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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.

NRC STAFF PRESENT:

DONNA-BETH HOWE, Ph.D.

CINDY FLANNERY, ALT. DFO

MOHAMMAD SABA

ASHLEY TULL

SANDRA WASTLER, DFO

DUANE WHITE

CARLEEN SANDERS

RONALD ZELAC, Ph.D.

EDWARD LOHR

JAMES MONTGOMERY

JACKIE COOK

JASON RAZO

ROBERTO TORRES

ALSO PRESENT:

CHRIS GALLAGHER, ASNC

CYNTHIA SANDERS, GA

DARICE BAILEY, TX

DARLENE METTER, TRAB

DAVID WALTER, AL

DAWN EDGERTON, CBNC

DEAN BROGA, ABMP

DEBBIE GILLEY, FL/OAS/CRCPD

ALSO PRESENT:

GERALD WHITE, AAPM

GLORIA ROMANELLI, ACR

GONZALO PEREZ, CA

HENRY ROYAL, ABNM

HUGH CANNON, SNM

JEAN ST.GERMAIN, ABMP

JENNIFER CARLIN YOUNG, AACE

JENNIFER ELEE, LA/CRCPD

JENNIFER GRANGER, CA

KIM GILLAM, VA

LYNNE FAIROBENT, AAPM

MARION EADDY, NC

MELISSA CACIA, AACE

MELISSA MARTIN, ACR

MICHAEL FORD, TRAB

MICHELE BEAUVAIS, William Beaumont Hospitals

MIKE PETERS, SNM

MIKE STEVENS, FL

PHILLIP SCOTT, CA

RICHARD MARTIN, ASTRO

ROBERT DANSEREAU, NY

ROBERT YOUNG, TN

SALLY CHEEVER, Physics Consultants, Inc.

SANDOR ERDELYI, SIRTEX

ALSO PRESENT:

SHAWN SEELEY, ME

SUSAN LANGHORST, WUSTL

A G E N D A

P R O C E E D I N G S

(1:03:41 p.m.)

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Here.

MS. WASTLER: Dr. Jeffrey Williamson.

DR. WILLIAMSON: Here.

MS. WASTLER: Ms. Sally Schwarz.

MS. SCHWARZ: Here.

MS. WASTLER: Mr. Ralph Lieto.

MR. LIETO: Present.

MS. WASTLER: Dr. Subir Nag.

DR. NAG: Yes.

MS. WASTLER: Dr. William Van Decker.

DR. VAN DECKER: Present.

MS. WASTLER: Dr. Douglas Eggli.

DR. EGGLI: Present.

MS. WASTLER: Dr. Orhan Suleiman.

DR. SULEIMAN: Present.

MS. WASTLER: Dr. James Welsh.

DR. WELSH: Here.

MS. WASTLER: Dr. Darrell Fisher.

DR. FISHER: Present.

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

MR. SABA: Mohammad Saba.

MR. LOHR: Mr. Lohr.

MR. WHITE: Duane White.

MR. RAZO: Jason Razo.

MS. SANDERS: Carleen Sanders.

MS. WASTLER: Region Four.

MR. MONTGOMERY: Jim Montgomery.

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

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

MS. FLANNERY: Here.

MS. WASTLER: And our Oklahoma contingent?

MS. TULL: I'm here.

MS. WASTLER: That's Ashley Tull.

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

she calls your name.

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

MS. SANDERS: Present.

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

MS. BAILEY: Present.

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

MR. WALTER: Here.

MS. TULL: Dawn Edgerton with CBNC.

MS. EDGERTON: Here.

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

MS. GILLEY: Here.

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

MS. WASTLER: Yes, she did.

MS. TULL: Henry Royal with ABNM.

MR. ROYAL: Here.

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

MS. WASTLER: Yes, he did.

MS. TULL: Jean St. Germain, ABMP.

MS. ST. GERMAIN: Here.

MS. TULL: Jennifer Carlin Young, AACE.

MS. YOUNG: Here.

MS. TULL: Jennifer Elee with the State of Louisiana. Kim Gillam with the State of Virginia.

MS. GILLAM: Here.

MS. TULL: Lynne Fairobent, AAPM.

MS. FAIROBENT: Here.

MS. TULL: Marion Eaddy with the State of North Carolina.

MR. EADDY: Here.

MS. TULL: Melissa Cacia with AACE.

MS. CACIA: Here.

MS. TULL: Melissa Martin, ACR.

MS. MARTIN: Here.

MS. TULL: Michael Ford with the Texas Radiation Advisory Board.

MR. FORD: Present.

MS. TULL: Michele Beauvais with the William Beaumont Hospital.

MS. BEAUVAIS: Here.

MS. TULL: Thank you. Sorry if I mispronounced your last name.

MS. BEAUVAIS: It's okay.

MS. TULL: Mike Peters with SNM.

MR. PETERS: Here.

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

MR. STEVENS: Present.

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

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

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

MR. MARTIN: Here.

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

MR. DANSEREAU: Present.

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

MR. YOUNG: Present.

MS. TULL: Salli Cheever with Physics Consultants.

MS. CHEEVER: Here.

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

MS. LANGHORST: I'm here.

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

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

MS. TULL: Hi.

MS. ROMANELLI: Gloria Romanelli with ACR.

MS. TULL: Okay.

DR. ZELAC: Ronald Zelac, NRC staff.

MS. TULL: Hello, Ron.

DR. ZELAC: Hello.

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

MS. WASTLER: Yes, she is.

MS. TULL: Okay.

MS. WASTLER: She just came in.

MS. TULL: Thank you.

MS. WASTLER: All right. With that. Dr. Malmud, our Chairperson, will conduct today's meeting. Following a discussion of each of the agenda items, the Chair, at his option, may entertain comments or questions from members of the public who are participating today. I would remind you that this meeting is being transcribed, and ask that prior to speaking that you introduce yourselves.

Dr. Malmud, with that, I will turn the

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Is there a second to the motion?

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

DR. HOWE: Dr. Malmud?

CHAIR MALMUD: Yes.

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

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

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

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

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

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

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

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

DR. WILLIAMSON: What section is that?

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

DR. WILLIAMSON: Okay. Thank you.

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

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

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

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

MS. WASTLER: Okay.

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

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

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

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

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

CHAIR MALMUD: This is Malmud. Please do,

Dr. Williamson.

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

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

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

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

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

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

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

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

CHAIR MALMUD: Please do.

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

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

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

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

DR. EGGLI: This is Doug Eggli.

CHAIR MALMUD: Yes, Dr. Eggli.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Who is speaking, please?

DR. HOWE: This is Dr. Howe.

CHAIR MALMUD: Thank you.

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

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

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

CHAIR MALMUD: Please.

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

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

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

CHAIR MALMUD: Thank you. Is anyone aware

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

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

CHAIR MALMUD: To get a preceptor statement for --

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

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

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

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

CHAIR MALMUD: Please do.

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

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

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

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

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

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

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

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

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

DR. NAG: Oh, okay.

DR. HOWE: So having the certification

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

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

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

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

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

CHAIR MALMUD: Yes, thank you.

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

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

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

CHAIR MALMUD: Thank you for that clarification.

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

MS. TULL: Yes.

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

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

DR. WILLIAMSON: Thank you.

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

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

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

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

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

CHAIR MALMUD: Any further discussion of that motion?

MS. SCHWARZ: Yes.

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

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

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

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

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

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

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

because this has been addressed in the past.

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

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

MR. LIETO: Question, please?

CHAIR MALMUD: Mr. Lieto.

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

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

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

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

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

MR. LIETO: Thank you.

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

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

CHAIR MALMUD: Who was speaking then?

MS. SCHWARZ: Sally Schwarz.

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

DR. NAG: Jeff?

DR. WILLIAMSON: Yes.

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

DR. WILLIAMSON: Why don't you try?

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

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

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

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

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

DR. WELSH: Jim Welsh.

CHAIR MALMUD: Yes.

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

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

CHAIR MALMUD: I believe some -- hello.

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

DR. WILLIAMSON: No, you are correct, so

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

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

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

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

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

DR. NAG: Yes.

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

CHAIR MALMUD: Yes, please.

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

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

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

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

MS. SCHWARZ: Sally Schwarz, Dr. Malmud.

CHAIR MALMUD: Yes.

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

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

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

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

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

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

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

MS. FAIROBENT: Dr. Malmud, Lynne Fairobent.

CHAIR MALMUD: Yes?

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

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

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

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

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

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

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

people are not applying.

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

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

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

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

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

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

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

CHAIR MALMUD: We'll take both

populations.

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

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

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

CHAIR MALMUD: Twenty percent of what number?

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

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

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

CHAIR MALMUD: Is that within a year?

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

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

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

CHAIR MALMUD: Right.

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

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

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

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

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

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

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

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

CHAIR MALMUD: Yes, please.

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

CHAIR MALMUD: Do you currently have

anyone pending who has not been able to achieve that?

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

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

CHAIR MALMUD: Yes?

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

CHAIR MALMUD: Yes.

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

CHAIR MALMUD: Thank you. Now we have

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

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

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

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

CHAIR MALMUD: Yes?

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

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

DR. METTER: Yes. Darlene Metter from

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

CHAIR MALMUD: And --

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

CHAIR MALMUD: Yes?

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

CHAIR MALMUD: Yes.

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

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

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

MS. LANGHORST: Yes, this is Susan Langhorst.

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

MS. LANGHORST: You are correct. Thank you.

CHAIR MALMUD: Thank you.

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

CHAIR MALMUD: Yes. Would you identify your organization?

MS. MARTIN: ACR.

CHAIR MALMUD: Thank you.

MS. MARTIN: I think Lynne Fairobent

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: This is Malmud.

MS. TULL: Dr. Malmud, this is Ashley. Can I answer that?

CHAIR MALMUD: Please do, actually.

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

MS. WASTLER: Thank you.

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

MR. LIETO: No.

CHAIR MALMUD: Who said no?

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

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

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

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

CHAIR MALMUD: I was ask --

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

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

MR. LIETO: Yes.

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

MR. LIETO: Yes.

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

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

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

Right?

MR. LIETO: Correct.

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

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

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

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

required, period.

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

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

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

CHAIR MALMUD: Is there anyone who objects --

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

CHAIR MALMUD: Who is speaking, please?

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

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

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

CHAIR MALMUD: And completed the training.

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

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

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

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

program directors are not pleased with.

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

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

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

MR. FORD: I think the board certification

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

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

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

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

MR. FORD: Understood.

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

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

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

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

CHAIR MALMUD: This is Malmud. To which

point are you referring, Dr. Eggli?

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

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

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

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

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

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

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

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

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

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

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

DR. NAG: Right.

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

certified, for whom a preceptor is not available?

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

CHAIR MALMUD: That is your motion.

DR. NAG: Right.

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

DR. WILLIAMSON: Second.

CHAIR MALMUD: Who seconded, please?

DR. WILLIAMSON: Jeff Williamson.

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

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

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

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

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

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

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

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

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

DR. WILLIAMSON: Okay. I stated my opinion.

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

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

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

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

CHAIR MALMUD: The motion is that for

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

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

CHAIR MALMUD: That's correct.

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

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

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

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

DR. WILLIAMSON: Let's vote on it.

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

CHAIR MALMUD: Yes.

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

CHAIR MALMUD: Shall we call the motion?

DR. WILLIAMSON: Yes.

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

(Vote taken.)

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

DR. WILLIAMSON: I abstained.

CHAIR MALMUD: Williamson seconded it, but abstained.

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

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

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

DR. NAG: So 15 minutes for each?

CHAIR MALMUD: That sounds fair.

PARTICIPANT: Total.

CHAIR MALMUD: Someone said total.

PARTICIPANT: It's 2:30.

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

MS. WASTLER: That's correct.

CHAIR MALMUD: I said 30 minutes.

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

CHAIR MALMUD: That's correct.

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

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

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

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

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

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

MR. LIETO: Dr. Malmud?

CHAIR MALMUD: Yes. Who's speaking?

MR. LIETO: This is Ralph Lieto.

CHAIR MALMUD: Yes, Ralph.

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

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

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

CHAIR MALMUD: Is that the issue?

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

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

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

DR. WILLIAMSON: The question is what --

CHAIR MALMUD: For example, right now --

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

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

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

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

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

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

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

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

DR. HOWE: I am.

DR. NAG: Howe, are you there?

DR. HOWE: I am here.

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: That was Sandra Wastler.

MS. WASTLER: Yes, I'm sorry.

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

DR. NAG: Yes.

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

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

further discussion is needed.

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

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

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

MR. LIETO: This is Ralph Lieto.

CHAIR MALMUD: Yes, Ralph?

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

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

MS. GILLEY: Debbie Gilley. May I speak?

CHAIR MALMUD: Yes.

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

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

MS. GILLEY: There's no requirement for us

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

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

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

MS. GILLEY: Okay.

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

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

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

CHAIR MALMUD: Yes.

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

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

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

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

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

MR. LIETO: This is Ralph Lieto.

CHAIR MALMUD: Yes, Ralph.

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

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

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

CHAIR MALMUD: Thank you, Dr. Williamson.

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

CHAIR MALMUD: Okay.

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

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

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

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

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

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

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

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

Now we have a far more complicated set of

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

CHAIR MALMUD: That's a philosophical question?

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

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

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

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

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

CHAIR MALMUD: Yes, please do.

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

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

a comment.

CHAIR MALMUD: Please do.

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

CHAIR MALMUD: I agree with both of you.

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

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

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

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

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

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

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

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

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

DR. THOMADSEN: Thank you.

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

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

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

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

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

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

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

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

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

DR. NAG: This is Dr. Nag.

CHAIR MALMUD: Thank you.

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

DR. WILLIAMSON: I'll accept that.

CHAIR MALMUD: Thank you. So there --

MR. LIETO: Dr. Malmud.

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

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

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

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

DR. FISHER: This is Fisher.

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

DR. FISHER: Fisher.

CHAIR MALMUD: Yes?

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

CHAIR MALMUD: Is there a second to your motion?

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

DR. WILLIAMSON: I have a question.

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

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

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

DR. WILLIAMSON: Okay. I would --

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

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

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

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

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

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

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

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

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

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

DR. METTER: Darlene Metter from TRAB.

MS. WASTLER: Thank you.

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

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

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

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

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

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

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

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

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

DR. METTER: Yes, I am.

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

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

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

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

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

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

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