that person has been
17 already precepted, but that preceptor is now not
18 available to confirm the preceptorship?

19 CHAIR MALMUD: This is Malmud. Thank you,
20 Dr. Nag. I think I heard someone else wanting to make
21 a statement.

22 MR. LIETO: This is Ralph Lieto. I would
23 think it wouldn't matter. I mean, I believe, if
24 memory serves me right, that we're trying to address
25 either situation, where a preceptor is either not

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1 available because he's not living, or just not
2 available to sign the preceptor form.

3 CHAIR MALMUD: Anyone wish to address this
4 with a potential solution to the problem?

5 DR. NAG: Well, I mean, the two are
6 different. If that person already has been precepted,
7 then that's a different method because then that means
8 the person was precepted. And, for example, the
9 Director of the Training Program, or the Chief of the
10 Department would say this person was precepted by so
11 and so, and we have a letter from him saying that he
12 was precepted on this year, on this date. Whereas,
13 the second problem is more difficult, and that is that
14 person was never precepted. Then he has to be
15 precepted all over again, but the two are different.

16 CHAIR MALMUD: Thank you, Dr. Nag. This
17 is Dr. Malmud. Shall we accept your comment with the
18 first issue to be a recommendation? And the
19 recommendation is that in the absence of the
20 availability of the preceptor to certify his or her
21 role as preceptor, that the preceptor's administrative
22 supervisor, whether that be the Chairman of the
23 Department, or the Director of the Division, that his
24 or her certification of knowledge of the preceptorship
25 would be adequate?

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1 DR. NAG: Yes, that is my recommendation,
2 or that's my motion.

3 CHAIR MALMUD: Is there a second to the
4 motion?

5 MS. SCHWARZ: Dr. Malmud, I have a
6 question. Sally Schwarz. I'm just wondering if the
7 preceptor is not available, and the supervisor is not
8 an authorized user, is that acceptable in the terms of
9 the way the regulation is written? And I know that
10 the answer is probably no, and so my other question
11 would be, could we at least consider the thought of
12 not requiring at least four certified individuals,
13 this preceptor statement? I mean, I think that that
14 would certainly help in a significant number of
15 situations.

16 DR. HOWE: Dr. Malmud?

17 CHAIR MALMUD: Yes.

18 DR. HOWE: This is Dr. Howe. I'd like to
19 just add a clarification here. According to NRC
20 regulations, the preceptor does not have to be the
21 person that provided you with the training, so if you
22 were preceptor 20 years ago, and your preceptor has
23 died, then you can get a new preceptor to sign the
24 statement. And if your preceptor is no longer
25 available for any reason, you can get a different

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1 person to be the preceptor for the statement for your
2 training and experience. And we clearly define the
3 preceptor as someone who can verify, and doesn't
4 necessarily have to be the person that directed you,
5 or provided the training.

6 CHAIR MALMUD: Thank you, Dr. Howe. Dr.
7 Nag, did you wish to say something?

8 DR. NAG: Yes, Dr. Nag. Yes. There's a
9 problem with that, because the new preceptor would be
10 unwilling to sign because that person had not observed
11 you doing the procedure. So, therefore, a new person
12 can say that -- my solution that the administrative
13 person, he is only certifying that you were precepted
14 by someone else, and not that he, himself precepted
15 you. Whereas, the new preceptor, if you ask me to
16 certify someone who was precepted by someone else 10
17 or 20 years ago, I have no idea what that person did,
18 so I see a problem there. Whereas, I think it's the
19 easier solution to say that the administrative
20 director of the preceptor can certify that that person
21 was precepted by this preceptor.

22 DR. WILLIAMSON: This is Jeff Williamson.
23 I'm wondering if it wouldn't help if the staff could
24 read us out of Part 35 the precise definition of
25 preceptor, and remind us precisely what the preceptor

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1 must attest to. I think that would help focus, at
2 least help focus my thoughts, which I'm struggling
3 trying to find it here.

4 MS. WASTLER: No problem. We will read it
5 to you.

6 DR. HOWE: Jeff, this is Dr. Howe. The
7 definition of a preceptor is as follows. "Preceptor
8 means an individual who provides, directs, or verifies
9 training and experience required for an individual to
10 become an authorized user, an authorized medical
11 physicist, an authorized nuclear pharmacist, or
12 radiation safety officer."

13 DR. WILLIAMSON: What section is that?

14 DR. HOWE: That's in 35-2.

15 DR. WILLIAMSON: Okay. Thank you.

16 DR. NAG: And this is Dr. Nag. Would you
17 also remind us, things have been changing so many
18 times, although, initially, there was a need for
19 preceptor, I believe in some of our previous
20 discussions, we had said that if that person was board
21 certified, our recommendation was that a preceptor
22 statement would not be needed. Where are we with
23 that?

24 CHAIR MALMUD: This is Malmud. Who wishes
25 to address Dr. Nag's question?

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1 MS. WASTLER: Ashley, do you have a list
2 of the previous recommendations with you?

3 MS. TULL: I do. I'll have to pull them
4 up. Hang on just a second.

5 MS. WASTLER: Okay.

6 MS. TULL: I know that our status is that
7 we are just reviewing them at this point.

8 MS. WASTLER: Right. We don't have a
9 formal response to that particular motion at this
10 point in time, but we can remind you of what your
11 motion was.

12 DR. NAG: Right. And if my memory serves
13 me right, the recommendation of ACMUI was that if the
14 person is board certified, then we do not need that
15 preceptor statement. But that has not so far been
16 approved by the Commissioners. Am I right?

17 MS. WASTLER: Right. We would have to --
18 what we're doing is, when we finish up the T&E
19 discussion, or as we finished up each one, we've
20 started looking at each of the recommendations, and we
21 will be proposing responses, so we're in that process.

22 DR. WILLIAMSON: This is Jeff Williamson.
23 May I ask -- may I make a statement about this that
24 might help.

25 CHAIR MALMUD: This is Malmud. Please do,

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1 Dr. Williamson.

2 DR. WILLIAMSON: Okay. Here is what I
3 perceive to be an essential problem, and I'll just use
4 the authorized 35.5-5, "Training for an authorized
5 nuclear pharmacist", as an example. So we suppose
6 that there is a nuclear pharmacist who has received
7 their training sometime in the past. The individual
8 who administered that training or was in a position to
9 have direct knowledge of the performance of the
10 candidate, let us suppose is not available, may be
11 dead, may be unreachable, it doesn't matter. So what
12 is needed then to comply with the regulations for this
13 person, individual now to become an authorized nuclear
14 pharmacist after-the-fact, is that they must have a
15 written attestation signed by a preceptor authorized
16 nuclear pharmacist that the individual has
17 satisfactorily completed the requirements in
18 Paragraphs A.1, A.2, A.3 or B.1 of this section, and
19 has achieved a level of competency sufficient to
20 function independently as an authorized nuclear
21 pharmacist.

22 So here's the essential difficulty. I
23 think as a representative of the institution, they
24 could certainly verify that the applicant has
25 satisfactorily completed those requirements. But on

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1 what basis, what possible basis would such an
2 individual, who has had no contact with the trainee,
3 attest to the level of competency of this person? I
4 think this is really the essence of the problem, and
5 that makes many of us who are in administrative
6 positions, where we've taken over a program, somewhat
7 uncomfortable signing these things.

8 CHAIR MALMUD: Thank you for that, Dr.
9 Williamson. Though we cannot attest to the competency
10 of an individual, we can attest to the fact that the
11 individual received the requisite training, can we
12 not?

13 DR. WILLIAMSON: We can do that, because
14 we keep records, and we are representatives of the
15 institution. And just like a registrar, we would
16 basically say this training has been completed. It
17 would be analogous to -- we would be functioning as a
18 registrar of a training program, rather than a
19 formalized degree curriculum.

20 DR. NAG: This is Dr. Nag. This is quite
21 analogous to what we do for our residents, because the
22 residential training director may have long since
23 left, or died, or whatever, or gone to a different
24 hospital. The new training program director attests
25 to the fact that the person completed the residency

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1 training program satisfactorily, but does not attest
2 to the competency of that person at that point. And
3 they say that there were no negative things, or there
4 was no negative things in the file.

5 DR. METTER: This is Darlene Metter from
6 TRAB. May I make a comment?

7 CHAIR MALMUD: Please do.

8 DR. METTER: Regarding residency training,
9 before a person has completed a residency, it is the
10 program director, as part of the training
11 requirements, to say that the individual is able to
12 competently and independently practice said area of
13 specialty, and so that is actually a statement that
14 the resident receives before graduation.

15 My concern about the issue regarding the
16 unavailability of a preceptor, if the preceptor has
17 passed on, that's one point. But another would be if
18 a preceptor maybe will not want to sign a preceptor
19 statement, and the individual claims the preceptor is
20 unavailable, that's my concern, that perhaps we need
21 to address. What does "unavailability" mean? If it
22 means that he's gone for today, and he'll be back next
23 week, but then at this point in time he's unavailable,
24 but the preceptor did not want to sign the statement,
25 so he'll find somebody else to sign it for him while

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1 the preceptor is on vacation. You know, I think we
2 need to specify exactly what you mean by non-
3 available. And if somebody has finished a program,
4 and their training has been that long ago, what have
5 they been doing in the interim that makes them
6 competent to practice as an authorized user at this
7 point in time?

8 DR. NAG: Dr. Nag. The second part is
9 addressed in that seven year recency of training, so
10 I think the seven year thing we can discuss
11 separately. But your first issue is valid, that
12 suppose the preceptor is there, is not really happy
13 with him, and this individual goes to another person
14 and have it signed off, but then if that person is
15 there, a second preceptor would not be signing off if
16 they did not personally train them. Usually, when the
17 preceptor has moved on, and the new person who is
18 there on their behalf would be the person signing off.

19 DR. EGGLI: This is Doug Eggli.

20 CHAIR MALMUD: Yes, Dr. Eggli.

21 DR. EGGLI: In our program, not only do we
22 keep copies of the performance of the residents, we
23 actually keep copies of preceptor statements for those
24 who request that statement on completion of their
25 residency. I think as Dr. Nag mentioned earlier, the

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1 biggest problem is those who didn't get a preceptor
2 statement on completion of their residency program,
3 and comes back later and want one.

4 In the current environment, not only is
5 there a sense of responsibility on the part of the
6 preceptor, but there's a heightened sense of
7 liability. And I think that to get someone else to
8 write a preceptor statement for you seems unlikely,
9 and that the biggest problem is that people who may
10 well have been qualified but didn't bother to get a
11 preceptor statement on exit from their training, now
12 find themselves in a practice situation where they
13 need to become an authorized user, and they are going
14 to have trouble obtaining one.

15 DR. METTER: This is Darlene Metter again
16 from TRAB. I actually have a situation, a resident
17 didn't really complete our program, but he did part of
18 his training with us about six years ago, and he's now
19 wanting to be an authorized user, but has not even
20 done nuclear medicine for the last six years, and so
21 there's a problem there. I do not know what they've
22 been doing, and it's difficult for me to say that the
23 person currently now is competent.

24 CHAIR MALMUD: Excuse me. This is Malmud.
25 Why is that a problem? It's only a problem in that

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1 that individual cannot get attestation for that which
2 you are not sure the individual received. It would be
3 a problem if the individual had received the training,
4 and could not obtain proof of it.

5 DR. METTER: The person only did a part --
6 didn't complete the program.

7 CHAIR MALMUD: So that's the statement
8 that would be released by your institution.

9 DR. NAG: I mean, if the person did not
10 complete this, then you say that the person did not
11 complete. Then the problem is when the person
12 completes the program, and completes everything, and
13 is now wanting a statement, and the preceptor is not
14 there.

15 DR. METTER: Well, actually, at the --
16 okay.

17 DR. NAG: So if part of the training was
18 Place A, and part of the training in Place B, what
19 they would need would be two preceptor statements
20 saying that they did one year here, and the other one
21 that would say they did one year or two years at Place
22 B.

23 DR. METTER: No, Place B never occurred.
24 The person did another -- in another area modality,
25 did not continue in nuclear medicine. But the problem

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1 is they actually became a radiologist, and then tried
2 to use the one year for that at that time.
3 Unfortunately, it's about another six months, and it
4 will be to the seven years.

5 DR. HOWE: That sounds like an issue that
6 the regulatory authority would handle on a case-by-
7 case basis.

8 CHAIR MALMUD: Who is speaking, please?

9 DR. HOWE: This is Dr. Howe.

10 CHAIR MALMUD: Thank you.

11 DR. HOWE: But what I wanted to point out
12 is that the attestation process is a performance-based
13 process, so that if you -- you can verify someone has
14 training by looking at documentation. And if you
15 didn't provide that training, how do you attest that
16 the person is competent to function independently? You
17 have many ways of evaluating the individual to see if
18 you believe you can sign off on that attestation. You
19 can ask them questions, you can observe them working,
20 you can do any number of things, and we haven't
21 specified what those things are, for you to feel
22 comfortable, as a preceptor, to make that final
23 statement that you believe they can function
24 independently as an authorized user, nuclear
25 pharmacist, medical physicist, et cetera.

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1 CHAIR MALMUD: Thank you, Dr. Howe. May
2 I ask a naive question? That is, how many individuals
3 in the last year have not been able to be certified
4 for lack of finding someone to certify that they
5 really did have training?

6 MS. CHEEVER: This is Salli Cheever from
7 Physics Consultants. May I speak?

8 CHAIR MALMUD: Please.

9 MS. CHEEVER: I have a lot of experience
10 in having authorized users to radioactive materials in
11 Maine. The issue that comes up frequently for us is
12 somebody who might have obtained board certification
13 over seven years ago, but has not been added to a
14 radioactive materials license. In that case, in the
15 interest of the seven year recency of training, we
16 typically have them have the preceptor filled out by
17 whoever they're currently working under the
18 supervision of.

19 CHAIR MALMUD: Yes. Malmud, again. And
20 has this been accepted?

21 MS. CHEEVER: It has been accepted in the
22 State of Maine, as long as they can find somebody
23 who's willing to attest to the fact that they can work
24 independently.

25 CHAIR MALMUD: Thank you. Is anyone aware

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1 of situations in which this has not been satisfactory
2 to achieve certification for someone who truly is
3 trained?

4 DR. WILLIAMSON: To receive certification
5 or to get a preceptor statement?

6 CHAIR MALMUD: To get a preceptor
7 statement for --

8 DR. WILLIAMSON: Williamson. I believe we
9 have had in our institution ex-trainees come back and
10 request preceptor statement regarding competency to
11 function independently as a radiation safety officer,
12 and we have turned those people down.

13 DR. EGGLI: This is Doug Eggli. I have
14 turned down several coming back years later asking for
15 preceptor statements.

16 CHAIR MALMUD: Oh, I understand. This is
17 Malmud. Go ahead.

18 MS. GILLEY: This is Debbie Gilley. May
19 I speak?

20 CHAIR MALMUD: Please do.

21 MS. GILLEY: You're asking for information
22 from a population that's still in flux. Some of the
23 agreement states have yet to adopt this section of
24 Part 35, so we're really not going to know the
25 ramifications of it until all of the agreement states

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1 are in compliance. NRC, there's only about 20 percent
2 of the licenses, the rest are maintained by the
3 agreement states.

4 DR. WILLIAMSON: Could I ask a question of
5 the NRC staff?

6 MS. WASTLER: Of course you may, Dr.
7 Williamson.

8 DR. WILLIAMSON: As I recall, the Form
9 313A has a place where the preceptor statement must
10 sign, or where the preceptor must sign and check off
11 various things, including the attestation to function
12 independently as whatever. If the person, the
13 preceptor, let's say, has died, or really is
14 unavailable by any reasonable standard, and the
15 individual has a letter which was signed and dated by
16 the preceptor prior to the death of the individual, of
17 the preceptor, can this -- do your current procedures
18 allow this letter to be advanced as a preceptor
19 statement in lieu of actually signed the Form 313A?

20 DR. HOWE: Dr. Williamson, this is Dr.
21 Howe. The NRC Form 313A series are voluntary forms.
22 They do list out in a convenient manner the
23 information that must be provided for training and
24 experience, but you can provide the same information
25 in another form. So provided the preceptor statement

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1 in the letter, that's the statement requirements that
2 are in the regulations that the person can function
3 independently as a authorized whatever, then that
4 would be acceptable. But many cases, we don't get
5 those words, we get they've been through our program.
6 But if they met the criteria in the preceptor
7 attestation statement, we would accept any format that
8 it comes in.

9 DR. NAG: This is Dr. Nag. Now, again,
10 based on that, and based on the fact that the board
11 certification includes a preceptorship, I would
12 assume, or at least I'm assuming that the
13 commissioners will go along with our recommendation
14 that board certification automatically means that the
15 preceptor statement is there, and that, therefore, an
16 additional preceptor statement is not required. In
17 that case, the only concern we have now are for the
18 non-board certified people who had the preceptorship,
19 where the preceptor is no longer living, or no longer
20 at that same place. Hopefully, I'm right.

21 DR. HOWE: Dr. Nag, I hate to inform you,
22 but during the last -- the T&E regulations, board
23 certification and the attestation were separated.

24 DR. NAG: Oh, okay.

25 DR. HOWE: So having the certification

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1 does not automatically mean that the attestation is
2 there. That has to be provided separately by the
3 applicant.

4 DR. WILLIAMSON: This is Jeff Williamson.
5 Did we, as a group, vote to recommend to the
6 Commission that that be changed, so that per our
7 previous recommendation, board certified individuals
8 would no longer have to produce a separate attestation
9 statement?

10 MS. TULL: This is Ashley Tull. I'm
11 looking at the recommendations from the last meeting,
12 and the answer is yes, that was a formal motion, but
13 the NRC is reviewing it, so --

14 DR. WILLIAMSON: Well, I think that what
15 I would say to -- in support of what Dr. Nag has said,
16 is I would simply, for that cohort of individuals,
17 reaffirm that motion we made as our recommendation how
18 to solve this problem, and then we could move on to
19 the discussion of the non-board certified people.

20 DR. METTER: This is Darlene Metter from
21 TRAB. Can I make a statement, please?

22 CHAIR MALMUD: Yes, thank you.

23 DR. METTER: Is there, first of all, on
24 the ABR here? May I speak? I'm a radiologist, and
25 I'm a program director, regarding the issue. As far

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1 as for the American Board of Nuclear Medicine, meeting
2 the 700 and 200 hours that are required in 35.390 is
3 not a problem in all the therapies. As far as the
4 American Board of Radiology, prior to taking the oral
5 board exam, the program director needs to have a
6 preceptorship's attestation that says that the
7 resident has completed 700 hours of classroom training
8 and experience, and at least 80 hours of -- training
9 and experience, and at least 80 hours of classroom and
10 laboratory training, and then provide the three I-131
11 cases before they take their nuclear radiology part of
12 the oral board exam. And if they do that, and then
13 they also pass their ABR oral exam, then on their ABR
14 certificate they have AU eligible on that.

15 Program Directors who have residents that
16 do not complete the 700 hours prior to taking the oral
17 board exam, and particularly the section on nuclear
18 radiology, do not get that statement, so being board
19 certified does not automatically say in radiology that
20 they completed the 700 hours that are required.

21 CHAIR MALMUD: Thank you for that
22 clarification.

23 DR. WILLIAMSON: This is Jeff Williamson.
24 I would like to ask a follow-up question of the last
25 speaker, if I may?

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1 MS. TULL: Yes.

2 DR. WILLIAMSON: If the individual has a
3 board certification certificate that says AU eligible,
4 that does not replace the need to have a separate
5 preceptor statement, because nowhere along the line
6 have they had a preceptor statement signed that would
7 attest to their competency to practice independently,
8 would they have?

9 MS. TULL: No. They still need to go with
10 the attestation and fill out 313 AUD, or 313 AUT.
11 Yes, they still have to complete that. With that,
12 they submit their board certification certificate with
13 that wording on it.

14 DR. WILLIAMSON: Thank you.

15 CHAIR MALMUD: Dr. Williamson, I believe
16 that you made a motion -- actually, earlier, there was
17 an earlier motion by Dr. Nag which wasn't seconded, so
18 are you making a motion, Dr. Williamson, with regard
19 to our previous recommendation?

20 DR. WILLIAMSON: Yes. I think that maybe
21 with respect to this issue, I would propose the
22 following motion; that individuals that have received
23 board certification in the appropriate area, is board
24 certification that has been recognized by the
25 Commission as appropriate for the kind of

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1 certification being sought, that these individuals
2 should not be required to produce a separate preceptor
3 statement.

4 CHAIR MALMUD: Is there a second to Dr.
5 Williamson's motion?

6 MS. SCHWARZ: Sally Schwarz, I second the
7 motion.

8 CHAIR MALMUD: Any further discussion of
9 that motion?

10 MS. SCHWARZ: Yes.

11 CHAIR MALMUD: Which you will recall is a
12 restatement of an earlier motion that we had made and
13 passed.

14 DR. METTER: This is Darlene Metter again
15 from TRAB. I do have a comment on that. With that
16 then be for becoming an authorized user under 35.390?
17 Is that what you're requesting --

18 DR. WILLIAMSON: I think this would be
19 intended to apply to any board certification mechanism
20 that had been recognized by the Commission as being
21 acceptable, so this would mean in your case that those
22 diplomates that had AU eligible on their certificates
23 would be included in this motion, and those that did
24 not would not be included in this motion.

25 DR. METTER: Okay. The aim for the ABR,

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1 though, is not to obtain training and experience for
2 35.390. It was to obtain it for 35.290, and 35.292.
3 So they actually go 700 hours of training and
4 experience, and a minimum of 80 hours of classroom and
5 laboratory training.

6 DR. WILLIAMSON: I think that the motion,
7 as I made it, perhaps I'm missing something, was
8 intended to be independent of the specific
9 requirements, because they would be very different for
10 radiation oncologists in 490 and 690, they would be
11 different for medical physicists in 35.51, I believe.
12 But the language that's in the regulations regarding
13 what a preceptor must attest to is, I think, identical
14 for all of the authorized personages, whatever they
15 be.

16 DR. NAG: Hi. This is Dr. Nag. I think
17 we are going away from our topic of discussion today,
18 which is preceptor not available. What Dr. Williamson
19 has stated was something that is a point of the
20 discussion from the previous one, as that has already
21 been submitted to the NRC, so I don't think we are
22 serving any purpose by making this motion. We should
23 make a motion that is directed to the preceptor not
24 being available. And if you want you can say for
25 those who are board certified, this is not applicable

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1 because this has been addressed in the past.

2 DR. WILLIAMSON: Well, I accept your
3 friendly amendment to this motion.

4 CHAIR MALMUD: This is Malmud. Therefore,
5 Dr. Williamson's motion has been amended by Dr. Nag's
6 recommendation. Any further discussion of this
7 amended motion?

8 MR. LIETO: Question, please?

9 CHAIR MALMUD: Mr. Lieto.

10 MR. LIETO: Yes, this is Ralph Lieto. A
11 question of clarification to Dr. Williamson. Is this
12 motion meant to address any individual who is not
13 board certified regardless of when the training was
14 received?

15 DR. WILLIAMSON: No, this is very focused.
16 It's basically saying that the prior motion addresses
17 the issue of the missing preceptor for this class of
18 people, and we have yet to discuss what to do with the
19 other class.

20 MR. LIETO: This is Ralph Lieto again. So
21 we're talking about those class of individuals who are
22 not board certified, but have received training within
23 the past seven years.

24 DR. WILLIAMSON: No, we're not talking
25 about that. We're talking about individuals that are

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1 board certified, and simply pointing out that as a
2 consequence of the prior motion that we approved in
3 the last meeting, that the issue of the missing
4 preceptor is resolved for board certified individuals.

5 MR. LIETO: Thank you.

6 CHAIR MALMUD: Therefore, there is a
7 motion that has been moved, amended, and seconded.
8 Any further discussion?

9 MS. SCHWARZ: Dr. Malmud, could the court
10 reporter please restate the motion that we're
11 discussing, because it's confusing.

12 CHAIR MALMUD: Who was speaking then?

13 MS. SCHWARZ: Sally Schwarz.

14 CHAIR MALMUD: Thank you, Sally. Dr.
15 Williamson, would you repeat the motion, or Dr. Nag,
16 or the court reporter, any of the three.

17 DR. NAG: Jeff?

18 DR. WILLIAMSON: Yes.

19 DR. NAG: Do you want to restate your
20 motion with the amendment that I made, or you want me
21 to do that?

22 DR. WILLIAMSON: Why don't you try?

23 DR. NAG: Okay. What I would say is that
24 for those who are board certified, the preceptor not
25 being available does not apply because board certified

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1 individuals do not require preceptor -- do not require
2 a separate preceptor statement as per the ACMUI
3 recommendation made on, whenever, June or August,
4 whenever that was.

5 CHAIR MALMUD: Does that answer your
6 question, Sally Schwarz?

7 MS. SCHWARZ: Yes, it does, Dr. Malmud.
8 Thank you.

9 CHAIR MALMUD: Thank you. Any further
10 discussion of the motion?

11 DR. WELSH: Jim Welsh.

12 CHAIR MALMUD: Yes.

13 DR. WELSH: I would like to add that board
14 certification also state specifically that that
15 individual was AU eligible.

16 DR. NAG: Yes, I accept that amendment,
17 that board certification with AU eligible.

18 CHAIR MALMUD: I believe some -- hello.

19 MR. LIETO: This is Ralph Lieto. I
20 thought the motion would apply to those other
21 individuals that required preceptor statements, that
22 were board certified. In other words, not just Aus,
23 but this would apply to nuclear pharmacists, RSOs, and
24 AMPs. Am I incorrect in that assumption?

25 DR. WILLIAMSON: No, you are correct, so

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1 I think we can't use the terminology AU eligible. I
2 would recommend that we use the terminology,
3 certification recognized by the Commission.

4 MS. SCHWARZ: That would be fine. I
5 agree. Sally Schwarz.

6 DR. WELSH: Jim Welsh here. I agree with
7 that.

8 DR. NAG: And then as a follow-up to that,
9 now we need to make a motion about those who are not
10 board certified, what do we do if the preceptor is not
11 available.

12 CHAIR MALMUD: We will do that, Dr. Nag.
13 But first we want to get a vote on this motion.

14 DR. NAG: Yes.

15 MS. FAIROBENT: Dr. Malmud, Lynne
16 Fairobent. May I speak?

17 CHAIR MALMUD: Yes, please.

18 MS. FAIROBENT: One thing that troubles me
19 about this motion, recognizing that although we may
20 remain optimistic that the ACMUI recommendation to no
21 longer require a preceptor statement for those who are
22 board certified does fall on favorable light. If it
23 does not, this motion then still has -- those
24 individuals, this situation would still apply. And in
25 order for the recommendation to be truly accepted,

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1 there would have to be a rule making to change the
2 current regulation.

3 DR. NAG: Yes. Well, then you are
4 correct.

5 MS. FAIROBENT: Excuse me. For that
6 period of time, those who are board certified who not
7 have preceptor's available, still are in this dilemma
8 situation.

9 MS. SCHWARZ: Sally Schwarz, Dr. Malmud.

10 CHAIR MALMUD: Yes.

11 MS. SCHWARZ: I agree with what Lynne
12 Fairobent is stating, and I'm wondering if it would be
13 possible for the ACMUI committee's representatives or
14 representative to actually present this motion to the
15 Commission, as well as being able to address the
16 motion that the staff has taken to the Commission in
17 regard to the issue that -- what Lynne was just
18 stating. I really feel it would be advantageous for
19 a representative of the ACMUI to be present in terms
20 of presenting this motion to the Commission.

21 CHAIR MALMUD: We certainly can do that.
22 I don't believe we've yet had a vote on the motion.

23 DR. WILLIAMSON: Well, maybe what we need
24 to do to -- I think that would be a separate motion,
25 so why don't we stay with the matter at hand. It

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1 sounds like what Lynne has done is appropriately
2 raised the issue of trying to make the recommendation
3 we made retroactive. So somehow we need to add
4 language to it that makes it retroactive to include
5 all applicants for authorized positions, who have been
6 trapped, not been able to achieve that status because
7 their preceptors have not been available. So I would
8 add to the statement, we also recommend that the
9 relief from the requirement of needing a preceptor
10 statement in the event that the preceptor cannot be
11 made available with reasonable effort, be made
12 retroactive prior to the date of any rule change
13 complying with this recommendation.

14 DR. NAG: I don't believe I understand
15 what that actually meant.

16 DR. WILLIAMSON: I believe that Lynne's
17 point is, correct me if I'm wrong, is that if this
18 recommendation we've made is accepted from the date
19 forward of implementing this new regulation, board
20 authorized individuals who not have preceptors
21 available will not have an issue. But there still be
22 a body of potential authorized personages between the
23 passage of the current rule and the date of any
24 revised rule that arises from these recommendations.
25 That group of people will continue to be

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1 disenfranchised. I believe that's your concern, Lynne.
2 Is that right?

3 MS. FAIROBENT: Dr. Malmud, Lynne
4 Fairobent.

5 CHAIR MALMUD: Yes?

6 MS. FAIROBENT: Jeff, that's part of it.
7 My real concern goes to the fact that I think there's
8 potentially a likelihood that the initial
9 recommendation of not requiring a preceptor statement
10 for those board certified would not be accepted. So,
11 in that case, the current regulation would stay, and
12 everybody board certified still would be impacted by
13 not having a preceptor available.

14 DR. NAG: Yes, this is Dr. Nag.

15 CHAIR MALMUD: Thank you, Lynne. Dr. Nag?

16 DR. NAG: Yes, this is Dr. Nag. That's
17 what I thought that Lynne was meaning. And,
18 therefore, that's why I did not understand Dr.
19 Williamson's statement. I think, Lynne, your concern,
20 if the commissioners don't accept board certification,
21 and still require preceptor statement, then that
22 portion would be addressed by the next statement that
23 we are going to make, which is what do we do for those
24 who are not board certified and preceptor is not
25 available? The same thing would also apply for the

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1 board certified people, so we haven't addressed that
2 portion yet, but when we address that, the same thing
3 would apply.

4 CHAIR MALMUD: Thank you, Dr. Nag. This
5 is Dr. Malmud again. I still am not satisfied that I
6 understand the scope of the problem. And I would like
7 to ask a member of NRC staff, perhaps Dr. Howe, how
8 many instances she is aware of in which individuals who
9 have applied for authorized user status, are being
10 denied the status? I do recognize what Dr. Eggli
11 said, and that is that there are individuals who might
12 have trained there without documentation prior to this
13 administration, who were denied the opportunity for
14 him to sign off, but it doesn't mean that they hit a
15 brick wall. I'm curious as to whether these people
16 have eventually found another means currently of
17 achieving authorized user status, or whether there's
18 a large population that has not. Therefore, I'm
19 asking Dr. Howe or another representative of the NRC
20 staff what they believe the order of magnitude is of
21 this problem.

22 DR. HOWE: This is Dr. Howe. We are not
23 receiving requests from the regions to address this
24 issue for individuals. Our understanding in ACMUI
25 meetings is that the regulations are very clear, and

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1 people are not applying.

2 DR. EGGLI: This is Dr. Eggli. I believe
3 that to be true.

4 DR. HOWE: So we are not seeing it as an
5 issue here, because it's being handled before it gets
6 to the NRC.

7 CHAIR MALMUD: In that case, Dr. Howe, may
8 we hold -- we have representation from the regions
9 with us on this call today. May I ask some of the
10 regions how many of these issues they're aware of?
11 Region One?

12 MS. WASTLER: Dr. Malmud, I believe Region
13 Four is on. Jackie or Roberto?

14 MS. COOK: Okay. What is it you're trying
15 to find out now?

16 CHAIR MALMUD: We're trying to find out
17 how many individuals who have applied for authorized
18 user status, and have not been board certified, or
19 been able to get their preceptor to sign off, either
20 because they didn't get the training, or the preceptor
21 is gone. How many are pending approval, or have been
22 denied approval?

23 MS. COOK: This is non-certified, non-
24 board certified individuals.

25 CHAIR MALMUD: We'll take both

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1 populations.

2 MS. COOK: Okay. As far as board
3 certified individuals are concerned, we are -- we do
4 think that it is a problem getting them to get
5 preceptor attestation. We agree with you all trying
6 to change it.

7 MS. WASTLER: But the question, Jackie, is
8 do you have -- how many applicants are coming in with
9 a board certification --

10 MS. COOK: It's difficult to get your
11 board certified, and it's difficult to find somebody
12 to preceptor you, if you already have certification
13 saying that you do have this training. It's difficult
14 to find. Given a percentage, maybe about like 20
15 percent.

16 CHAIR MALMUD: Twenty percent of what
17 number?

18 MS. COOK: Of the people that come in.
19 Let me think of a number. I don't know. Per year, in
20 a year's time?

21 CHAIR MALMUD: Yes. In other words, are
22 you aware of five or six people in your region who
23 applied for authorized user status, and have not been
24 able to get it because of the inability to find the
25 person to sign off for them?

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1 MR. TORRES: This is Roberto Torres,
2 Region Four. I have like within the last year one or
3 two individual physicians seeking authorization, and
4 the alternative that we're giving them is you can
5 still work under the supervision, and then have
6 someone from that institution, after being supervised
7 for some time, to sign the preceptor attestation. In
8 a little while, they come back with the preceptor
9 attestation.

10 CHAIR MALMUD: Is that within a year?

11 MR. TORRES: Well, these two individuals,
12 as my memory serves, yes, they came back several
13 months later with a signed preceptor attestation.

14 CHAIR MALMUD: So several months later.
15 And how many in Region Four remain, who have tried to
16 get authorized user status, and have been unsuccessful
17 in doing so?

18 MR. TORRES: Cases I've been processing,
19 none, but that's me. I'm just one --

20 CHAIR MALMUD: Right.

21 MR. TORRES: I'm going to ask Jackie the
22 same question.

23 MS. COOK: I haven't had any, but Jim
24 Montgomery also is on the line. He may have had some.

25 MR. MONTGOMERY: Yes. No, I have -- I do

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1 not recall any either in the past year, probably even
2 more than the past year. I think it's very unusual in
3 Region Four to see this.

4 CHAIR MALMUD: Would I be incorrect in
5 concluding that in Region Four, at least, that there
6 is a process in place for someone to receive
7 authorized user status by getting another individual
8 at the institution to which they're going to sign off
9 for them with regard to their certification?

10 MS. COOK: Yes, after they've been under
11 them for a period of time, under their supervision for
12 a period of time.

13 CHAIR MALMUD: Yes. Thank you. How about
14 other regions in the country, besides Region Four?

15 MS. CHEEVER: This is Salli Cheever from
16 PCI in Maine. May I speak?

17 CHAIR MALMUD: Yes, please.

18 MS. CHEEVER: Three -- we do amendments
19 for authorized users, and we have gone that route, as
20 well, had somebody work at an establishment for a
21 period of time until an authorized user on that
22 particular radioactive materials license is willing to
23 sign the preceptor for that person to be added to the
24 license.

25 CHAIR MALMUD: Do you currently have

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1 anyone pending who has not been able to achieve that?

2 MS. CHEEVER: We don't have anybody
3 specifically board certified.

4 MS. WASTLER: Dr. Malmud, this is Sandra
5 Wastler.

6 CHAIR MALMUD: Yes?

7 MS. WASTLER: I don't think there's any --
8 I don't think we have anybody from the other regions,
9 but it's our understanding that they do similar type
10 situations in the other regions. And I would also
11 point out that if they have a question as to whether
12 a person should be granted, that, basically, they have
13 the ability to send it into headquarters, and raise
14 the question. And, at which time, we bring it to
15 ACMUI for that decision.

16 CHAIR MALMUD: Yes.

17 MS. WASTLER: So there's also that point.
18 And I would also mention, again, the point that Debbie
19 Gilley had made, that not all the agreement states
20 have implemented Part 35, and they have the majority
21 of the licensees, in 34 states to handle the -- the
22 agreement states, so it's a mixed situation. So
23 you're only seeing a small subset of the numbers from
24 the NRC's perspective.

25 CHAIR MALMUD: Thank you. Now we have

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1 about 30 participants in today's phone conference.
2 May I ask an open question of the 30? Is any of you
3 aware of someone that you know has been adequately
4 trained, and has been unable to achieve authorized
5 user status currently? I don't mean someone you might
6 have said no to, who then found another route, but I
7 mean someone who is still pending, to your knowledge?

8 MS. GILLEY: Dr. Malmud, Debbie Gilley.
9 Is this related to people who are board certified? Is
10 that the limitation of this question?

11 CHAIR MALMUD: No, the question is across
12 the board, but let's take board certified first. Does
13 anyone know someone who's board certified, who's been
14 denied authorized user status?

15 MS. FAIROBENT: Dr. Malmud, this is Lynne
16 Fairobent.

17 CHAIR MALMUD: Yes?

18 MS. FAIROBENT: I am aware of several
19 board certified medical physicists who do consulting
20 work, who are unable to get listed on a license as an
21 AMP because they are not directly associated with the
22 facility. And yes, it is a problem.

23 CHAIR MALMUD: Yes. Someone else wanted
24 to say something?

25 DR. METTER: Yes. Darlene Metter from

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1 TRAB. In 2005, the graduates from radiology that
2 became board certified by the ABR do not have that,
3 the words AU eligible, because that was the time when
4 the ABR was, I believe, trying to sort that out with
5 the NRC. And so candidates who have been board
6 certified by the ABR in 2005 at this point do not have
7 a process to become authorized users. ABR is,
8 however, compiling a 50 question exam which will be
9 available in May of -- or Spring of `08, which they
10 can take to obtain that AU eligible addendum to their
11 certificate.

12 CHAIR MALMUD: And --

13 MS. LANGHORST: Dr. Malmud, this is Sue
14 Langhorst.

15 CHAIR MALMUD: Yes?

16 MS. LANGHORST: I'm the Radiation Safety
17 Officer here at Washington University in St. Louis.

18 CHAIR MALMUD: Yes.

19 MS. LANGHORST: And I would not submit an
20 application for an authorized user to my committee, or
21 in our case we're a broad scope, so we approve our
22 own, if they did not meet the qualifications. So I'm
23 sure that other RSOs don't even submit that to NRC, or
24 agreement states if they know that it does not meet
25 the requirements. Plus, as far as radiation safety

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1 officers go, there's a problem sometimes in getting a
2 preceptor statement if you are coming into a job that
3 has a different type of use, say like HDR use, that
4 you've not had that experience before, and there's no
5 RSO to preceptor under. And so RSOs are in a peculiar
6 situation, because there's only one allowed per
7 license.

8 COURT REPORTER: I'm sorry for the
9 interruption. This is the court reporter. Whoever
10 spoke, could I please get your name again?

11 MS. LANGHORST: Yes, this is Susan
12 Langhorst.

13 CHAIR MALMUD: Susan Langhorst from
14 Washington University in St. Louis. That's L-A-N-G-H-
15 O-R-S-T. Am I correct?

16 MS. LANGHORST: You are correct. Thank
17 you.

18 CHAIR MALMUD: Thank you.

19 MS. MARTIN: Dr. Malmud, this is Melissa
20 Martin. May I speak?

21 CHAIR MALMUD: Yes. Would you identify
22 your organization?

23 MS. MARTIN: ACR.

24 CHAIR MALMUD: Thank you.

25 MS. MARTIN: I think Lynne Fairobent

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1 brought up a good question. We've mostly been
2 focusing on authorized users as physicians. We really
3 haven't had a lot of this applied yet to the
4 physicists, and particularly those physicists that may
5 be going in as RSOs. I think Sue Langhorst just
6 brought up the problem. It is going to be a problem.
7 We haven't seen it yet, because most states have not
8 been enforcing these regulations, as yet. There's a
9 large number, and I can't give you that number, of
10 people with board certification that would right now
11 qualify them as RSOs for facilities. Again, they're
12 going to be applying for jobs as single entities.
13 There is no existing RSO, and there is no preceptor
14 available, or I think it's just puts the board
15 certified physicist in a very, I don't know, unstable
16 relationship to try to come up with that statement.

17 DR. WILLIAMSON: This is Jeff Williamson.
18 I would like to support what was just said. Our
19 Radiation Safety Officer, Dean Broga, is not on the
20 line, but he has related to me, he has received
21 requests from resident graduates of our radiology
22 program who subsequently seek to become RSOs on
23 nuclear medicine licenses, and he has turned these
24 individuals down, because he did not have a personal
25 relationship with the individuals during their

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1 training, and does not feel he is in a position to
2 attest to their competence to be an RSO.

3 CHAIR MALMUD: Thank you, Dr. Williamson.
4 Addressing your point, Dr. Williamson, how would you
5 propose that those individuals achieve authorized user
6 status?

7 DR. WILLIAMSON: Well, I think that my
8 preference would be, as I stated earlier, to, one,
9 eliminate the requirement for a preceptor statement
10 for board certified individuals. Secondly, if that
11 could not be done, redefine the duties of the
12 preceptor to basically that of verifying that the
13 training had been administered, and the performance of
14 the individual as a trainee had been satisfactory. I
15 think that would be a lot easier for RSOs, for
16 example, to review the paper trail or documentation of
17 a given resident's training, and sign off on that; as
18 opposed to competency, which is very difficult to do
19 without having had a personal relationship,
20 supervisory relationship with the individual.

21 MS. WASTLER: Dr. Malmud, this is Sandra
22 Wastler. A couple of points. I believe, and I don't
23 have in front of me the motions that the committee has
24 made in the past two meetings, but I do know that we
25 have talked about, or the committee has motions with

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1 regards to definitions of preceptor statement, and
2 also with regards to the RSO. And I'm wondering if
3 those two issues might not already have been, I don't
4 want to say resolved, but raised, at least identified
5 and proposed resolutions put forward by the committee.
6 And, like I said, I don't have it in front of me.
7 Ashley can -- if you have those, you can tell me if
8 I'm right or wrong.

9 MS. TULL: You're right. I have them in
10 front of me. This is Ashley.

11 MS. WASTLER: And the other thing, just to
12 remind you that it's 10 after 2, and we're still on
13 the first topic.

14 CHAIR MALMUD: Perhaps Ashley could email
15 this text to the committee members so we could look at
16 it and see the language.

17 DR. WEINER: It's in the meeting summary
18 that was sent out before the last meeting, and it's
19 also posted on the web. I can send out the links if
20 you want me to right now.

21 MS. SCHWARZ: Ashley, one question.
22 Excuse me. Sally Schwarz. I do have a question, that
23 maybe you could take these motions out of the flowing
24 text, and just kind of make the motions listed
25 individually and on a separate sheet, that way you

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1 could just have a sheet of the motions that we could
2 receive.

3 CHAIR MALMUD: This is Malmud.

4 MS. TULL: Dr. Malmud, this is Ashley.

5 Can I answer that?

6 CHAIR MALMUD: Please do, actually.

7 MS. TULL: Okay. There's a memo that is
8 generated that is just the name of each motion, and
9 then the NRC response to each one. And I'm currently
10 working on that, so it will go to the entire
11 committee. But as far as all the motions being listed
12 out, they are all listed, and it's in the meeting
13 summary, which isn't too long of a document.

14 MS. WASTLER: Thank you.

15 CHAIR MALMUD: This is Malmud again. What
16 I'm trying to do is simplify this a bit, if at all
17 humanly possible. And would this satisfy everyone, if
18 there were a statement that said the ACMUI once again
19 recommends the elimination of the preceptor statement
20 for authorized users for board certified individuals.

21 MR. LIETO: No.

22 CHAIR MALMUD: Who said no?

23 MR. LIETO: This is Ralph Lieto. We can't
24 specify just authorized users. We need to say board
25 certified individuals, because I think it does apply

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1 also to the AMPs, as well as the Aus, the authorized
2 nuclear pharmacists, the RSOs.

3 CHAIR MALMUD: So, Ralph, are you saying
4 then that it would state eliminate the preceptor
5 statement for board certified individuals?

6 MS. TULL: Dr. Malmud, this is Ashley.

7 CHAIR MALMUD: I was ask --

8 MS. TULL: Could you read the words from
9 the previous motion?

10 CHAIR MALMUD: Yes. If you wish, but I
11 was trying to get a question answered by Ralph, if I
12 may do that first.

13 MR. LIETO: Yes.

14 CHAIR MALMUD: Ralph, your preference
15 would be to eliminate the preceptor statement for
16 board certified individuals. Am I correct so far?

17 MR. LIETO: Yes.

18 CHAIR MALMUD: And that we redefine that,
19 instead of certifying competency, we're certifying
20 that the requisite training was administered during
21 the training program.

22 MR. LIETO: That's acceptable to me. This
23 is Ralph Lieto. That would be acceptable to me.

24 CHAIR MALMUD: For those who require
25 preceptor statements because they're not boarded.

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1 Right?

2 MR. LIETO: Correct.

3 CHAIR MALMUD: Okay. So I think we've
4 reduced it to two components; one, eliminate the
5 preceptor statement for board certified individuals.
6 And number two, redefine that for those who require
7 preceptor statements, that the preceptor statement
8 state that the training, the requisite training was
9 administered, period. Is that correct?

10 DR. NAG: Yes. This is Dr. Nag. Yes,
11 you're correct. And I would add for those who when
12 the preceptor is not available, that be the case. If
13 the preceptor is available, they can certify that they
14 did the training.

15 CHAIR MALMUD: I'm not sure that I heard
16 you well, Dr. Nag. Repeat that.

17 DR. NAG: Let me make the motion then.
18 The motion -- since we have previously made the motion
19 about the board certified individuals, we are -- we
20 should concentrate now on what to do if the preceptor
21 is not available. So what we can say in the following
22 motion is that if preceptor is not available, then,
23 number one, for board certified individuals, the board
24 certification is adequate proof of preceptorship, and,
25 therefore, a separate preceptor statement is not

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1 required, period.

2 Number two, for non-board certified
3 individuals, a preceptor statement that would certify
4 that the person receive this preceptor statement is
5 adequate, and a need for -- I mean, a statement of
6 competency is not required, because we cannot certify
7 -- someone who is not there cannot certify about the
8 competency. They can only certify that the training
9 was given.

10 CHAIR MALMUD: May I -- this is Malmud.
11 May I suggest that your second statement just end with
12 the part which says that they received the training?

13 DR. NAG: Yes. The other part was just
14 for clarification to the people who are on the
15 conference call.

16 CHAIR MALMUD: Is there anyone who objects
17 --

18 MR. FORD: Mr. Chairman, could I ask a
19 question?

20 CHAIR MALMUD: Who is speaking, please?

21 MR. FORD: This is Mike Ford, Chair of the
22 Texas Radiation Advisory Board. In this motion, then,
23 where is the competency certifying the individuals?
24 How is that attained for a person who's not board
25 certified?

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1 CHAIR MALMUD: From my reading of Dr.
2 Nag's statement, it would say that for the person who
3 -- that if the preceptor is not available, and the
4 person is not board certified, that they need a
5 statement indicating that the training was -- that
6 there is a record that the training was administered
7 and received.

8 DR. NAG: And that the person
9 satisfactorily completed that training.

10 CHAIR MALMUD: And completed the training.

11 MR. FORD: And yet, it's absent of an
12 assurance of competency. Is that correct?

13 CHAIR MALMUD: That is correct. And the
14 reason that I believe that the statement about
15 assurance of competency is omitted is that that is a
16 statement which most training program directors would
17 not wish to make on behalf of an individual who has
18 not been with them for a period of years.

19 MR. FORD: I certainly understand that.
20 I guess my concern is that at some point in time,
21 there needs to be an assurance of competency in a
22 person's record of training, and how is that proposed
23 to be accomplished?

24 CHAIR MALMUD: You're coming back to the
25 word "competency", which is a word that most training

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1 program directors are not pleased with.

2 MR. FORD: I understand, but that's
3 currently in the regulation as it stands, and there is
4 a requirement to assure competency within the
5 regulation itself.

6 CHAIR MALMUD: And we are recommending
7 that the word not be used. We understand that there's
8 a strong possibility that the Commission may reject
9 these recommendations. However, the Commission should
10 be aware of the fact, by now after all these
11 discussions I hope is aware of the fact, that they're
12 going to have great difficulty getting training
13 program directors to certify competency if that puts
14 the training program director at risk in terms of
15 liability.

16 DR. NAG: And this is Dr. Nag. The other
17 problem then is if we are at odds, and this is not
18 solved, then there will be no one who is competent,
19 because no one is going to certify the competency in
20 that case, other than those who are grandfathered,
21 there will be no one else who can be authorized user,
22 because it will refuse to certify to the competency,
23 then how is the Commissioner going to get someone to
24 certify someone is competent? We can say that --

25 MR. FORD: I think the board certification

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1 pathway is the answer to that, if I understand the
2 question correctly. I mean, board certification, in
3 and of itself, implies rather explicitly that there is
4 an attestation of competency to the certifying board.

5 DR. NAG: Yes, this is Dr. Nag. Again,
6 previously the Commissioners were not ready to accept
7 that. They wanted board certification, plus a
8 preceptor statement of competency. And this has still
9 not been resolved until -- we are hoping that will be
10 resolved. But what we are saying is, that anyone who
11 is the trainer can only say that they gave them the
12 training, that this person has received the training,
13 but it's almost impossible to say that person is
14 competent, to certify on the competency, especially if
15 the person who gives the training is no longer there.

16 MR. FORD: I understand. I guess it just
17 put my concern to a fine point. The board
18 certification I think is the pathway that would assure
19 competency. And if you don't have board
20 certification, perhaps the Commission should question
21 whether or not the person should be an AU under a
22 license.

23 CHAIR MALMUD: Well, with all due respect
24 to all of us who are board certified, board
25 certification does not assure life-long competency.

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1 MR. FORD: Understood.

2 CHAIR MALMUD: I mean, the courts are
3 filled with settlement against "competent"
4 specialists.

5 MR. FORD: But that's definitely gets you
6 a long passed the potential incompetence, I guess, out
7 there. And there is a requirement for continuing
8 education along the way, as well, to maintain your
9 board --

10 CHAIR MALMUD: And I might add that the
11 continued education process does not assure
12 competency. The difficulty is with the word
13 "competency", and with, as Dr. Eggli eloquently
14 expressed earlier, the risk of liability on behalf of
15 someone who certifies competence on behalf of someone
16 else.

17 DR. EGGLE: Dr. Malmud, this is Doug
18 Eggli. I think that we are sort of reliving what
19 we've done before. I would like to propose that we
20 actually make a simple statement that we need to make
21 no comment on this particular item, because this item
22 is fully encompassed in motion two from the June 12-
23 13th meeting, and, therefore, no further action is
24 required on this point.

25 CHAIR MALMUD: This is Malmud. To which

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1 point are you referring, Dr. Eggli?

2 DR. EGGLI: This whole discussion of
3 preceptor not available, because I actually have this
4 text in front of me. Motion two fully encompasses
5 this whole issue, and we really need not to make any
6 further comment on it.

7 CHAIR MALMUD: And, therefore, are you
8 making a motion that there be no further comment on
9 the issue of --

10 DR. EGGLI: Yes. And let me propose that
11 we state that no comment is required on this issue
12 because its resolution is fully contained in motion
13 two from June 12-13, 2007.

14 CHAIR MALMUD: Thank you, Dr. Eggli. Is
15 there a second to that motion of Dr. Eggli's?

16 DR. NAG: This is Dr. Nag. I thought --
17 again, without the motion in front of me, I cannot
18 fully comment, but I thought the comment about the
19 board certification, about the --

20 DR. EGGLI: There is also comment in this
21 motion about alternative pathway, non-board certified
22 people.

23 DR. NAG: Okay. And does it make a
24 comment about what if the preceptor is not available?

25 DR. EGGLI: What it says -- well, it says

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1 that the -- I don't know if it says preceptor not
2 available, but it pretty closely covers it.

3 DR. NAG: No, no, but -- this is Dr. Nag.
4 You know, what I have been trying to tell all along
5 today is that we have discussed about board certified
6 individuals. We have discussed about non-board
7 certified individuals getting a preceptor. The only
8 thing we needed to hone down today was if the non-
9 board certified does not have the preceptor, but that
10 preceptor is not available to certify, and we should
11 restrict it only to that group. And we seem to be
12 going out of that focus. So I think we have
13 adequately resolved all the other parts of it. It's
14 only for the small group that we haven't adequately
15 covered, and that was the reason for making my motion
16 a few minutes ago. And we should resolve that motion
17 and go on to the next topic of the seven year recency
18 of training.

19 CHAIR MALMUD: All right. So, Dr. Nag,
20 your motion relates only to those who are not board
21 certified, and for whom the preceptor is not available
22 for a statement. Is that correct?

23 DR. NAG: Right.

24 CHAIR MALMUD: And what is your motion on
25 behalf of those individuals who are not board

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1 certified, for whom a preceptor is not available?

2 DR. NAG: And that motion was that the
3 preceptors who are there now, I mean, whoever is the
4 -- let me see. The supervisor or the administrative
5 person who is in that position certifies to (a) that
6 the training was given, and (b), that that person
7 satisfactorily completed that training.

8 CHAIR MALMUD: That is your motion.

9 DR. NAG: Right.

10 CHAIR MALMUD: Is there a second to Dr.
11 Nag's motion?

12 DR. WILLIAMSON: Second.

13 CHAIR MALMUD: Who seconded, please?

14 DR. WILLIAMSON: Jeff Williamson.

15 CHAIR MALMUD: Thank you, Dr. Williamson.
16 Any further discussion of Dr. Nag's motion?

17 DR. WILLIAMSON: Well, I'm not sure what
18 exact -- I'm not sure that this is wise, because what
19 it's doing is redefining the concept of what it means
20 to be a preceptor for one small group of people, while
21 holding all the other groups of people that have a
22 preceptor to a higher standard. So it seems to me if
23 we're going to drop the concept of testifying to the
24 competency of somebody to independently practice from
25 one subgroup, we should drop it from all.

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1 DR. NAG: No, but -- Dr. Nag. Now for the
2 other subgroup, the ones who are board certified, we
3 don't need that preceptor statement at all, so it
4 doesn't apply any more.

5 DR. WILLIAMSON: Well, what about the
6 subgroup that is not board certified, and has
7 available a preceptor.

8 DR. NAG: If they have it, available a
9 preceptor, then that preceptor should be able to
10 certify that they have given the training.

11 DR. WILLIAMSON: What if they don't --
12 what if they see that this other group, because
13 they're dead, gets -- escapes this liability, and
14 refuse to sign it?

15 CHAIR MALMUD: Well, I think that that's
16 unlikely, Jeff, that somebody would refuse to sign
17 something under those circumstances. That's kind of
18 a willful act.

19 DR. WILLIAMSON: Well, I wonder if we
20 think that it's adequate health and safety for the
21 preceptor to sign off on the satisfactory completion
22 of treatment for one subgroup. Why can't we make
23 that the rule for all subgroups still requiring a
24 preceptor statement? I would agree with that. I
25 think that would be a good idea.

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1 CHAIR MALMUD: Dr. Williamson, you're
2 looking for consistency in a set of regulations which
3 have not been consistent in the past, and are unlikely
4 to be so in the future. I appreciate the spirit of
5 your statement, but it might be best if we simply
6 dealt with this small group, resolve it and moved on.

7 DR. WILLIAMSON: Okay. I stated my
8 opinion.

9 CHAIR MALMUD: And I think -- I personally
10 see the merit in your statement. I understand the
11 motivation for it, and we've discussed it many times,
12 and we all have a sense of frustration about certain
13 inconsistencies. However, Dr. Nag does point out that
14 we can deal with this one group and move on, and it
15 might be helpful if we could do that. You did second
16 the motion, by the way.

17 DR. WILLIAMSON: I did, so that it could
18 be discussed. I couldn't comment on it without
19 seconding.

20 CHAIR MALMUD: The motion has been moved
21 and seconded. If there's no further discussion, all
22 in favor?

23 DR. THOMADSEN: I'm sorry, this is
24 Thomadsen. Could you just please re-read the motion?

25 CHAIR MALMUD: The motion is that for

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1 those who are not covered by board certification, but
2 who are not board certified, and who are not able to
3 access their preceptors because of departure of the
4 preceptor for one reason or another, that they should
5 be able to obtain a preceptor statement, a current
6 preceptor statement from someone else, and that would
7 be adequate to get them authorized user status.

8 DR. WILLIAMSON: Wait a minute. I think
9 that the point of Dr. Nag's statement was that this
10 replacement preceptor would only have to testify --
11 only have to verify the satisfactory completion of
12 training. I think that was --

13 CHAIR MALMUD: That's correct.

14 DR. EGGLI: This is Doug Eggli. That's
15 exactly the recommendation we made for everybody in
16 motion two the last time; that individuals seeking
17 authorization under the pathway, the rewritten
18 attestation, would not include the word "competency",
19 but would, instead, read "has met the minimum training
20 and experience requirements." I mean, essentially, I
21 come back to the thing that I think this does cover
22 this subgroup.

23 DR. WILLIAMSON: Well, I would agree. I
24 think we've already dealt with it, so I think we
25 should just move on.

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1 CHAIR MALMUD: Well, we all are in
2 agreement it appears. Can we vote for agreement?
3 There's a motion on the floor.

4 DR. NAG: This is Dr. Nag. I mean --

5 DR. WILLIAMSON: Let's vote on it.

6 DR. NAG: -- this will be consistent now.
7 Then we have --

8 CHAIR MALMUD: Yes.

9 DR. NAG: -- one for the group who are not
10 board certified. It is consistent, so we should be
11 able to vote right now, and go on to the next, number
12 two.

13 CHAIR MALMUD: Shall we call the motion?

14 DR. WILLIAMSON: Yes.

15 CHAIR MALMUD: All in favor? Any opposed?
16 Any abstentions?

17 (Vote taken.)

18 CHAIR MALMUD: It's unanimous. May we
19 move on to the next item, which is the seven --

20 DR. WILLIAMSON: I abstained.

21 CHAIR MALMUD: Williamson seconded it, but
22 abstained.

23 DR. NAG: This is Dr. Nag. When we move
24 on, can we know what is the total time we have, how
25 much time we should spend on number two, and number

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1 three, so that we finish. Otherwise, we'll have to go
2 into our next meeting, and how much time do we have?

3 CHAIR MALMUD: Dr. Nag, we have 30 minutes
4 remaining.

5 DR. NAG: So 15 minutes for each?

6 CHAIR MALMUD: That sounds fair.

7 PARTICIPANT: Total.

8 CHAIR MALMUD: Someone said total.

9 PARTICIPANT: It's 2:30.

10 CHAIR MALMUD: It's 2:30, and we have
11 until 3:00. Am I correct?

12 MS. WASTLER: That's correct.

13 CHAIR MALMUD: I said 30 minutes.

14 DR. NAG: So 15 minutes for number two,
15 and 15 minutes for number three.

16 CHAIR MALMUD: That's correct.

17 DR. NAG: So when we discuss, we should
18 keep that in mind so we don't stray out of our focus.

19 CHAIR MALMUD: Let's begin the discussion.
20 The seven year recency of training. Who wishes to
21 attack that? Would someone first define the problem?

22 DR. WILLIAMSON: I'll try and take a stab
23 at it. This is Jeff Williamson. I believe that the
24 regulations, as written, are not clear what form, what
25 constitutes acceptable remedial training, or

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1 supplementary training for an individual who has
2 completed all of the training requirements more than
3 7 years ago, be it board certification, residency, or
4 whatever. And that the problem before us is to come
5 up with a clarification of what's required.

6 DR. NAG: And this is Dr. Nag. In
7 addition to what Dr. Williamson said, I think it's
8 not only that it's more than 7 years, plus has not
9 been in that field for more than 7 years, because I
10 could have been -- I am board certified more than 7
11 years ago, but I'm in the field even now, so that's
12 not a problem for me. But if I left the field, and I
13 was doing only research for the last 7 years, then I
14 came back, then it would be a problem.

15 DR. WILLIAMSON: Well, that's right. That
16 has not been practicing radiation, that radiation
17 medicine modality for 7 years. That's correct.

18 MR. LIETO: Dr. Malmud?

19 CHAIR MALMUD: Yes. Who's speaking?

20 MR. LIETO: This is Ralph Lieto.

21 CHAIR MALMUD: Yes, Ralph.

22 MR. LIETO: I would like to have staff
23 read what this issue is, because I thought it was a
24 little bit different from what my two colleague
25 members are identifying. I thought it related to

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1 where an individual had maybe been not named on a
2 license, such as a broad scope license, or something
3 of that nature, and but had been practicing for more
4 than 7 years, because there are such individuals out
5 there that are not on licenses, but have been
6 practicing either under supervision, and/or other
7 circumstances where they weren't named on a specific
8 license.

9 DR. WILLIAMSON: Well, I think it fits
10 under what we said. So an example might be a
11 radiation oncologist has worked for 7 years in a
12 center that has only electronic teletherapy sources.
13 And now wishes to -- moves to a place where he, among
14 other things, has to practice Cobalt-60 teletherapy.
15 How is it that the person is going to be, with minimum
16 hassle, acquire authorized user privileges to practice
17 Cobalt-60 teletherapy, not having been named on a
18 license for 7 years, not having practiced Cobalt-60
19 teletherapy, but having performed very closely related
20 and similar mega voltage beam linac-based therapy.

21 CHAIR MALMUD: Is that the issue?

22 DR. WILLIAMSON: That's one issue. The
23 other issue was a competent radiation oncologist or
24 competent authorized medical physicist works in a
25 practice where they acquire an gamma stereotactic

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1 unit. What training and experience do both the
2 radiation oncologist and authorized medical physicist
3 need in order to become authorized personages for that
4 new modality, which neither of them have had direct
5 experience practicing before?

6 CHAIR MALMUD: I would ask a question, Dr.
7 Williamson. Do you wish to be that prescriptive?
8 This is Malmud asking.

9 DR. WILLIAMSON: The question is what --

10 CHAIR MALMUD: For example, right now --

11 DR. WILLIAMSON: What would I, for
12 example, have to do, who have been now, for example,
13 suppose I continue my administrative path in life, and
14 I don't practice HDR brachytherapy for more than 7
15 years, what exactly must -- what is it I must do in
16 order to reinstate my practice credentials?

17 CHAIR MALMUD: And my question of you was,
18 do you wish the NRC to be that prescriptive?

19 DR. WILLIAMSON: I wish them to be -- have
20 reasonable criteria, yes.

21 DR. NAG: This is Dr. Nag. It's not
22 whether we wish it or not, but the NRC has a
23 requirement that the -- whenever you are submitting
24 for a license, it has -- the training has to be within
25 the last 7 years. So if it was not within the last 7

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1 years, and you haven't been practicing in the last 7
2 years, what do you need to do? So it is an NRC
3 requirement that we have to meet, but how do we meet
4 that?

5 DR. WILLIAMSON: For example, if I were a
6 physician, would I have to go back to medical school,
7 would I have to repeat my residency? What would I
8 have to do? Would it suffice to take the vendor's
9 training course? What -- I think some reasonable --
10 some guarantee of reasonable set of criteria that
11 would proximate the kind of self-guidance and mentored
12 study that I would have to do in order to prepare
13 myself to reintegrate with the modality I haven't
14 practiced for a while, or one that was a slight
15 variation of what I had been practicing.

16 DR. NAG: This is Dr. Nag. May I ask a
17 question from Dr. Howe?

18 CHAIR MALMUD: Please go ahead, if Dr.
19 Howe is available.

20 DR. HOWE: I am.

21 DR. NAG: Howe, are you there?

22 DR. HOWE: I am here.

23 DR. NAG: Okay. I'm going to give you a
24 not hypothetical, let's say someone who did training
25 10 years ago, had the full training, was fully board

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1 certified, practiced for two or three years, and did
2 HDR and brachytherapy, and everything, and then went
3 to a different center that did not do brachytherapy
4 for the last 7 years. Now came back to a new center,
5 where he is going to start brachytherapy again, so he
6 wants to be on the license. So he's board certified,
7 he had all the training, has not practiced that
8 particular modality for 7 years, and now wants to get
9 back. Right now do we need for that individual? In
10 that case if that was me, what would I have to do?

11 DR. HOWE: Dr. Nag, we handle these cases
12 on a case-by-case basis, and we look for relevant
13 continuing education, and continuing experience. And
14 so you may submit an application today that does not
15 indicate that you have continuing experience with it,
16 but as Roberto indicated from Region Four, we may
17 instruct you to come back at some later date, which we
18 don't specify, because it could be -- it's generally
19 not days, and it may not be a few weeks, but generally
20 within a few months, you come back and you say I have
21 now been using this device at this facility under the
22 supervision of this authorized user, and then that
23 authorized user gives us a statement about your
24 ability to handle the device, and essentially a
25 preceptor statement --

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1 DR. NAG: This is Dr. Nag. So under those
2 circumstances, may I put out something for discussion;
3 and that is, if a person has been adequately trained
4 in that modality but has not been using that modality
5 for the last 7 years or more, that person be required
6 to submit a preceptor statement which will certify
7 that the person is, I won't use the word "competent",
8 but the person has now received the required training
9 to adequately use that modality. Would something like
10 that be satisfactory? Because this person was already
11 well-trained, but now because he has not used that
12 modality for 7 years, requires some type of a letter
13 or certification that that person has now shown that
14 he can use that modality again.

15 DR. HOWE: Dr. Nag, we have found in the
16 past that people have been willing to make the
17 statement, and then when they provide the experience
18 that they're talking about, the basis for the
19 statement, that the individual spent two weeks
20 observing MRI, CT scans, ultrasound, everything but
21 nuclear medicine. So we generally ask for a little
22 bit more than just a statement, because we do want to
23 make sure the person was exposed to things that we
24 regulate. But the other point is that when we get
25 these cases, in many cases we bring them to the ACMUI

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1 for their evaluation, because we do consider the ACMUI
2 to be an important resource for us in determining the
3 adequacy of training and experience for cases that are
4 outside the norm.

5 DR. NAG: Well, this is Dr. Nag. That was
6 my reason for making the statement that they now have
7 the experience in that modality, so if I want a
8 license now for HDR, I cannot give you a statement
9 that we observed CT scan, or we observed something
10 else. I have to have a statement, or I have to have
11 a preceptor who would be ready to sign off that this
12 person has witnessed me, and has trained me in the use
13 of HDR, whether it be a company representative, or it
14 be an authorized user at the new institution.

15 MS. WASTLER: Well, Dr. Nag, it seems like
16 this approach is actually less flexible than the
17 approach that we try to put forward right now. This
18 is Sandra Wastler.

19 DR. NAG: Okay. What you are putting
20 forward -- what I'm trying to do is --

21 mS. WASTLER: What's currently in the
22 regulations.

23 DR. NAG: -- to put forward into a broad
24 statement so that we don't have to bring each and
25 every one of this to the ACMUI.

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1 CHAIR MALMUD: If I may, this is Dr.
2 Malmud.

3 MS. WASTLER: There's not that many of
4 them, though.

5 CHAIR MALMUD: That was Sandra Wastler.

6 MS. WASTLER: Yes, I'm sorry.

7 CHAIR MALMUD: If I may, it's been my
8 observation, as well as my experience, that the NRC
9 has been more flexible than the ACMUI in reviewing
10 credentials, and that if there is a feeling that the
11 individual's experience in one way or another
12 satisfies the regulations, that person is granted the
13 privilege requested. I have observed that the ACMUI on
14 a positive recommendation from the NRC has rejected an
15 individual. I think you were on the committee then.

16 DR. NAG: Yes.

17 CHAIR MALMUD: In which the NRC staff was
18 more flexible. And in the interest of the bottom
19 line, which was delivering patient care competently,
20 so my feeling is that it isn't broken. I wouldn't try
21 and fix it. And I'm not aware of situations in which
22 there has been inflexibility regarding that issue.

23 DR. NAG: Dr. Nag. In that case, my
24 statement would be that regarding Item 2, the ACMUI
25 already adequately addresses this issue, and no

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1 further discussion is needed.

2 CHAIR MALMUD: Is there someone who would
3 be willing to second Dr. Nag's observation?

4 MS. SCHWARZ: I would second Dr. Nag's
5 motion, Sally Schwarz.

6 CHAIR MALMUD: Thank you. I've made my
7 statement, which would also second it, but I'm not
8 seconding it as Chair. Are all in favor of just
9 moving this forward as it is?

10 MR. LIETO: This is Ralph Lieto.

11 CHAIR MALMUD: Yes, Ralph?

12 MR. LIETO: Is the motion basically then
13 to leave things as is, and that issues brought to the
14 regions regarding recentness of training will be
15 referred to the ACMUI?

16 CHAIR MALMUD: It will be referred to the
17 ACMUI only when there is disagreement at the level of
18 the region.

19 MS. GILLEY: Debbie Gilley. May I speak?

20 CHAIR MALMUD: Yes.

21 MS. GILLEY: What are we going to do about
22 the agreement states?

23 CHAIR MALMUD: Same thing for the
24 agreement states, I would assume.

25 MS. GILLEY: There's no requirement for us

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1 to bring issues before the ACMUI, that is part of
2 compatibility.

3 CHAIR MALMUD: I don't think it's a
4 requirement.

5 MS. WASTLER: Debbie, this is Sandra
6 Wastler. I think the agreement states would have to
7 have some kind of internal process similar to what we
8 would be doing to make those kind of decisions.

9 MS. GILLEY: Okay.

10 MR. FORD: Could I make a comment, Mr.
11 Chairman?

12 CHAIR MALMUD: Yes. Who's speaking,
13 please?

14 MR. FORD: This is Mike Ford with the
15 Texas Radiation Advisory Board.

16 CHAIR MALMUD: Yes.

17 MR. FORD: The State of Texas that I do
18 not represent, although I do represent the Advisory
19 Board, whose current regulations are not compliant
20 with the new 10 CFR 35, does have a process that
21 brings forth those special cases in front of the
22 Medical Committee of the Texas Radiation Advisory
23 Board, which has board certified physicians in those
24 medical specialities that do evaluate those cases on
25 a case-by-case basis. And in the last five years,

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1 there's been about two that have been evaluated by the
2 board.

3 CHAIR MALMUD: Thank you. So you're in
4 agreement with leaving things as they are.

5 MR. FORD: There needs to be an
6 alternative process in those special cases, there
7 needs to be a process that avails itself, but you
8 can't write a regulation that's going to cover
9 everything. I do agree.

10 CHAIR MALMUD: Thank you. Then we will
11 agree that for both the regions and for the states,
12 that they will deal with it internally. If there's
13 agreement, there's no need to take it any further. If
14 there's disagreement, it can be brought on a case-by-
15 case basis to the ACMUI or NRC, but it's on an
16 elective case-by-case basis. It's worked in the past,
17 and there's been -- I know that some of you have
18 difficulty accepting this, but there's been greater
19 flexibility within the NRC than there has within the
20 ACMUI. Some said --

21 MR. LIETO: This is Ralph Lieto.

22 CHAIR MALMUD: Yes, Ralph.

23 MR. LIETO: I don't know if I agree with
24 the Chairman's statement about the flexibility of the
25 NRC being greater than that of the ACMUI. I think one

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1 instance, does that reflect what goes on at the
2 regional level regarding this issue. But I would
3 accept that as long as this is communicated to the
4 regions, that where -- that the licensee can disagree
5 with the region's assessment, and refer this to the
6 ACMUI, I agree that probably the number of cases are
7 going to be quite small, and I think it would fit into
8 the charge of the ACMUI.

9 DR. WILLIAMSON: I would add - this is
10 Jeff Williamson. Provided that the various internal
11 mechanisms in NRC and in the agreement states are
12 similar to those of the rigor employed by healthcare
13 providers, themselves, then I think that -- if I could
14 summarize the discussion, the NRC and the Texas
15 Advisory Board is making the case that those are the
16 -- they try to uphold reasonable criteria that are
17 essentially reflecting current practice patterns in
18 the community.

19 CHAIR MALMUD: Thank you, Dr. Williamson.

20 DR. WILLIAMSON: I think with that, I do
21 think that we can't say ACMUI, because there exists no
22 ACMUI in many of the agreement states. So I think we
23 have to make some specification of what this internal
24 process is like.

25 CHAIR MALMUD: Okay.

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1 MS. WASTLER: I would point out, Dr.
2 William - this is Sandra Wastler - that these
3 regulations or any guidance documents that you as
4 ACMUI would impact reflect back to the NRC licensees.
5 And then when the states implement Part 35, they will
6 implement it and develop processes, and they have the
7 ability to look at and use similar processes to what
8 we have in our guidance documents. It's available to
9 them.

10 DR. WILLIAMSON: And just a comment for
11 our Chairman, I think what you are thinking, in my
12 experience as examples of rigidity by the Committee,
13 there have been times where the ACMUI has not agreed
14 that, for example, basic educational credential
15 criteria could be relaxed, such as not having a
16 graduate degree, and so forth. So there have been
17 such instances, but I am not aware of an instance
18 where we disagreed over the 7-year rule.

19 CHAIR MALMUD: You are correct. That
20 being the case, and we have finished the discussion
21 within 20 minutes, that leaves 10 minutes for the last
22 item, which is the increased complexity versus
23 additional benefit. Would some care to restate that
24 issue as a problem, or as an opportunity? Anyone on
25 staff wish to state it?

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1 DR. NAG: This is Dr. Nag. I'm not even
2 clear what that meant. I mean, is it increased
3 complexity of the procedure, or increased complexity
4 of the rule making or what? I'm not at all clear.

5 MS. TULL: This is Ashley. I believe it
6 was of the regulations.

7 CHAIR MALMUD: I'm sorry. Who was
8 speaking?

9 MS. TULL: This is Ashley. It was the
10 increased complexity of the regulations for the new
11 Part 35.

12 DR. WILLIAMSON: This is Jeff Williamson.
13 I think I can recall what the issue was, is that over
14 the past several years, we have taken what was a
15 relatively straightforward recommendation, or
16 straightforward set of rules, if you were board
17 certified in these areas by these certifying bodies,
18 you automatically could be an authorized personage,
19 period, plus/minus the recency of training rule, which
20 was always there. If you didn't have board
21 certification, here is the pathway you had to follow.
22 These were hardwired into the regulation. We did not
23 have all of these discussions about what constitutes
24 a preceptor statement.

25 Now we have a far more complicated set of

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1 rules requiring basically certification boards to be
2 certified by the Commission, the certification
3 processes have become far more complex, and now have
4 numerous divisions within them as to what constitutes
5 an AU-worthy certification versus not. And so the
6 question is, have we increased public health and
7 safety one bit by all of this additional cost and
8 complexity to the regulation?

9 CHAIR MALMUD: That's a philosophical
10 question?

11 DR. WILLIAMSON: It's not a philosophical
12 question. I think the question to the Commission, and
13 to their staff, have we spent tax payer dollars wisely
14 on this whole business? Have we -- all this process
15 of going through several revisions of the rule, have
16 we improved access to health care, have we improved
17 patient safety? I think it is worth bringing up.
18 It's more than a philosophical question.

19 CHAIR MALMUD: Do you have an opinion
20 regarding the issue?

21 DR. WILLIAMSON: I do. I think that it --
22 I don't wish to make it about nuclear medicine,
23 because I think there were some other issues there,
24 but I would say that in radiation therapy, and in
25 medical physics, while there have been on the whole

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1 some improvements, especially I think recognizing the
2 more diverse and global role that the medical
3 physicist does play in radiation medicine, we have
4 overall not gained anything in terms of health and
5 safety with these more complicated regulations, which
6 do seem to pose a risk to some groups of practitioners
7 in terms of making it difficult for them to continue
8 to practice, or possibly even excluding them from
9 practice in some situations. I do not think in
10 balance it's been a good thing.

11 MS. LANGHORST: Dr. Malmud, this is Sue
12 Langhorst. May I speak?

13 CHAIR MALMUD: Yes, please do.

14 MS. LANGHORST: Okay. My opinion is it's
15 added no health and safety benefit, for instance, for
16 radiation safety officers. If you're certified by the
17 American Board of Health Physics, that certification
18 exam did not change one bit in order to be approved by
19 the NRC, and yet people who were certified prior to
20 this date that got inserted into the regulations, even
21 though they passed the exact same exam, are not
22 considered to be RSO-eligible. And that is hurting a
23 lot of licensees who then can't get an RSO to cover
24 their license.

25 DR. NAG: This is Dr. Nag. If I may make

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1 a comment.

2 CHAIR MALMUD: Please do.

3 DR. NAG: Okay. My feeling is that the
4 increased complexity instead of bringing additional
5 benefit is actually having less beneficial effect,
6 because of exclusion of category of people who can
7 provide the service for the patient. Number two, the
8 fact that the hospitals have very strict hospital
9 privilege covers very adequately the group of people
10 who can supply or who can give the service to the
11 patient. And, therefore, I think relaxing the rule
12 would probably be of more benefit to the public and
13 the patient at-large, rather than increasing the
14 complexity.

15 CHAIR MALMUD: I agree with both of you.

16 DR. THOMADSEN: This is Bruce Thomadsen.
17 Can I just ask a question?

18 CHAIR MALMUD: Yes. I just wanted to -- I
19 agree with both the observations. However, I seem to
20 recall that the reason for some of this was that there
21 was concern about freestanding units, in which there
22 was no hospital credentials committee to review the
23 credentials. Wasn't that the issue that was raised?

24 MS. WASTLER: Yes, I believe that is the
25 case.

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1 CHAIR MALMUD: Okay. Thank you. I just
2 wanted to clarify how that occurred. Dr. Thomadsen.

3 DR. THOMADSEN: Well, actually, you just
4 addressed, being new to the committee, I was not sure
5 what the problem was that this rule was set up to fix.

6 CHAIR MALMUD: As I recall, and my memory
7 may be incorrect, it was that there was concern about
8 freestanding radio therapy units, freestanding
9 radiology departments, small concessions dissociated
10 from the hospitals, and the concern regarding
11 radiation safety issues in those kinds of
12 organizations that were not part of the standard
13 credentialing process within a large medical facility.

14 DR. THOMADSEN: I have a feeling that
15 board certification did not provide adequate sorting
16 for these people?

17 CHAIR MALMUD: No. No. There was no
18 concern among ACMUI regarding board certification. We
19 were quite adamant in insisting that board
20 certification should be considered adequate training,
21 and that putting additional restrictions above board
22 certification was really treading upon the traditional
23 turf of the American Specialty Boards. And we were
24 very concerned about that, and we remain concerned
25 about that. And these things have happened not by a

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1 direct assault on the authority of the boards, but
2 through the backdoor, sometimes as an unintentional
3 consequence of a new regulation. Nevertheless,
4 troubling to all of us on the ACMUI. For example, for
5 those individuals who take the boards and don't pass
6 them, they have to fulfill the alternate pathway.
7 Well, if they have to fulfill the alternate pathway,
8 and 10 percent don't pass the boards, or 20 percent
9 depending upon whose database you use, but certainly
10 it's not less than 10, and no more than 20 percent who
11 don't pass the boards, must have fulfilled the
12 alternate pathway. Therefore, the boards must teach
13 to the alternate pathway. Therefore, as an unintended
14 consequence, the boards must comply with the NRC,
15 rather than the traditional role of the boards as
16 being relatively independent. And that's how that
17 arose, Dr. Thomadsen.

18 DR. THOMADSEN: Thank you.

19 DR. WILLIAMSON: Jeff Williamson. I think
20 I can agree with the second part of your statement,
21 Leon, but the earlier part, that the main reason the
22 training and experience requirements were revised
23 being the perceived deficiency of the freestanding
24 clinics, I don't think is quite correct. There was --
25 this process, I'll remind everyone, started more than

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1 a decade ago, I believe in - when was the Institute of
2 Medicine report on radiation regulations published?
3 I believe it was 1995 or '96.

4 CHAIR MALMUD: That's before my time. I
5 wasn't part of the committee then.

6 DR. WILLIAMSON: Yes. So the concern was,
7 actually, that the board certification mechanisms did
8 not adequately address the technical aspects of
9 radiation safety practice. And, therefore, these
10 requirements needed to be stiffened, so in the case of
11 low-risk modalities, the decision was made that
12 diagnostic imaging, for example, there would be
13 effectively no clinical requirements for clinical
14 competency, only technical requirements. This was
15 reflected by revisions in the policy on medical
16 practice, and intrusions therein, for starting with
17 300, and moving on in graded steps, 300, 400, and 600.
18 It was -- we came to the conclusion, and the NRC
19 agreed, that clinical and technical safety competence
20 could not be separated, so the regulations, the
21 training and experience requirements retained much of
22 the flavor of the old ones. However, it was felt that
23 the radiation safety component needed to be more
24 prescriptively defined than it had been. So that is,
25 I think how we moved into this era.

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1 Then there was -- basically, came to the
2 view that it was much more inconvenient for them to
3 have to amend the regulations periodically to de-
4 certify and certify new boards by hardwiring them into
5 the regulations; and, therefore, we are now -- they
6 put in place a set of criteria to accept board
7 certification mechanisms within the language of the
8 rule.

9 CHAIR MALMUD: Thank you, Dr. Williamson,
10 for that historical perspective, which corrects the
11 first half of my statement. I appreciate that. So
12 that's how we got to where we are. By the way,
13 speaking of where we are, it's 3:00. How do we feel
14 about this issue? Does it need to be discussed
15 further?

16 DR. WILLIAMSON: I think maybe there might
17 be consensus for a general motion that the current 10-
18 year odyssey of revising training and experience
19 regulations over and over again has not only not
20 improved health and safety in many practice areas, it
21 has diminished safety or possibly patient access to
22 health care.

23 MR. FORD: Mr. Chairman, I'd like to -
24 this is Mike Ford of the Texas Radiation Advisory
25 Board. I would like to wholeheartedly support Dr.

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1 Williamson's statement that he just made, and further
2 add, or summarize by saying that we view this on TRAB
3 as a very complex solution to a non-existent problem.
4 And we are very concerned. The reason we're one of,
5 I guess, the lone holdouts, or one of the few holdouts
6 in changing, in the State of Texas in changing this
7 regulation to conform to CFR 35 requirements, because
8 we feel like it is in the wrong direction, and we're
9 very concerned with the changes we're taking. People
10 have been board certified for 10, 15, 20 years and
11 saying that they're no longer qualified to be an AU on
12 a license, whereas, someone who can go through 15 to
13 17 weeks of training, and receive a preceptor
14 statement would be an AU qualified person without
15 board certification.

16 DR. NAG: This is Dr. Nag.

17 CHAIR MALMUD: Thank you.

18 DR. NAG: Dr. Nag. I agree with both the
19 previous speakers, except that I would say rather than
20 saying has reduced patient safety, I would say has not
21 increased patient safety, but has reduced access, or
22 has hampered access.

23 DR. WILLIAMSON: I'll accept that.

24 CHAIR MALMUD: Thank you. So there --

25 MR. LIETO: Dr. Malmud.

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1 CHAIR MALMUD: I'm sorry, someone else
2 wanted the floor. Who is that?

3 MR. LIETO: This is Ralph Lieto. I know
4 we're running out of time, and obviously, it sounds
5 like this issue is going to require further
6 discussion, because I think it really gets to the
7 whole underlying tone of Part 35 T&E. Do we wish to
8 make this an agenda item for the next meeting, which
9 will be our face-to-face meeting?

10 CHAIR MALMUD: We certainly can, if you
11 wish to.

12 DR. NAG: Again, this is Dr. Nag. We
13 probably don't even need to resolve it, but we can
14 just have a statement so that this would be there with
15 the Commissioners, saying that the ACMUI feels that
16 the answers or degree of reactivity of the T&E has not
17 increased patient safety, but has reduced patient -
18 access to patient care. I mean, just that one
19 statement is just enough for them to ruminate on this,
20 and I don't think it requires further discussion at
21 this point. We can always get --

22 DR. FISHER: This is Fisher.

23 CHAIR MALMUD: I'm sorry. Who is this?

24 DR. FISHER: Fisher.

25 CHAIR MALMUD: Yes?

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1 DR. FISHER: I would propose that given
2 the hour, we postpone this discussion. The motion
3 that is being suggested by Dr. Nag is quite far-
4 reaching, and I think it requires more discussion. I
5 move that we postpone this discussion until our next
6 meeting in Washington.

7 CHAIR MALMUD: Is there a second to your
8 motion?

9 MR. LIETO: This is Ralph Lieto. I
10 second.

11 DR. WILLIAMSON: I have a question.

12 CHAIR MALMUD: Dr. Williamson, you have a
13 question?

14 DR. WILLIAMSON: Yes, to the staff. When
15 do the responses, staff responses to these
16 recommendations need to be delivered up to the
17 Commission?

18 MS. WASTLER: We don't have strict due
19 date on that, sir.

20 DR. WILLIAMSON: Okay. I would --

21 mS. WASTLER: We do have the time, yes.

22 DR. WILLIAMSON: I would make the
23 suggestion that it would be politically prudent to
24 include this sort of statement to the Commissioners in
25 whatever document moves up to them, so I would be

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1 concerned about letting all of these specific
2 recommendations move up without this more general
3 criticism being contained in there, which I suspect
4 there may be a lot of broad support for within the
5 committee.

6 DR. METTER: This is Darlene Metter. I'm
7 sorry. Can I just make one more statement as a TRAB
8 person, regarding Dr. Nag's statement, that the
9 complexity of the process of becoming an authorized
10 user has decreased patient accessibility, do you have
11 documentation, evidence-based on that? Any data on
12 that, because I'm not totally aware of that.

13 CHAIR MALMUD: Dr. Nag, a question was
14 asked of you.

15 DR. NAG: Yes. Well, I mean, it's hard to
16 get documentation. People say now that are not
17 applying. Now if they're not applying, how do you
18 document how many are not applying? So it's very hard
19 to document that.

20 CHAIR MALMUD: Dr. Nag, I don't think that
21 was Dr. Metter's question. I think her question was,
22 are you aware of any patients that have had their care
23 interfered with by these problems? Am I correct?

24 DR. METTER: Well, yes. I'd like to know
25 any data, any objective data on any -- actually, a

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1 project or a survey that has actually documented the
2 basis of Dr. Nag's statement, because on evidence-
3 based medicine, I'd like to see the evidence for his
4 statement.

5 MS. WASTLER: Could you identify yourself
6 for the court reporter?

7 DR. METTER: Darlene Metter from TRAB.

8 MS. WASTLER: Thank you.

9 DR. WILLIAMSON: On the physics side, it
10 is difficult to document a causal connection between
11 the training and experience requirements, and the
12 availability of an adequate pool of physicists. The
13 fact that there is a serious shortage of experienced
14 practitioners in physics, I think is beyond doubt, and
15 there is good data supporting that.

16 CHAIR MALMUD: Yes. I think that we all
17 agree that that's so, but I recognize that Dr.
18 Metter's question does have validity, and that is that
19 I'm not aware of any patient who has been negatively
20 impacted by the complexity. I am aware of the
21 difficulties that it has caused for the professionals
22 involved.

23 DR. WILLIAMSON: Well, I can tell you that
24 in our community, in our practice we now have six
25 different clinics that we have to staff, and we have

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1 had to postpone patient HDR treatments because we do
2 not have enough individuals to go around to staff all
3 of these places, to be able to do treatments in a way
4 that is convenient for the various practitioners.

5 CHAIR MALMUD: And that shortage of
6 individuals is based upon the increased complexity of
7 the regulations?

8 DR. WILLIAMSON: Well, it's been very --
9 it's very difficult to get our practitioners on the
10 license, yes. Get our physicists on the license,
11 especially when -- so I would say yes, it has.

12 DR. METTER: May I say another comment?
13 Darlene Metter again from TRAB. You know, I know that
14 we have physicists, radiation safety officers, and
15 physicians, radiation oncologists, nuclear medicine
16 radiologists, I don't think you can put them all on
17 the same level of what you've just stated. I under the
18 physics of what you have said, but I think it's a
19 little different when you're actually dealing with the
20 actual true contact with patient care.

21 DR. WILLIAMSON: Well, the HDR treatments
22 cannot take place without the physical presence of an
23 authorized medical physicist. Are you aware of that?

24 CHAIR MALMUD: That's a question to you,
25 Dr. Metter.

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1 DR. METTER: Yes, I am.

2 MR. LIETO: This is Ralph Lieto. It's not
3 anecdotal, but I know of at least four cases where
4 licensees were not able to get individuals on the
5 license as physician RSOs, and as a result, they had
6 to restrict some of the activities that they were able
7 to do relating to pharmaceutical therapy. So if
8 you're asking for some peer reviewed literature or
9 article on it, I don't think anybody is going to put
10 something like that into the literature, but there
11 have been numerous personal and anecdotal cases
12 presented to both the ACMUI members, and other people
13 that are involved in this teleconference that know of
14 situations having occurred. So I can't -- I don't
15 think we need to go to this issue of not acting based
16 on the fact that there's not some documented, peer
17 reviewed study that's addressed it.

18 DR. WILLIAMSON: I think that taken all
19 that's been said, however, maybe we need to work on
20 crafting the statement more carefully, so that it is
21 less easy to attack by the staff and the committee.

22 CHAIR MALMUD: Yes, perhaps a more
23 temperate statement would prevail. And we can achieve
24 that at the next meeting, as we make this an agenda
25 item for the next meeting.

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1 It being 3:10, may I use the Chairman's
2 prerogative to bring this meeting to a close?

3 MS. WASTLER: Yes, you may, Dr. Malmud.
4 And for the NRC, I want to thank everybody for their
5 participation.

6 CHAIR MALMUD: I thank you all, the
7 members of the Committee, the members of the NRC
8 staff, and all of our guests for your participation in
9 what was a lengthy call, but a necessary one, and I
10 think a productive one. Thank you all very much.

11 (Whereupon, the proceedings went off the
12 record at 3:08:30 p.m.)

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