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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TUESDAY

MAY 23, 2006

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OPEN SESSION

TELECONFERENCE

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The meeting convened by teleconference at
3:18 p.m., EDT.

MEMBERS PRESENT:

- LEON S. MALMUD, M.D. ACMUI Chairman
- EDGAR BAILEY Member
- DOUGLAS F. EGGLI, M.D. Member
- RALPH P. LIETO Member
- SUBIR NAG, M.D. Member
- SALLY WAGNER SCHWARZ Member
- ROBERT E. SCHENTER, Ph.D Member
- WILLIAM VAN DECKER, M.D. Member
- RICHARD J. VETTER, Ph.D. Member
- JEFFREY F. WILLIAMSON, Ph.D. Member

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NRC STAFF:

THOMAS ESSIG, Designated Federal Official,

NMSS/IMNS/MSIB

CYNTHIA M. FLANNERY

NMSS/IMNS/MSIB

DONNA-BETH HOWE

NRC

ANGELA MacINTOSH

NMSS/IMNS/MSIB

MOHAMMAD SABA

NRC

C O N T E N T S

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P R O C E E D I N G S

(3:18 p.m.)

MR. ESSIG: Okay. Dr. Malmud, if I may, let me open the meeting with my --

DR. MALMUD: Please do.

MR. ESSIG: -- Designated Federal Official's opening comments.

As the Designated Federal Official for this meeting, I am pleased to welcome you to this publicly noticed conference call meeting of the ACMUI. My name is Thomas Essig. I am Branch Chief, the Material Safety Inspection Branch, and have been designated as the Federal Official for this Advisory Committee in accordance with 10 CFR, Part 7.11.

Present today as the alternate Designated Official is Cynthia Flannery, Team Leader for Medical Radiation Safety within the Material Safety and Inspection Branch.

This is an announced meeting of the Committee. It is 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 May 9th, 2006 edition of the Federal Register, 71 FR 26994.

The function of the Committee is to advise

1 the staff on issues and questions that arise on the
2 medical use of byproduct material. The Committee
3 provides counsel to the staff, but does not determine
4 or direct the actual decisions of the staff or the
5 Commission.

6 The NRC solicits the views of the
7 Committee and values them very much. I request that
8 whenever possible you try to establish a consensus on
9 the various issues that we will discuss during this
10 conference call, but I also value minority or
11 dissenting opinions. If you have such opinions,
12 please allow them to be read in the record.

13 As part of the preparation for this
14 meeting, I have reviewed the agenda for members and
15 employment interests based on the general nature of
16 the discussion that we're going to have today. I have
17 not identified any items which pose a conflict for the
18 members.

19 If, however, during the course of our
20 business other members determine that they have a
21 conflict of interest in matters before the Committee,
22 please state it for the record and recuse yourself
23 from that particular aspect of the discussion.

24 At this point I would like to perform a
25 roll call of members who may be participating today.

1 Dr. Malmud, Health Care Administrator.
2 DR. MALMUD: Yes, sir.
3 MR. ESSIG: And Committee Chair.
4 Dr. Douglas Eggli, nuclear medicine
5 physician.
6 DR. EGGLI: Present.
7 MR. ESSIG: Dr. David Diamond is not
8 present. Dr. Subir Nag, radiation oncologist.
9 DR. NAG: Yes.
10 MR. ESSIG: Dr. William Van Decker,
11 nuclear cardiologist.
12 DR. VAN DECKER: Yes.
13 MR. ESSIG: Ms. Sally Schwarz, nuclear
14 pharmacist.
15 DR. SCHWARZ: Yes.
16 MR. ESSIG: Dr. Richard Vetter, Radiation
17 Safety Officer.
18 DR. VETTER: Present.
19 MR. ESSIG: Dr. Jeffrey Williamson,
20 therapy physicist.
21 DR. WILLIAMSON: Present.
22 MR. ESSIG: Mr. Ralph Lieto, nuclear
23 medicine physicist.
24 MR. LIETO: Present.
25 MR. ESSIG: Mr. Edgar Bailey, State

1 Representative.

2 MR. BAILEY: Present.

3 MR. ESSIG: And Dr. Robert Schenter,
4 Patient Advocate Representative.

5 (No response.)

6 MR. ESSIG: And Dr. Schenter has not made
7 the call yet.

8 And Dr. Ohran Suleiman, Center for Drug
9 Evaluation and Research, USFDA.

10 (No response.)

11 MR. ESSIG: Dr. Suleiman was not able to
12 attend.

13 Dr. Leon Malmud, ACMUI Chairperson, will
14 conduct today's meeting with discussion of each agenda
15 item. The Chair, at his option, can entertain
16 comments or questions from members of the public who
17 are participating with us.

18 I will turn it over to you, Dr. Malmud.

19 DR. MALMUD: Thank you, Mr. Essig.

20 I notice that in the agenda it says
21 "Opening Remarks by Tom Essig." And you have 35
22 minutes for remarks.

23 MR. ESSIG: Yes, yes. And that was a
24 typo. It should have been five minutes.

25 DR. MALMUD: So it is 3:00 to 3:05.

1 MR. ESSIG: Yes, sir.

2 DR. MALMUD: And at 3:05 we begin the meat
3 of the meeting.

4 MR. ESSIG: Yes, and since we started the
5 meeting actually at 3:15, it is now 3:20, and it is
6 time to start the meeting, and Dr. Howe is poised at
7 the phone here ready to roll on 535.

8 DR. MALMUD: In that case I'll be happy to
9 open the session with the introduction of Dr. Donna-
10 Beth Howe of the NRC, who will present to the ACMUI
11 the potential changes to 10 CFR 35, which is an
12 unfinished item from the April '06 meeting, and you
13 should have with you the PowerPoint presentation from
14 that meeting.

15 Dr. Howe.

16 DR. HOWE: Yes, and we're going to be
17 starting on Slide No. 8 because we successfully got
18 through Slides 1 through 7.

19 I would like to reiterate that this is
20 potential changes to 10 CFR Part 35. The internal
21 procedures at NRC are for us to submit a memo to the
22 Regulatory Guidance Branch on changes we believe need
23 to be made to the regulations, and they are the ones
24 that will decide whether and when any changes are
25 made. So this is preliminary to any changes.

1 But I do need the ACMUI to approve or
2 disapprove or give me changes to things that I'm
3 proposing at this point.

4 So without any further ado, Item No. 8 or
5 Slide No. 8 is supervised work experience, and this is
6 to bring 10 CFR 35.190(a) and 290(a) into conformance
7 with the language in 10 CFR 35.390(a). And in 190 and
8 290, the text in the existing regulation says that you
9 must have training and experience to cover the topics
10 in the alternate pathway, and it has been interpreted
11 by some people that does not include the hours or the
12 requirement for the work experience to be under the
13 supervision of an authorized user.

14 And so the recommended change is in
15 conformance with what we have in 390(a), is the change
16 alter hours of training and experience to as described
17 in Paragraph C(1)(i) through C(1)(ii)(g), and so that
18 would include the introductory text at the beginning
19 of Paragraph (i).

20 Do you have any discussion?

21 DR. MALMUD: Is there any discussion?

22 MR. LIETO: This is Ralph Lieto. I'm
23 still not quite sure in reading this. What is it that
24 is not being covered? Because it seems like the
25 training and experience topics, the alternate pathway

1 are reference to those sections or am I off base here?

2 DR. HOWE: The interpretation is that the
3 topics are, indeed, included, but what is not being
4 included is that introductory text on C at the
5 beginning that says the supervised work experience.
6 "The work experience under the supervision of an
7 authorized user who meets the requirements in" and
8 then the appropriate section is not being picked up
9 because they're only picking up the topics, and the
10 topics would be that text that's in the capital
11 letters for 190 and then in 290, I believe it's also
12 in the capital letters.

13 DR. WILLIAMSON: This is Jeff Williamson.

14 I must confess I'm a little confused as
15 well. I'm looking at Paragraph 35.290 in the --

16 DR. HOWE: Yeah, let's focus on one of
17 them.

18 DR. WILLIAMSON: -- printed edition,
19 revised as of January 1st, 2006, to make sure I
20 understand what language is changed, and I'm not sure
21 where in the -- perhaps you could read the paragraph,
22 the full paragraph, and tell us exactly where the
23 insertion occurs. Maybe that would help. It would
24 help me.

25 DR. HOWE: Yes. In Paragraph A(1) of 290,

1 it says, "Complete 700 hours of training and
2 experience in basic nuclear handling techniques of
3 radiation safety applicable to the medical use of
4 unfilled byproduct material for," and we've revised
5 this to say, "imaging and localization studies that
6 includes the topics listed in Paragraph C(1)(i) and
7 C(1)(ii)."

8 And by saying C(1)(i) and C(1)(ii), that
9 when you read it, you skip right down to the topics,
10 and so you're not necessarily kicking in the
11 supervised work experience text that starts at the
12 beginning of C(1)(ii). It says only the topics.

13 DR. WILLIAMSON: All right. So the change
14 is not the 35.290(a) but 35.290(a)(1).

15 DR. HOWE: That's correct.

16 DR. WILLIAMSON: Okay. That's one.

17 DR. HOWE: Sorry.

18 DR. WILLIAMSON: The way I'm confused
19 here. So the motion isn't quite complete.

20 DR. HOWE: Okay. And so what I'm
21 recommending saying is that instead of saying the
22 training that includes instead of saying the topics,
23 I would say "as described in" and then I would start
24 the beginning of the description at C(1)(ii), and I
25 would conclude it at the bottom of C(2)(ii).

1 So I would go C(1)(ii) through
2 C(2)(ii)(g), and that leaves out how the hours are
3 split up in C(1) for the Board certification pathway,
4 but includes the work supervision under supervised
5 authorized user.

6 MR. LIETO: Dr. Malmud, this is Ralph
7 Lieto.

8 DR. MALMUD: Yes, Ralph.

9 MR. LIETO: You know, Jeff's direction
10 here has kind of helped out a little bit, but I think
11 that really this change would need to be tabled. I
12 would like to see this with the strikeouts and the
13 additions because from what I'm hearing, it's almost
14 like we're adding something here rather than
15 clarifying, and I'm really reluctant to have any
16 change in this rule that's going to potentially be
17 interpreted as an added requirement.

18 DR. HOWE: The intent was not to have it
19 be an added requirement, but just to bring in
20 conformance with the text in 390, which is clear that
21 you start at the beginning of a section and you end at
22 the end of the next one. So all of the text in
23 between is captured.

24 DR. WILLIAMSON: Somehow there are two
25 things you're changing. One is you're arguing that

1 the current text -- this is Jeff Williamson, by the
2 way -- states topics listed in Paragraph C(1)(i) and
3 C(1)(ii) of this section, you believe that it is not
4 clear that this includes all of the subsections in
5 C(1)(i) and C(1)(ii). So that's one problem.

6 And another problem is you are also
7 changing the phrase from "includes the topics listed
8 in Paragraph" so-and-so to "training and experience as
9 described in Paragraph."

10 So somehow it seems like we're making the
11 word "certification requirement" more prescriptive
12 now.

13 DR. HOWE: Okay. I can table this and
14 bring it back in a longer red line strikeout.

15 DR. WILLIAMSON: It is very subtle, I must
16 confess. I'm trying to --

17 DR. HOWE: If you look at --

18 DR. WILLIAMSON: -- understand what's
19 missing from the current text.

20 DR. HOWE: The attempt originally when
21 they revised the regulation for the board
22 certification was to make sure that the number of
23 hours required under the board certification route was
24 not split into specific hours for training and
25 experience as specific hours for work experience. So

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1 it was supposed to be a total number of hours, and you
2 could sort the hours out however was best for the
3 individual for the board certification route.

4 And then the alternate pathway, you had to
5 have specific hours and training and experience. And
6 so when they rewrote it, they used two different
7 approaches, one approach in 190 and 290, and then
8 another approach in 390.

9 And I believe the approach in 390 is much
10 clearer, and so that's why I was recommending that
11 this be revised to be in conformance with 390, but I
12 can table this if you want.

13 DR. WILLIAMSON: May I ask one last
14 question of clarification? So is the intent that
15 under the board certification route that 80 hours must
16 be classroom and laboratory and no more than 620 can
17 be practical training and experience, or is it
18 intended that this more prescriptive split as opposed
19 to just 700 hours total be implemented only for the
20 alternate pathway?

21 DR. HOWE: The split, let's say, on 290
22 between 80 hours for training and experience and the
23 rest of the hours in supervised work experience was
24 intended only for the alternate pathway. The board
25 certification route is supposed to be just a total of

1 700 hours.

2 And so there was a little bit of tricking
3 writing in how to get there.

4 DR. WILLIAMSON: I see, and I'm worried
5 that your phraseology make the board certification
6 have to divvy it up in prescriptive ways.

7 DR. HOWE: No, by starting it C(1)(ii),
8 you have skipped Paragraph 1.

9 Do we have some kind of phone call going
10 on?

11 DR. MALMUD: Is there someone else
12 engaging in another call?

13 DR. HOWE: Okay. When you look at the
14 text in 290, you'll see that Paragraph A(1) starts
15 with C(1)(ii).

16 DR. WILLIAMSON: I see.

17 DR. HOWE: By starting at C(1)(ii), you
18 have skipped the preliminary information in C(1).

19 DR. WILLIAMSON: I see.

20 DR. HOWE: And the preliminary information
21 in C(1) is what splits the hours. So the board
22 certification doesn't split the hours. It just has
23 total hours.

24 DR. WILLIAMSON: Okay. Makes sense.

25 DR. HOWE: And if you looked at the

1 wording in 390, you would see that the way it's
2 written in 390(a)(1), and it says as described in
3 Paragraph B(1)(i) through B(1)(ii)(e), you skip B(1)
4 which has the hours breakdown. You go directly to
5 B(1)(i), and then you continue all the way till you
6 get down to the clinical case work so that you've
7 included the text at the beginning of (ii) that says
8 "work experience under the supervision," and that
9 makes it very clear that this work supervision is
10 under an authorized user as opposed to just having to
11 cover the topics.

12 MR. BAILEY: Dr. Malmud.

13 DR. MALMUD: Yes, sir.

14 MR. BAILEY: This is Ed Bailey.

15 I'm going to have to drop off the line.

16 DR. MALMUD: Did you have a comment, Mr.
17 Bailey?

18 MR. BAILEY: Not on this issue. Okay?

19 DR. MALMUD: Thank you.

20 MR. ESSIG: And did someone else join
21 while in the last few minutes or so who hasn't been
22 recognized?

23 DR. SCHENTER: Bob Schenter.

24 I just joined.

25 MR. ESSIG: Okay. Thank you.

1 DR. MALMUD: Now, Dr. Williamson, this is
2 Malmud.

3 DR. WILLIAMSON: Yes.

4 DR. MALMUD: Dr. Williamson?

5 DR. WILLIAMSON: Yes.

6 DR. MALMUD: Did Dr. Howe's explanation
7 satisfy your concern?

8 DR. WILLIAMSON: For one part of the
9 change, yes. I think that it's changing it from
10 Paragraph C(1)(i) and Paragraph C(1)(ii) to Paragraph
11 C(1)(i) to C(1)(ii)(a) through (f) I agree is a
12 clarifying change. I see no harm in that.

13 DR. MALMUD: Thank you.

14 DR. VAN DECKER: Dr. Malmud.

15 DR. MALMUD: yes.

16 DR. VAN DECKER: This is Bill Van Decker.

17 DR. MALMUD: Yes, Bill.

18 DR. VAN DECKER: I have to say that when
19 I initially looked at this my belief had been that the
20 intention had been as has kind of been brought out by
21 the current verbiage that the goal here was to make
22 sure that the clinical training and experience part
23 was not wrapped into being a didactic experience and
24 that it was under the supervision of an authorized
25 user who was capable of doing that.

1 I think that that as a gestalt is probably
2 what we're looking for.

3 I would also agree with Mr. Lieto that as
4 the conversation has gone on and the rulemaking
5 language has gone, I'm starting to feel uncomfortable
6 about making sure we don't get unintended consequences
7 in this, and as such, I would probably prefer
8 personally to see this thing out in long hand with all
9 of the rulemaking language, although if what I've said
10 is the concept, I don't think that I'll have any
11 personal problems with it.

12 DR. EGGLI: This is Doug Eggli.

13 DR. MALMUD: Yes, Dr. Eggli.

14 DR. EGGLI: I actually have the printed
15 version in front of me since I printed it out and I am
16 looking at it, and I think Dr. Howe is, in fact,
17 accomplishing what she has set out to do, and I do not
18 believe with the printed copy in front of me that the
19 prescriptive piece of C(1) is included. It just
20 simply adds that it has to be under the supervision of
21 an authorized user.

22 So I believe that, in fact, the intent has
23 been accomplished.

24 DR. MALMUD: Thank you, Dr. Eggli.

25 Do we need a motion to approve this?

1 MS. FLANNERY: Yes.

2 DR. MALMUD: Is there a motion to approve
3 this?

4 DR. EGGLI: This is Eggli.

5 So approved or so moved, rather.

6 DR. MALMUD: Eggli makes the motion. Is
7 there a second?

8 DR. VETTER: Dick Vetter seconds it.

9 DR. MALMUD: Vetter seconds it.

10 Any further discussion?

11 DR. WILLIAMSON: Jeff Williamson here.

12 Now having understood one part of this
13 rulemaking proposal, I'm having difficulty
14 understanding why the language as written doesn't
15 obligate, you know, the board certification to having
16 training carried out under the supervision of an
17 authorized user because it basically says -- oh, I
18 see. You want to replace "includes the topics listed
19 in Paragraph C(1)(i)" with "as described in Paragraph
20 C(1)(i) through" whatever.

21 That is the major change; is that correct?

22 DR. HOWE: That's correct.

23 DR. WILLIAMSON: So you believe that
24 currently this makes a loophole in 290 where someone
25 could have the 700 or some board could come along and

1 700 hours of training and experience supervised by
2 short order cooks instead of authorized users, for
3 example, is theoretically possible.

4 MR. LIETO: This is Ralph Lieto.

5 Let me take a look from your side of the
6 fence here, you know, not being on the side with the
7 short order cook. What is being recommended would
8 preclude, say, radiation safety being done and
9 provided under a medical physicist or an RSO because
10 it says it has to all be done under an authorized
11 user.

12 So if someone went to someplace and had
13 didactic work done or even some type of a training
14 course where you're doing hands on work under the
15 auspices of a medical physicist for an hour or so,
16 that wouldn't be recognized the way the rewording
17 would occur.

18 DR. HOWE: Mr. Lieto, the intent is that
19 the work experience for everyone in 190, 290 or 390 be
20 under the supervision of an authorized user. That
21 doesn't necessarily mean that the authorized user has
22 to, you know, provide or be supervising directly all
23 of the work experience, but the work experience should
24 be under the authorized user.

25 We're not talking about the didactic

1 classroom training because that can be provided by
2 anyone.

3 DR. WILLIAMSON: Well, I think that to
4 answer -- this is Jeff Williamson -- to answer Ralph,
5 he raises a good point. What they're trying to
6 exclude is forget the short order cook, which was
7 intended to be amusing and not serious, but I guess
8 you could sort of imagine a nonclinical facility
9 staffed by physicists and radiopharmacists that would
10 do everything except prescribe and deliver treatments
11 to patients, but receive radionuclides and, you know,
12 do all of these tests and so on. That's what they're
13 trying to exclude.

14 They want this to occur in the context of
15 a clinical operation, I think. Is that the intention?

16 DR. HOWE: That's correct.

17 MR. LIETO: Well, I guess I still feel
18 that this should be tabled so that we can see it all
19 laid out in the language. I see feel uncomfortable
20 with approving a change without seeing how this
21 wording is exactly going to be fitted into the
22 proposed rulemaking.

23 DR. HOWE: Now, I would also remind you
24 that this is a potential. So we would send this as a
25 memo to the Rulemaking Branch, and so if they elevate

1 it to actual rulemaking, you will see this many times
2 before it becomes a proposed rule or a final rule.

3 So this is not your one and only
4 opportunity to comment on specific words.

5 MR. ESSIG: Yes, this is Tom Essig.

6 Just to remind us what we're discussing
7 here, as Dr. Howe just articulated, the process is
8 that my branch would send what we call a user need
9 request to the Rulemaking and Guidance Branch. They
10 would prioritize in the other rules that they have in
11 front of them. This may, depending on the basis that
12 we articulate, the safety basis, that will kind of
13 determine where we are to rank priority-wise.

14 If it's merely a clarification and doesn't
15 have a strong safety basis, it may be ranked in the
16 medium to low priority, and if it has a strong safety
17 basis, it could be elevated, but even then, it is
18 pitted against those rules that have already been
19 prioritized as having a high safety basis, and that
20 would probably impact the timing that the Rulemaking
21 and Guidance Branch would undertake it.

22 But as Dr. Howe noted, you will have
23 definitely, even if it gets through those wickets, you
24 will have many more bites at the apple.

25 PARTICIPANT: This is (unintelligible).

1 So let me ask you this. Is this going to
2 be sent out; after we approve this, is this going to
3 be sent out as being endorsed by the ACMUI or
4 recommended by the ACMUI?

5 DR. MALMUD: For those that we agree on,
6 yes. I mean, if the committee, as we did in the
7 meeting last month, we had the first seven items. I
8 believe we moved and passed on all of them.

9 MS. FLANNERY: A minor change to one.

10 MR. ESSIG: With minor changes, and we
11 just wanted to pick up where we left off, and that's
12 the purpose of today's call. So if there are changes
13 that the members wish to offer, modifications,
14 clarifications or just outright tabling of it,
15 certainly we'll be responsive to that.

16 DR. WILLIAMSON: This is Jeff Williamson.

17 I think with the discussion and the
18 combination of this nice, yellow/white book, Code of
19 Federal Regulations, I am able to agree with it. I
20 would offer a friendly amendment that we change the
21 slide to read "35.190(a)(1)" and "35.290(a)(1)" from
22 its current reading of 35.190(a) and 25.290(a).

23 DR. HOWE: That's okay.

24 DR. MALMUD: That's a motion from Dr.
25 Williamson.

1 DR. WILLIAMSON: It's a suggestion to
2 modification of the motion on the table, which is Dr.
3 Eggli's motion.

4 DR. EGGLI: Yeah, this is Eggli.

5 I accept the modification.

6 DR. MALMUD: All right. The motion has
7 been made. Is there a second to the modified motion?
8 Dr. Eggli?

9 DR. WILLIAMSON: I will second it.

10 DR. MALMUD: All right. Any further
11 discussion?

12 DR. EGGLI: This is Eggli again.

13 Again. to reassure the people who don't
14 have the printed copies in front of them, I also now
15 have a printed version of 390 in front of me, and the
16 language change that Dr. Howe is proposing is
17 completely consistent with the language as exists in
18 Part 390.

19 DR. MALMUD: All right. All in favor?

20 (Chorus of ayes.)

21 DR. MALMUD: Any opposed? I'm sorry.

22 MR. LIETO: Ralph Lieto, opposed.

23 DR. MALMUD: Ralph Lieto opposes. Any
24 other opposed?

25 (No response.)

1 DR. HOWE: Abstentions?

2 DR. MALMUD: Sally Schwarz abstains.

3 DR. SCHWARZ: No, I was for.

4 DR. MALMUD: I'm sorry.

5 DR. HOWE: I was just asking. I was just
6 asking if there were any abstentions because I hadn't
7 heard any.

8 DR. MALMUD: Oh, I'm sorry.

9 DR. HOWE: Sorry, Dr. Malmud.

10 DR. MALMUD: I apologize. All right. So
11 there's one who is not in agreement. No abstentions.
12 The motion carries. Thank you.

13 Dr. Howe.

14 DR. HOWE: Okay. Slide No. 9 is a problem
15 that has been identified to us, and we're bringing it
16 to the ACMUI to see if you think it's something that
17 we should pursue. It's not something that would
18 happen overnight, and that is we have been told that
19 it is and we also know that most facilities use unit
20 doses, and that very few facilities will elute
21 generators. Even broad scopes will use unit dosages,
22 and in 290, we require each authorized user to have
23 supervised work experience under a 200 authorized user
24 in eluting generators, and we are asking the ACMUI
25 whether it believes it would be a good idea or not to

1 explore the idea of possible two training and
2 experience pathways for 200 physicians, one for
3 physicians that can only administer unit dosages and
4 the other for physicians who are permitted to prepare
5 radioactive material.

6 So this is more of a concept type of thing
7 that we're asking you for versus specific rule
8 language.

9 DR. EGGLI: Mr. Chairman, this is Eggli.

10 DR. MALMUD: Dr. Eggli.

11 DR. EGGLI: We actually discussed this
12 topic at the last ACMUI meeting, and again, commercial
13 pharmacies are generally willing to help it in that
14 line and provide that generating elution experience.
15 I do not believe here is any real difficulty in
16 obtaining that particular experience.

17 DR. MALMUD: Are there other comments
18 besides that of Dr. Eggli?

19 DR. VETTER: This is Dick Vetter.

20 How would the NRC track these two
21 different means of training?

22 DR. HOWE: I think that would depend upon
23 how a rule language change came about. We might have
24 something that indicated that you had training
25 experience up to a certain point, and if you had up to

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1 that point which didn't include generator elution,
2 then we would authorize unit dosages only.

3 So I'm not sure how it would work out, and
4 so I did not provide specific rules, potential rule
5 text for it.

6 DR. VETTER: This is Dick Vetter again.

7 What I'm envisioning is a physician who
8 would train under the route where he or she received
9 permission or has the training for unit dosages, and
10 then one day moves to a facility where they have a
11 generator, and they're not using unit doses. As a
12 matter of fact, the physicians aren't going to be
13 administering anyway. It's the technologists who
14 administer the dose, but the physicians are the
15 authorized users. The technologists work under the
16 supervision of the authorized user.

17 So I envision that down the road a ways it
18 could get a little bit complicated.

19 DR. HOWE: It could.

20 DR. SCHWARZ: I'm Sally Schwarz.

21 I have a comment, a question also in
22 regard to this. If you eventually are establishing
23 two different physician authorizations, one that uses
24 unit doses and one that elutes generators, will you
25 then similarly change the requirements for training

1 for these physicians who are only going to be using
2 unit doses?

3 Because it seems that essentially what
4 you're saying that they most likely wouldn't be
5 preparing radiopharmaceuticals, which then it seems
6 like the amount of didactic training maybe could drop
7 down significantly for the group only using unit
8 dosages.

9 DR. HOWE: Those are the kinds of things
10 that would be discussed in detail if you decided that
11 it would be beneficial to go and explore this as a
12 rulemaking option. And how that would come out I
13 don't know at this point. It's just way too early.

14 It would also affect how we have
15 authorized, the authorizations we have in 35.100, 200
16 and 300 that allows physicians with 290 physicians to
17 prepare radioactive drugs. So there are a number of
18 interacting part that would have to be worked out,
19 length of training and experience, how we would
20 designate between the two, and then how it would
21 affect 100, 200 and 300 materials.

22 So there are a number of issues that would
23 be discussed if it went to rulemaking.

24 DR. WILLIAMSON: This is Jeff Williamson.

25 Could I ask a question, namely, because I

1 think the nuclear medicine experts in our group? This
2 seems like it's a lot of additional complexity to
3 create another two tracks within 35.200 and 300, and
4 does the experience eluting generators really
5 contribute materially to patient safety and quality
6 treatment or, you know, as an alternative to leaving
7 it alone?

8 Simply dropping it from the regulations,
9 would that substantially diminish or jeopardize public
10 safety?

11 DR. EGGLI: This is Eggli.

12 Let me speak to that issue if I might.
13 When we reviewed iodine incidence, two or three of
14 those errors were committed by central pharmacies, and
15 I think if the authorized user doesn't really have a
16 feel for what goes on in a central pharmacy, they're
17 less well prepared to catch the errors that are made
18 in a central pharmacy.

19 I would personally be reluctant to remove
20 that requirement, and again, I do not believe there is
21 a serious burden trying to achieve it.

22 DR. WILLIAMSON: I guess my question is:
23 does eluting a generator, which seems to me has
24 nothing to do with Iodine 131, which is the issues you
25 address, it has to do with technetium based agents; am

1 I not correct?

2 DR. EGGLI: We get wrong things out of our
3 central pharmacy all the time that we catch. I think
4 the comment is generally extendable to technetium
5 labeled radio pharmaceuticals as well.

6 DR. WILLIAMSON: So what does the rating
7 the generators have to do with learning the category
8 and modes of failure of a commercial pharmacist?
9 That's my question.

10 DR. MALMUD: That's your question, Doug,
11 to you from Dr. Williamson.

12 DR. EGGLI: Yeah, I know. I need to think
13 about that a little more. I guess I think that it's
14 in general a useful experience, and I would be
15 reluctant to remove it.

16 DR. WILLIAMSON: I think that my advice,
17 just my suggestion for you guys, for the nuclear
18 medicine part of our community, is this is a lot of
19 complexity for a very indirect way of getting at
20 something that, you know, I have no basis for
21 disagreeing with you on that it's important to
22 understand the failure modes upstream of product
23 cycles when you buy something.

24 But maybe it would be better to modify the
25 regulation in a more straightforward way that gets at

1 what your concern is that wouldn't be so complex and
2 clumsy as creating this very artificial two track
3 pathway.

4 Because even if you get unit doses, you
5 know,, it just seems very strange. That's all.

6 MR. LIETO: this is Ralph Lieto.

7 To answer Jeff's question, one thing that
8 needs to be understood is that everything that happens
9 in that department is under the auspices of the
10 authorized user and that includes all of the
11 formulation of kits that go on, the distribution, the
12 quality control and so forth.

13 And so they should have an appreciation
14 and a good basic understanding of what those
15 operations entail, and like Dr. Vetter indicated
16 earlier, you know, they may learn it, and if they were
17 not required to learn this and go into a setting where
18 you do have like a pharmacy operation and they are an
19 authorized user, they need to understand what types of
20 problems will arise from that. And so I would support
21 keeping it in there.

22 The other point I wanted to make is that
23 unless there is a specific request from a professional
24 society to change this, I think the NRC ought to just,
25 you know, run as far away from this as possible.

1 Leave things as they are because I think you're just
2 going to open up a hornet's nest trying to come up
3 with some type of rulemaking language that's going to
4 create this second track and then expect that from
5 state to agreement state to NRC state that these
6 credentialings are going to follow this person. I
7 think it's just a very, very large problem.

8 My question to NRC staff is that at the
9 last meeting we had, I thought, agreed that there were
10 other opportunities by which individual physicians
11 could get this training which would be going to
12 centralized pharmacies, also getting what was called
13 dummy or dead generators and practicing on those.

14 It has come to my attention on this issue
15 since the last meeting that some licensees that
16 provide training on this topic have been told they
17 have to be done with live generators that elute
18 activity. And I don't know if that's just a
19 misunderstanding or maybe a regional interpretation,
20 but I think that really needs to be addressed from
21 headquarters down to the regions.

22 DR. SCHWARZ: Sally Schwarz.

23 Since I'm a nuclear pharmacist and have
24 been involved in eluting generators and training
25 residents for about 30 years, I think that certainly

1 it's a process to understand as far as nuclear
2 medicine is concerned. I don't know that you
3 necessarily need to perform the elution. You can
4 observe the elution. You can use the dummy generators
5 and Rob was pointing out.

6 I know Mallinckrodt will provide those
7 dumb inflation generators to us, and that might be a
8 route to go that even observing the elution of a
9 generator would be useful in terms of training. The
10 fact that you elute it one time is maybe explaining
11 techniques to learn, but I don't know. I mean,
12 observing might be satisfactory as well or at least
13 the use of the nonradioactive generators, I mean, that
14 certainly could be something that's allowed as opposed
15 to a radioactive generator.

16 But then if you're using non-radioactive
17 generators and you're talking about training for
18 radionuclidic acuity analysis, you don't have really
19 any way to do that step. So the observation of the
20 procedure is, again, maybe sufficient as well.

21 But I think two pathways probably becomes
22 more problematic than it's worth.

23 DR. HOWE: This is Dr. Howe.

24 Just a clarification. Our requirements in
25 290 is that the applicant have work experience under

1 supervision of an authorized user, and it's eluting
2 generator systems appropriate for preparation of
3 radioactive drugs for imaging and localization
4 studies.

5 Also measuring and testing the eluate for
6 radionuclide purity and processing the eluate for
7 reagent kits to prepare labeled radioactive drugs; so
8 that is not watching somebody elute a generator, and
9 that's not a generator with no radioactivity. That
10 certainly could be an old generator that doesn't give
11 a lot of activity, but there's supposed to be the
12 performance part of that is that they have experience
13 eluting the generator under supervision and that they
14 have experience in measuring and testing for the
15 radionuclide purity and processing for radioactive
16 drugs.

17 DR. MALMUD: Thank you for clarifying
18 that, Dr. Howe.

19 This is Dr. Malmud.

20 There is a discussion ongoing then
21 regarding this issue. Any other comments regarding
22 the issue?

23 DR. VAN DECKER: Yes, Dr. Malmud. This is
24 Bill Van Decker.

25 Let me weigh in.

1 DR. MALMUD: Doctor.

2 DR. VAN DECKER: I also would agree with
3 just about what everyone has said so far, that
4 creating two tracked categories in 200, which is a
5 diagnostic radioisotope category is going to create
6 tremendous difficulties as far as people changing
7 sites, and I think that it adds tremendous complexity
8 to something that does not need to be there, and that
9 there are other ways to go about making sure that
10 people have experience, even if they are going to unit
11 does sites.

12 And I think that having that flexibility
13 allows us to create access for studies and it brought
14 a variety of venues, and I think that that's important
15 for the patient population in the country.

16 DR. MALMUD: Thank you, Dr. Van Decker.

17 Is the feeling of the Committee therefore
18 that we should not alter the current regulation with
19 regard to this issue?

20 DR. EGGLI: This is D. Eggli.

21 That is my feeling.

22 DR. VETTER: This is Dick Vetter.

23 I agree.

24 DR. SCHWARZ: I agree.

25 Sally Schwarz.

1 MR. LIETO: Ralph Lieto.

2 I agree.

3 DR. WILLIAMSON: Jeff Williamson.

4 I agree.

5 DR. HOWE: Dr. Malmud, has someone made a
6 motion?

7 DR. MALMUD: No. I was just asking what
8 they were thinking. I will ask for a motion now and
9 the motion would be presented by whom? Dr. Van
10 Decker?

11 DR. VAN DECKER: Well, I thought Dr. Eggli
12 would take the lead, but I would say that my motion
13 would be that although some of the statements here
14 about unit dosing being most common are all true, that
15 we believe that attempting to create artificial
16 categories within diagnostic 200 would add a
17 tremendous level of complexity that is not necessary
18 for safety and would limit access to patients and,
19 therefore, we would not recommend this situation.

20 MEMBER EGGLI: This is Eggli. Although I
21 would have made the motion, I could not have done it
22 as eloquently as Dr. Van Decker. But I will certainly
23 second it.

24 CHAIRMAN MALMUD: This is Malmud. May we
25 abbreviate the motion to simply state that the

1 committee reaffirms its commitment to the regulation
2 as it exists?

3 MEMBER EGGLI: It's not nearly as eloquent
4 as Dr. Van Decker.

5 CHAIRMAN MALMUD: I understand. But I
6 thought that brevity might prevail.

7 MEMBER VAN DECKER: Dr. Malmud, which one
8 of us is from New Jersey?

9 (Laughter.)

10 CHAIRMAN MALMUD: You're from Jersey.

11 (Laughter.)

12 Is that acceptable to you, Dr. Van Decker?

13 MEMBER VAN DECKER: That is acceptable to
14 me, Dr. Malmud.

15 CHAIRMAN MALMUD: And then, the second to
16 the motion would be Dr. Eggli?

17 MEMBER EGGLI: Acceptable.

18 CHAIRMAN MALMUD: All in favor of the
19 motion?

20 (Chorus of ayes.)

21 Any opposed?

22 (No response.)

23 It carries unanimously.

24 Thank you, Dr. Howe, for bringing the
25 concept before us. May we move on to the next item?

1 DR. HOWE: Yes. On slide number 10 --
2 actually, slide number 10 and 11 are interrelated.
3 One addresses supervising authorized users, and the
4 other addresses the preceptor authorized user. So the
5 concepts are essentially the same.

6 And the issue is that in 390, you have the
7 board certification pathway, and then you have the
8 alternate pathway. And when you get to the person
9 that is -- is supervising the work experience in
10 paragraph (b)(2)(i), you end up with -- let me see.
11 The basic element is if you're coming to the board
12 certification pathway, which is 30 -- 390(a), you go
13 into the -- the critical experience is not included in
14 the board certification pathway. It's something that
15 is attested to after the certification part.

16 And if you look at the clinical part,
17 you'll see that instead of 390 requiring all four
18 types of clinical experience, it has an and/or at the
19 end. And so you could come through 390 with less than
20 four of the clinical experiences, and the board
21 certification pathway could also come through with
22 less than four of the clinical types of casework.

23 And when you get to the alternate pathway
24 and you have the supervising work experience, you read
25 that the supervising work experience -- only the

1 person coming through the B pathway has to have the
2 same experience in dosaging as the person they are
3 training. And they do that by coming through the
4 board certification pathway -- for people that have
5 come through the board certification pathway.

6 So I am recommending that the text in 390,
7 which very similar but not quite the same text shows
8 up in 392 and 394, be revised so that regardless of
9 how you get your authorization, if you're the
10 supervising authorized user you have to have clinical
11 experience in the same type of administration that you
12 are providing training for. That's the bottom line.

13 And so it's to rectify that, where it
14 says, "The supervising authorized user who meets the
15 requirements in 390(b) must have the experience in
16 administering dosages," I would recommend taking out
17 the letter B, so that anyone coming through the 390
18 process, whether it's A or B, the supervising
19 authorized user has experience in administering
20 dosages of the same dosage category as those required
21 in the regulation.

22 CHAIRMAN MALMUD: Thank you, Dr. Howe. Is
23 there discussion? Is that a motion, Dr. Howe?

24 DR. HOWE: I can't make a motion.

25 CHAIRMAN MALMUD: Yes. Is that something

1 you want to have presented as a motion?

2 DR. HOWE: Yes.

3 CHAIRMAN MALMUD: Does anyone care to make
4 that a motion?

5 MEMBER EGGLI: Sure. This is Eggli. I'll
6 do that.

7 MEMBER VETTER: I'm Dick Vetter. I'll
8 second it.

9 CHAIRMAN MALMUD: So Eggli makes the
10 motion, Vetter seconds it. Now it is open for
11 discussion. Does anyone wish to discuss the motion?

12 MEMBER LIETO: This is Ralph Lieto. I
13 think this is getting overly prescriptive. What this
14 is saying is that if you have an authorized user who,
15 let's say, may have experience in doing I-131 and
16 I-131 monoclonal antibodies, they would not be
17 qualified to supervise somebody doing a Zevalin
18 administration.

19 And I think that if you are an approved
20 user under 390 that, you know, there is just I think
21 a level of prescription that we're creeping into that
22 just makes this I think totally unnecessary. What is
23 -- I guess my question would be: what is the problem
24 that has been presented that we're trying to fix?

25 DR. HOWE: Just to clarify, Mr. Lieto, the

1 types of clinical experience that are required are two
2 different activity levels for oral I-131 and then two
3 different types of parental administration. So if the
4 drugs were in the same group, the I-131 monoclonal
5 antibody would come under group number 3.

6 So if you were giving a Zevalin versus a
7 Bexxar, and you were still in group 3, that would be
8 considered okay. So we're not going any deeper than
9 the types of clinical experiences that are in
10 subparagraph G in 390.

11 What we're saying is that we would -- in
12 one case you're expecting -- you're holding the
13 alternate pathway user to a higher standard than
14 you're holding the board certification supervising
15 authorizing --

16 MEMBER WILLIAMSON: But that is built into
17 the structure, certainly, of 35.400 and 600, and we
18 agreed a long time ago that 300 was kind of in the
19 middle where, you know, there had to be kind of a
20 transition from the 200 style of doing things to the
21 radiation oncology style of doing things, and that,
22 yes, board certification should count for something as
23 a -- you know, kind of a national seal of approval
24 that this person has generalizable clinical experience
25 and judgment and is able to do something a little bit

1 different than they were exactly trained for.

2 So I agree with Ralph. I think this is a
3 mistake.

4 CHAIRMAN MALMUD: Any other comments?

5 (No response.)

6 All right. A motion has been moved and
7 seconded. All in favor of the motion?

8 (No response.)

9 All opposed to the motion?

10 (Several negative responses.)

11 Any abstentions?

12 (No response.)

13 The motion is defeated.

14 Thank you. May we go on to the next item?

15 DR. HOWE: Item Number 11 is similar to
16 Item Number 10, and that says that the preceptor
17 authorized user should have the same qualifications as
18 the person that they are precepting. And the
19 difference, once again, is that the clinical
20 experience is not required. All the elements of the
21 clinical experience are not required in the board
22 certification route.

23 The clinical experience is attested to
24 outside of the clinical -- outside of the board
25 certification route, and so the change would be to

1 ensure that the preceptor authorized user, regardless
2 of the route they came through, has the same clinical
3 experience as the person that they are supervising --
4 the person that they are attesting for.

5 So that would ensure that if you have a
6 person that wants attestation for parental
7 administrations, they are a preceptor authorized user,
8 would have experience in parental administrations and
9 not just I-131.

10 CHAIRMAN MALMUD: Does anyone wish to make
11 a motion, so that we can discuss this issue?

12 MEMBER LIETO: This is Ralph Lieto. I
13 would move, based on the same arguments as before,
14 that this not be -- that the NRC not proceed further
15 with this suggested recommendation.

16 CHAIRMAN MALMUD: Is there a second to Mr.
17 Lieto's motion?

18 MEMBER SCHWARZ: I second the motion.

19 CHAIRMAN MALMUD: Dr. Schwarz seconds the
20 motion. Any further discussion?

21 (No response.)

22 All in favor of the motion, which is not
23 to make the change?

24 (Chorus of ayes.)

25 Any opposed to the motion?

1 (No response.)

2 The motion carries unanimously.

3 Next item?

4 DR. HOWE: Good. The next item is 35.396,
5 and we have had a number of people that have
6 erroneously interpreted 396(d) as standing alone. And
7 what we are recommending is just rewriting 396 so that
8 it is perfectly clear, that all of the text in
9 paragraph D is included -- is part of the requirement
10 for C1 or C2 -- B and C -- and that the current
11 paragraph D does not stand alone, and a person has to
12 have the experience in radiation oncology before this
13 paragraph comes into effect.

14 Now, our General Counsel has determined
15 that D does not stand alone, but we're just trying to
16 make it perfectly clear to people in more of a plain
17 English if that's possible, that the information in D
18 is part of the requirements in B and C, and doesn't
19 stand alone.

20 CHAIRMAN MALMUD: All right. Would
21 someone care to make that motion?

22 (No response.)

23 Would one of the radiotherapists or
24 physicists care to make the motion?

25 MEMBER WILLIAMSON: Jeff Williamson here.

1 So moved.

2 CHAIRMAN MALMUD: Is there a second to
3 that motion?

4 MEMBER VETTER: Dick Vetter. Second.

5 CHAIRMAN MALMUD: It has been moved and
6 seconded. Is there discussion of this motion?

7 MEMBER LIETO: I feel, without reading
8 this very carefully, which, you know, this is a long
9 section in the -- on page 589 and 590 of the Code of
10 Federal Regulations, I feel unable to discuss this
11 issue without it being explained in far more detail
12 and having an opportunity -- you know, an opportunity
13 to really study this.

14 DR. HOWE: Okay. Essentially, what I've
15 done is I have taken paragraph D1 to the end,
16 renumbered that C2. So all of that text in D1 is now
17 called C2. Okay? And the paragraph that was C is now
18 -- because Part J is no longer in the regulation, so
19 that simplifies the text a lot. That is now called
20 C1. Therefore, you see C1 and C2 are combined
21 together, and you need to meet those criteria.

22 And then, I went up into paragraph B,
23 which is where you are already an authorized user
24 under 400 or 600 uses, and I made it clear that those
25 individuals have to meet the requirement in C2, which

1 is the 80 hours of classroom; C3, which is the work
2 experience; and C4, which is the attestation.

3 MEMBER LIETO: I have to, you know,
4 understand the basic purpose of the 35.396. So this
5 is a special pathway for -- I think that lets either
6 authorized users under 35.400 or 600, regardless of
7 how they got there, or those who are board certified
8 according to a board recognized by the Commission for
9 35.400 or 600, to let them use a single class of
10 photon-emitting radionuclides, radiopharmaceuticals,
11 you know, essentially any beta emitter or low energy
12 radionuclide -- so, for example, strontium-89 -- for
13 example, metastron. Is that correct?

14 DR. HOWE: That's correct.

15 MEMBER LIETO: Okay. And so the concern
16 is that once somebody -- some physicist or fry cook
17 out on the street could come and say, "I have
18 completed 80 hours of training" and not even have an
19 M.D. and apply to be an authorized -- what is the
20 concern exactly?

21 DR. HOWE: The concern is the
22 interpretation of the rule. We have had people that
23 have mistakenly interpreted that paragraph D1 and --
24 let me see if I've got -- flip the page here. D1, D2,
25 D3 are stand-alone requirements and are not tied to

1 paragraphs A, B, and C. Well, they're not tied to A,
2 because A, you're already authorized under 390 for it.
3 But that they are not tied to paragraphs B and C,
4 and --

5 MEMBER LIETO: This is Ralph Lieto. Why
6 not just put the word "and" after paragraph C?

7 DR. HOWE: When you do that, it sounds as
8 -- that changes the regulation. That does not fix the
9 problem.

10 MEMBER WILLIAMSON: I'm not sure I see
11 there's a problem. This is very clear. It says that
12 -- if you read it from the beginning, it says you can
13 be a B or a C, and then do this different activity
14 that's not allowed directly under 35.400 or 600, if
15 you comply with D. And I would assume -- you know, it
16 doesn't say just D, but, you know, I would assume all
17 of the subparts of D, depending upon how they're
18 connected with -- strung together with conjunctions or
19 disjunctions, you know, would apply as specified, not
20 just the top part of D.

21 DR. HOWE: If this is the top of D, it's
22 -- our Office of the General Counsel says this is the
23 way -- you have to start at the beginning of this
24 paragraph, up at the top, and read. And when you
25 read, you essentially quit reading when you get to the

1 period at the end of C. So D cannot stand alone.

2 But we have people that don't interpret it
3 that way, and so we were just trying to write it in a
4 -- in a way that is easier to see that there is no
5 part of it that stands alone.

6 MEMBER LIETO: This is Ralph Lieto. I
7 would disagree with making these suggested changes,
8 because you're renumbering paragraphs, reordering
9 them. I -- you know, I would either at a minimum
10 table any action on -- by the committee on this
11 specific item, and at best I think we should just
12 leave it alone.

13 MEMBER NAG: This is Dr. Nag. You are
14 saying that there has been problems, that people were
15 saying that D was a stand alone. I mean, has anyone
16 really -- has anyone analyzed it based on only the 80
17 hours without having 490 or 690 training?

18 I thought it was quite clear they put 490 or
19 690, and then you have to have the extra 80 hours.
20 That's the way I have been telling the Radiation
21 Oncology Committee -- I mean, community anyway.

22 DR. HOWE: When you come into the NRC we
23 very clearly -- if people have the wrong
24 interpretation of this, we straighten them out fairly
25 quickly. But we have had -- we have seen a lot of

1 discussion on RADRAP where people have interpreted it
2 wrongly, and they haven't been in NRC jurisdiction.

3 MEMBER NAG: Yes. Also, when you said
4 that, I think I do remember seeing some ads basically
5 from some people who are offering an 80-hour training
6 to allow them to use yttrium and, you know, any of
7 these other things. So I guess -- I guess some people
8 are not clear.

9 DR. HOWE: That's our problem; some people
10 are not clear.

11 MEMBER WILLIAMSON: This is Jeff
12 Williamson. I think it reads pretty clearly to me.
13 And since the Office of General Counsel has given you
14 a -- told you basically that the interpretation is
15 sort of the obvious one, and, moreover, an
16 interpretation that adheres to the underlying intent,
17 I would not support the proposal, because I think it's
18 a lot of trouble and we'll probably make some other
19 mistakes which may have unintended consequences.

20 CHAIRMAN MALMUD: Is there any other
21 discussion of this?

22 MEMBER LIETO: Dr. Malmud, this is Ralph
23 Lieto. I don't know if we want to make this a
24 recommendation, but I think we should defeat this.
25 And I think using the current NRC information avenues

1 of their FAQs, the newsletter, and if staff feels
2 appropriate that this is something that licensees need
3 to be made aware, maybe an information notice, or all
4 three, that addresses this. But I think we should
5 stay away from rulemaking.

6 MEMBER NAG: This is Dr. Nag. Can we do
7 it in guidance, so that we make it clear that this
8 paragraph means you have to have 490 or 690 plus the
9 80 hours? If we can do it in guidance rather than
10 rulemaking.

11 DR. HOWE: Yes, we can.

12 MEMBER NAG: I would support to have it
13 done that way.

14 CHAIRMAN MALMUD: Dr. Nag, would you make
15 a motion that this be achieved via guidance?

16 MEMBER NAG: This is Dr. Nag. I make a
17 motion that the paragraph about 490 and 690 users
18 needing or requiring a further 80 hours training in
19 isotopes be clarified under guidance rather than
20 having a separate rulemaking.

21 CHAIRMAN MALMUD: Thank you. Mr. Lieto,
22 would you care to second that?

23 MEMBER LIETO: I will second that. And,
24 Mr. Chairman, just a point of order -- I think we had
25 a previous motion to approve this. So I think we

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1 would need to maybe -- I would like to urge my
2 committee members to defeat the first motion, and then
3 we could vote on the second one.

4 CHAIRMAN MALMUD: All right. I'll call
5 the vote on the first motion. All in favor?

6 (No response.)

7 All opposed?

8 (Several negative responses.)

9 Any opposed to the opposition?

10 (Laughter.)

11 So it's unanimous. We oppose the first
12 motion.

13 And now the second motion was to request
14 that Dr. Howe achieve the same goal via guidance. All
15 in favor?

16 (Chorus of ayes.)

17 Any opposed?

18 (No response.)

19 So that there is approval of Dr. Howe's
20 recommendation, but that it be achieved via guidance.

21 Thank you. Next item?

22 DR. HOWE: Thank you very much. Okay.
23 The next item is also -- 13 and 14 are related, and
24 they are dealing with medical physicists, authorized
25 medical physicists, specifically for 35.433 users,

1 which is the strontium eye applicator.

2 Slide number 13 is -- we brought this
3 issue to the ACMUI before in requesting exemptions for
4 individuals that don't meet the criteria for
5 authorized medical physicists that want to do the
6 strontium eye applicator decay corrections and other
7 activities that would be associated with this, and
8 we've had differing opinions on the ACMUI.

9 And one thing was the ACMUI indicated
10 they'd like to reexamine this issue and possibly come
11 up with a clear description of what the tasks are for
12 the medical physicist that is associated with the
13 strontium eye applicator use.

14 And so Item Number 13 -- or slide
15 number 13 would be a recommendation to revise 35.433
16 to expand the description of tasks responsible for --
17 the responsibility for the medical physicists prior,
18 during, and after use of strontium eye applicators, so
19 that we have a clear understanding of what this
20 individual needs to do and what his credentials ought
21 to be.

22 MEMBER NAG: This is Dr. Nag. Has anyone
23 written up any drafts of what these new things would
24 be?

25 DR. HOWE: No. This is something that we

1 would -- we would work on at a later date. I mean,
2 this is just saying this is an area that ACMUI would
3 like to move forward on with a potential rulemaking.

4 MEMBER NAG: I would support that. Do you
5 need me to make a motion?

6 CHAIRMAN MALMUD: Yes, thank you, Dr. Nag.

7 MEMBER NAG: Okay. I make a motion that
8 10 CFR 35.433 be revised to expand the description of
9 the tasks and responsibilities.

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

12 MEMBER WILLIAMSON: Second. Jeff
13 Williamson.

14 CHAIRMAN MALMUD: Dr. Williamson seconds
15 it. Any further discussion?

16 MEMBER WILLIAMSON: I think that I would
17 like to just ask a question of clarification. Is the
18 concept to develop a definition of AMP for manual
19 brachytherapy, not just strontium eye applicator?

20 DR. HOWE: That might be part of what
21 would happen. There may be a recognition with other
22 modalities also that there's a possibility we need
23 another medical -- another description of a medical
24 physicist that would get down into the manual
25 brachytherapy.

1 But I suspect that if this motion carries,
2 this is an item that will have a lot of debate with
3 the ACMUI, and it's not something that's going to be
4 fixed overnight.

5 MEMBER LIETO: This is Ralph Lieto. I
6 totally echo Dr. Howe's comments. I think this is
7 going to be a very, very large task, probably maybe
8 something needed in terms of a designation of manual
9 brachytherapy versus the old teletherapy designation
10 for medical physicist.

11 MEMBER NAG: Yes. I think -- isn't it
12 restricted only to strontium-90 eye applicator? It
13 may be a little bit easier to do that than to do the
14 whole manual brachytherapy. I think the whole manual
15 brachytherapy is going to be a far more difficult
16 task, and I would suggest restricting it only for the
17 I-plat.

18 CHAIRMAN MALMUD: Thank you. With that
19 discussion, may we move the motion?

20 MEMBER LIETO: I would like to respond.
21 You know, I think that there are many more challenging
22 roles for the physicist, medical physicist, in manual
23 brachytherapy than performing decay corrections for
24 strontium-90, which, you know, I certainly don't wish
25 to minimize their significance.

1 But I think that it is a fair observation
2 that the regulations as currently written kind of
3 marginalize or, you know, don't appreciate I think the
4 contribution that the qualified medical physicist does
5 play in manual brachytherapy, and there are many forms
6 of manual brachytherapy which are extremely
7 complicated. It is not just high-dose rate
8 brachytherapy which presents a risk to patients and
9 members of the public if not properly performed, and
10 if there is not a coordinated effort between the
11 authorized user and authorized medical physicist.

12 So I would recommend, in fact, you know,
13 generalizing this to consider the -- you know, some
14 regulatory mention of the more general role of the
15 medical physicist in manual brachytherapy.

16 MEMBER VETTER: This is Dick Vetter. I
17 just wanted to point out that paragraph 433 deals only
18 with strontium-90.

19 MEMBER NAG: Yes. I mean, that is
20 something that I -- I think that was my intention. I
21 was not trying to marginalize the manual brachytherapy
22 or criticizing manual brachytherapy. I was just
23 talking about only the I-plat selection, which is
24 under 433.

25 So I agree with you about the role in

1 manual brachytherapy, and that's why I was referring
2 not to manual brachytherapy under this item.

3 MEMBER WILLIAMSON: So I would just
4 propose changing your motion to 35.400.

5 MEMBER NAG: 35.433.

6 MEMBER WILLIAMSON: Yes, I would have
7 proposed changing it from 35.433 to 35.400, so they --

8 MEMBER NAG: Well, no, that is not my
9 intention. But then, you are trying to embark on a
10 much bigger task that will not -- we won't complete in
11 a few months. It will take probably years.

12 MEMBER WILLIAMSON: Maybe so, but perhaps
13 it's more worthwhile than this. You know, essentially
14 what they're asking -- the problem is they would
15 probably like undergraduate degree people to be able
16 to do decay corrections, because it causes problems to
17 have an authorized medical physicist do this one duty.

18 But I think that actually Dr. Howe has
19 brought up the larger problem, and it's -- so I would
20 suggest maybe it should be a different motion that
21 the, you know, NRC and ACMUI should give some future
22 consideration to the role of the physicist in manual
23 brachytherapy generally.

24 MEMBER NAG: That is fine, but I think
25 that should be a separate item, separate from the much

1 simpler task of doing the 35.433.

2 CHAIRMAN MALMUD: Thank you, gentlemen.
3 We do have a motion on the floor. May we move forward
4 with the motion? I think you had seconded it, Dr.
5 Williamson.

6 MEMBER WILLIAMSON: Yes.

7 CHAIRMAN MALMUD: All in favor?

8 (Chorus of ayes.)

9 Any opposed?

10 (No response.)

11 The motion carries.

12 MEMBER WILLIAMSON: I abstain.

13 CHAIRMAN MALMUD: Dr. Williamson abstains.

14 MEMBER NAG: Dr. Williamson, if you want
15 to make a separate motion that the role of medical
16 physicists in manual brachytherapy be sort of
17 reexamined and categorized, you can make a separate
18 motion. I have no problem with that.

19 MEMBER WILLIAMSON: Well, that's up to the
20 Chairman to allow that. It's not part of the intent.

21 CHAIRMAN MALMUD: I would suggest we bring
22 that up at a regular meeting. It's a significant
23 issue.

24 DR. HOWE: I think what I'm hearing is
25 that if -- the next time I bring up potential changes

1 to Part 35 I include that as one of the items of
2 interest to the ACMUI. That would be the appropriate
3 time.

4 CHAIRMAN MALMUD: Thank you, Dr. Howe.

5 DR. HOWE: Okay. Have we finished with
6 Item 15?

7 CHAIRMAN MALMUD: Yes, Dr. Howe.

8 DR. HOWE: Okay. Item 14 is an extension
9 of 13, and that is that if we have additional -- the
10 tasks described in 433, then we would have an easier
11 time to permit medical physicists with training and
12 experience in those specific tasks to use the manual
13 brachytherapy sources for 433. So the two are kind of
14 interrelated.

15 MEMBER LIETO: I'm really confused what
16 the intention of both this motion and the previous
17 motion are.

18 DR. HOWE: The first one was we have had
19 a number of requests for exemptions. And as we have
20 brought exemptions to the Board, to the ACMUI, one of
21 the concerns that came up was that 433 did not
22 adequately describe the tasks that were really
23 expected of the authorized medical physicist.

24 And then, 14 is kind of going into the
25 idea that once we describe those tasks you may decide

1 that you don't need an authorized medical physicist,
2 and it opens up the door to the other concept of
3 studying -- do we have a medical physicist for manual
4 brachytherapy?

5 MEMBER LIETO: This is Ralph Lieto. This
6 issue kind of strikes close to home here. This should
7 not be up here, because what is intimated by this
8 slide is that if you're an authorized medical
9 physicist, okay, on a license you are not authorized
10 to do strontium-90 decay corrections, which I totally
11 disagree with.

12 If you're an AMP, period, you're
13 authorized to do this. It doesn't state that you have
14 to be the AMP on that license. Okay? So, for
15 example, Jeff Williamson, as an AMP, if he got asked
16 to do decay corrections for strontium-90 for a
17 hospital in, say, Hawaii, okay, he could do that,
18 because he's an authorized AMP. It doesn't say he has
19 to be on that license.

20 What this is seeming to indicate is that
21 you need a license amendment to do strontium-90 decay
22 correction, even though you're the AMP on a license or
23 the license. And I think that's wrong.

24 MEMBER NAG: This is Dr. Nag. I think I
25 understood your slide 13, which is why I made the

1 recommendation. I don't think I understand slide 14,
2 because if you are an AMP that allows to do the
3 35.433, which is, you know, what has been described
4 previously, then slide 14 should not even be there.
5 You are not really understanding.

6 MEMBER WILLIAMSON: I mean, I agree.
7 Then, the motion that over my opposition was accepted
8 in the last slide it would seem to me would cover
9 this, and we need to have a more specific proposal
10 brought before us, and it's unnecessary to vote on at
11 this time.

12 DR. HOWE: Just to clarify, I guess to
13 address Mr. Lieto's point, we would never prohibit an
14 authorized medical physicist from doing this, because
15 that would still be part of the regulation. It just
16 would make it easier on those people that are
17 requesting exemptions to the regulation to demonstrate
18 they had training and experience that would qualify
19 them for an exemption.

20 MEMBER NAG: Yes, but that --

21 DR. HOWE: That was the intent.

22 MEMBER NAG: This is Dr. Nag. That would
23 be covered under your Item 13, because under Item 13
24 you are giving them -- you are mentioning what are the
25 specific requirements needed, and one of them would be

1 decay correction, and so on. So I think Item 13 will
2 cover Item 14 if Item 13 is written correctly.

3 MEMBER LIETO: Well, no, Dr. Nag, I have
4 to disagree there. This is Ralph Lieto again.
5 Item 14 is totally unnecessary, because all this --
6 what the regulation states is that an AMP shall
7 calculate the activity of each strontium-90 source
8 that is used to determine the treatment times for
9 ophthalmic treatment.

10 So if you're an AMP, you can do the decay
11 corrections automatically. There is nothing that
12 needs to be changed in 433. It doesn't need to be
13 revised. Okay? Because that task is automatically
14 authorized in the regulation.

15 So what Dr. Howe was intimating at was an
16 issue that we addressed as a committee where an
17 individual was not an AMP, did not have the
18 credentials to meet an AMP, and he was requesting a
19 variance from 433 to be allowed to do this. Okay?
20 And that's an entirely different ball game altogether.

21 So I would think that we could just move
22 on to slide 15 and not need to address the -- this
23 suggested revision to Section 433.

24 MEMBER NAG: That's exactly what I meant.
25 I think that slide -- Item 14 is really no problem

1 that needs to be resolved there, unless I'm missing
2 something.

3 MEMBER WILLIAMSON: Well, the problem that
4 -- I think the whole rationale for 13 and 14, I don't
5 know why there are two here --

6 THE COURT REPORTER: This is the Court
7 Reporter. Could you identify yourself, please?

8 MEMBER WILLIAMSON: Jeff Williamson. I
9 think the same thing has been stated twice. What's
10 driving this is not a reexamination of the role in
11 manual brachytherapy. It is -- Dr. Howe wants to
12 eliminate the role of the AMP in strontium-90 eye
13 applications. So unless your qualified person can
14 take care of this duty, they don't have as many
15 variances to grant. I think that's what drives both
16 these slides. Why there are two separate proposals,
17 I haven't a clue.

18 CHAIRMAN MALMUD: This is Malmud. I'm not
19 sure that it's fair to attribute a motive to Dr. Howe
20 without asking Dr. Howe what her purpose was.

21 DR. HOWE: This is Dr. Howe. I was trying
22 to address what the committee had indicated the last
23 time we looked at an individual that had applied -- a
24 licensee that had applied for an exemption for the eye
25 applicator and had a person that was not qualified to

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1 be an AMP.

2 And bringing it up in two aspects -- one
3 would actually recognize a medical physicist that had
4 training in those specific tasks to be qualified to do
5 that, in addition to an authorized medical physicist.
6 And the other was to more clearly explain what those
7 tasks were.

8 So to some extent, the discussion is
9 coming down to your earlier problems that had been
10 discussed in looking at an exemption request.

11 MEMBER VETTER: This is Dick Vetter.
12 Personally, I think it would read much more clearly if
13 you deleted the words "related to the use of manual
14 brachytherapy sources," because then it's focusing in
15 on one of the tasks that are -- that will be
16 delineated in Item 13.

17 So it would allow a medical physicist with
18 training and experience in the specific task of decay
19 correction, for example, to perform the task.

20 DR. HOWE: I think the assumption was
21 whatever those tasks were that came up out of 13 would
22 be what would be inserted in here.

23 MEMBER VETTER: Correct, but -- this is
24 Dick Vetter again. Correct. But as soon as you throw
25 in manual brachytherapy sources, it just throws the

1 whole thing wide open. I think we simply have to
2 focus on strontium-90 tasks.

3 DR. HOWE: The specific tasks related to
4 performing the strontium eye applicator.

5 MEMBER VETTER: Yes, correct. Whatever
6 the tasks are related to the strontium eye applicator.

7 DR. HOWE: Okay.

8 MEMBER VETTER: Does that make sense to
9 people?

10 MEMBER LIETO: This is Ralph Lieto. I
11 agree.

12 CHAIRMAN MALMUD: Is everyone else in
13 pretty much agreement?

14 MEMBER NAG: Yes. Dr. Nag agrees.

15 CHAIRMAN MALMUD: Thank you. Thank you
16 for clarifying that, Dr. Vetter.

17 MEMBER VETTER: Well, in that case I would
18 make a motion that we recommend revising paragraph 433
19 to permit a medical physicist with training and
20 experience in specific tasks identified to perform the
21 tasks of 35.433.

22 CHAIRMAN MALMUD: That's a motion from Dr.
23 Vetter. Is there a second to the motion?

24 MEMBER NAG: Dr. Nag seconds.

25 CHAIRMAN MALMUD: All right. Any further

1 discussion of the motion?

2 (No response.)

3 All in favor?

4 (Chorus of ayes.)

5 Any opposed?

6 (No response.)

7 The motion carries unanimously. Thank
8 you.

9 MEMBER WILLIAMSON: Oh, I'm sorry. Jeff
10 Williamson. I didn't vote.

11 CHAIRMAN MALMUD: Dr. Williamson abstains.
12 Let the record show Dr. Williamson abstained. Thank
13 you, Jeff.

14 The next item, Dr. Howe?

15 DR. HOWE: Okay. The next three items are
16 related to reportable medical events. In slide
17 number 15, the issue is -- and if you read through all
18 of the text you'll find that a medical event is if it
19 -- if the dose differs from the prescribed dose. And
20 for unsealed material, the prescribed dose can either
21 be in a written directive or in the procedures in the
22 Department. So we don't have a problem if there's no
23 written directive for the unsealed material.

24 But when we get to sealed material, uses
25 of gamma knives and HDRs, and other therapy type of

1 devices, if you don't have a written directive, and
2 the dose is given incorrectly from what one would
3 expect to give, or even if you gave a therapy dose to
4 someone who wasn't supposed to get a therapy dose,
5 it's not reportable under the reportable medical
6 events.

7 And we're trying to fix that loophole that
8 was identified by OGC by essentially saying an
9 administration requiring a written directive -- and we
10 would accept an oral directive meeting the
11 requirements of 35.40(a)(1) -- does not exist at the
12 time of the administration that would be reported as
13 a medical event.

14 MEMBER WILLIAMSON: Doesn't 35.3045
15 require -- is not having a written directive grounds
16 for a medical event?

17 DR. HOWE: No, it does not.
18 Unfortunately, the only way you can get to a written
19 directive is if the dose differs from the prescribed
20 dose, and for sealed sources that prescribed dose is
21 the -- by definition is the dose in the written
22 directive. So if there is no written directive, there
23 is no prescribed dose, and you can't differ.

24 MEMBER WILLIAMSON: But if they get the
25 therapy administration, regardless of whether it's

1 correct or incorrect, that's still a violation of
2 regulations, is it not?

3 DR. HOWE: It would be a violation of
4 regulations, but it would not be reportable. So NRC
5 would not be able to take whatever action it needed to
6 take, whether it was putting out information -- it
7 would not know the event occurred.

8 MEMBER WILLIAMSON: What would be the
9 basis for doing the calculation of error? I mean, if
10 there is no written directive, meaning no written
11 prescription by the authorized user, what would be the
12 basis for determining that error existed as opposed to
13 just a license violation or a violation of regulation?

14 DR. HOWE: Yes. In this case, I think you
15 have to separate it from violation. I think what
16 we're really looking at is: is NRC receiving reports
17 of errors in administration? And this is one type of
18 error that we would not receive a report on, and we
19 believe that it's an important error that we should
20 receive a report on.

21 MEMBER WILLIAMSON: I understand. Forget
22 the -- maybe I confused you with the way I asked the
23 question. Let me try to do it in a more simple way.
24 Granted, it's a problem that there could be two
25 problems to occur at once. No written directive or

1 other -- or written directive like thing, such as a
2 prescription, and an error being made in the treatment
3 delivery -- I agree both things could happen.

4 If there isn't a written directive or
5 written prescription, what would be the basis for
6 determining that there was an error? That's my
7 question to you. What would you use as a substitute
8 for what was the intended dose?

9 DR. HOWE: I think we would probably
10 depend upon our medical -- I think we would depend
11 upon our medical consultant in that case to --

12 MEMBER VETTER: This is Dick Vetter. I'm
13 confused about the exception you're making here for
14 oral. I think the regulations allow an oral directive
15 in an emergency, but that has to be followed up by a
16 written directive.

17 DR. HOWE: Right.

18 MEMBER VETTER: And, in fact, that's
19 consistent with Joint Commission. You can't allow an
20 oral directive. So at some point in time very soon
21 after delivery, even in an emergency, a written
22 directive has to have been provided.

23 MEMBER WILLIAMSON: Correct.

24 DR. HOWE: And so what we're saying is
25 that if you didn't have the written directive at the

1 time of administration, but you had an oral directive,
2 we would consider that oral directive to be a
3 legitimate written directive, you know, and you follow
4 that up.

5 So we're not trying to say we got you if
6 you didn't have a written directive because you had an
7 oral one. We're just saying you didn't have a written
8 directive, and you didn't have an oral directive at
9 the time of administration. We would consider that to
10 be reportable.

11 MEMBER WILLIAMSON: Well, I just don't
12 know how -- I appreciate the conundrum. You had a
13 situation where there wasn't a written directive,
14 where there wasn't an oral directive, where there
15 wasn't any piece of paper that clearly, you know,
16 defined what the authorized user's clinical intent
17 was, there's a problem in determining whether a given
18 treatment is a medical event or not.

19 And because of this, the unscrupulous
20 licensees could try to evade the reporting requirement
21 perhaps by burning the written directive or something.
22 Maybe this is the problem.

23 But, you know, having recognized the
24 problem, I'm not sure how you could solve it in
25 regulatory space. I mean, how would you change the

1 definition to substitute something else for the
2 written or oral directive? That's what I see as the
3 problem -- how you would do this in a regulatory
4 space.

5 DR. HOWE: Well, if you read 35.3045, you
6 have a medical event when a dose exceeds 5 rem
7 effective dose equivalent to an organ or tissue or
8 50 rem shallow dose equivalent to the skin from any of
9 the following, and this would be an administration
10 requiring a written directive --

11 MEMBER WILLIAMSON: Correct.

12 DR. HOWE: -- when a written directive
13 does not exist at the time of administration. So that
14 your diagnostic nuclear medicine facilities that don't
15 require a written directive are not in this category.
16 It's only those therapeutic things that would require
17 a written directive. There was no written directive,
18 and the dose that was delivered exceeded these much
19 smaller numbers, which are 5 rem and 50 rem through an
20 organ or tissue.

21 So you've got your dose levels there,
22 because they don't have to differ from something.
23 They are dose levels.

24 MEMBER LIETO: This is Ralph Lieto. I'm
25 still very confused by your basic assumption, because

1 3540, which is written directives, states, "A written
2 directive must be dated and signed by an authorized
3 user before the administration."

4 DR. HOWE: And, Ralph, what you're seeing
5 is that, is there a violation to NRC requirements?
6 And the answer is yes. Does the event have to be
7 reported to NRC? And the answer is no. Does NRC want
8 to hear about the event? We believe yes. So we're
9 not concerned with whether there's a violation of NRC
10 requirements.

11 What we're trying to do is hear about the
12 event when a therapeutic dose is given and there isn't
13 a written directive there for it. And it may be a
14 person that gets a therapeutic dose that was never
15 supposed to get any dose. That's not reportable to
16 the NRC.

17 MEMBER WILLIAMSON: Can I ask, is the
18 intention of your change to basically make any therapy
19 administration that does not have the legally required
20 written directive to be a medical event? Regardless
21 of whether it, in fact, turns out to have been
22 delivered in accord with the authorized user's
23 clinical intention or not.

24 So a new provision of medical event would
25 be any administration of byproduct material that meets

1 the criteria of requiring a written directive that
2 does not, in fact, have a written directive. That
3 becomes a medical event.

4 DR. HOWE: That is correct.

5 MEMBER WILLIAMSON: Okay. So it's
6 basically re-adopting as part of the definition of
7 medical event, the provision that used to be under I
8 think the concept of reportable event, that had to be
9 reported at least to the Radiation Safety Committee if
10 the written directive were improperly filled out.

11 DR. HOWE: I don't have the -- I don't
12 have those regulations in front of me.

13 MEMBER WILLIAMSON: It used to be. Okay.
14 So at least now I understand.

15 MEMBER VETTER: This is Dick Vetter. I
16 think an example that we addressed at our last meeting
17 was part of Dr. Eggli's report where a technologist
18 administered -- I don't know the exact amount, but
19 perhaps it was one millicurie of iodine-131, when in
20 fact they were supposed to administer 10 microcuries.

21 There was no written directive because 10
22 microcuries does not require a written directive, but
23 the technologist went ahead and administered the
24 1 millicurie anyway. Now that's not reportable
25 because a written directive was -- did not exist,

1 because the physician didn't write a written directive
2 because one wasn't required. So the technologist made
3 an error, and that's not reportable.

4 This change that Dr. Howe is proposing
5 would require that to be reported. Am I correct, Dr.
6 Howe?

7 DR. HOWE: Partially. We have the ability
8 to get to the unsealed material, because there are --
9 because the -- if the dosage differs from the
10 prescribed dosage, and the prescribed dosage for
11 unsealed material is defined as either what's in a
12 written directive or what's in -- let me look at -- to
13 get the specific words.

14 "Prescribed dosage means the specific
15 activity or range of activity of unsealed byproduct
16 material as documented in either a written directive
17 or in accordance with the directions of the authorized
18 user for procedures performed pursuant to 100 and
19 200."

20 So we can get to those diagnostic I-131s
21 that way. But if somebody was given a therapeutic
22 I-131 that wasn't even intended to get anything, they
23 came in for a bone scan and they got I-131, then we
24 would not be able to get to them. That would not be
25 reportable. And if you got a -- we have had people

1 get intervascular brachytherapy procedures that did
2 not have written directive.

3 MEMBER LIETO: Do you mean they weren't
4 supposed to get the intervascular brachytherapy and
5 they got it? Is that what you're saying? This is
6 Ralph Lieto.

7 DR. HOWE: We have had cases where the
8 cardiologist and the authorized users have not
9 discussed patients, and patients have been in line.
10 And so when they went to do the IVB, since they were
11 in line, they went ahead and gave the procedure. In
12 some cases they come back -- in most cases they've
13 come back afterwards and said, "Oh, yes, I would have
14 given it."

15 MEMBER LIETO: Well, but that violates 30
16 -- that violates Section 40. This is prior to
17 administration.

18 DR. HOWE: And we are not --

19 MEMBER LIETO: Reportable under that.

20 DR. HOWE: But we are not debating whether
21 the problem is whether there's a violation of the
22 regulations. What we're trying to fix here is that
23 NRC is made aware of incidences in which therapeutic
24 procedures are given without a written directive.

25 MEMBER WILLIAMSON: I think it's not

1 unreasonable. I think it will capture a very --
2 potentially a large set of events. It could, you
3 know, capture -- in addition to these egregious events
4 that you've talked about where the administration is
5 given to the wrong patient or given grossly
6 incorrectly relative to practice standards, it will
7 capture probably a much larger number of events where
8 there is some trivial omission of part of the
9 information required by the written directive -- you
10 know, like failing to sign it instead of just putting
11 your initials or something. I remember under the old
12 Part 35 that used to be a big deal. So I --

13 DR. HOWE: We weren't really trying to
14 capture those. We were really trying to capture the
15 ones in which there is no written directive.

16 MEMBER WILLIAMSON: I know. But -- and
17 I'm sympathetic to the concern. The problem is you're
18 going to capture a lot of innocuous ones as well. I
19 mean, you'll capture events where maybe the physician
20 filled out all of the blanks in the written directive
21 but forgot to sign it, or the physician gave an oral
22 emergency directive and neglected to sign it right
23 away and signed it at 25 hours instead of 24 hours.

24 You get a bunch of what I used to call
25 administrative misadministrations, not egregious cases

1 like you've mentioned, but essentially a sub-class of
2 events which there isn't any gross error but there has
3 been possibly, you know, a minor omission in filling
4 in all of the required information for the written
5 directive, so it wasn't quite proper, if you know what
6 I mean.

7 And, you know, that can happen. But, for
8 example, well -- so that's the issue. You capture the
9 events you want, but possibly at the expense of
10 capturing a much larger set than you intend.

11 And I think to answer Ralph, if you have
12 a license -- a violation of regulations, you're not
13 required to report it. Only certain types of
14 violations have to be reported, so their concern is
15 not that you would not be legally culpable for this
16 mistake but that NRC wouldn't find out about, you
17 know, erroneous treatments.

18 DR. HOWE: Until we did inspections, which
19 could be anywhere from a year, three years to five
20 years later.

21 MEMBER WILLIAMSON: That's right. And you
22 might not find, you know, the violation. And, you
23 know, the licensee is under no obligation I guess to
24 admit it to you necessarily. So I see the problem.

25 I'm not sure, though, what you want to do

1 about all of the other cases that would be captured.
2 You know, a good example would be in HDR intercavitary
3 brachytherapy, I think you have to use prescribed
4 dose. It's very clear. You have to use absorbed dose
5 to fill in the written directive, whereas in manual
6 brachytherapy/intercavitary brachytherapy, you could
7 use milligram hours or total reference air kerma.

8 So if an authorized user filled out the
9 written directive for high-dose rate intercavitary
10 brachytherapy and total -- in terms of total reference
11 air kerma, that's a technical violation. That is not
12 a complete and legal written directive, although it's
13 a clinically adequate one. So any treatment that was
14 -- high-dose rate treatment that was given with a
15 milligram hours or track prescription or written
16 directive would automatically become a medical event
17 under this change.

18 DR. HOWE: I don't think so. I think if
19 there were enough information that you could determine
20 whether what was given was what was intended, or what
21 was given was what wasn't intended. You could come
22 under another section of this.

23 This is not when a complete written
24 directive doesn't exist. It's just plain when a
25 written directive doesn't exist. But, I mean, the

1 technical words can be worked out if we -- if you
2 would allow us to move forward with adding this to our
3 rulemaking language.

4 MEMBER WILLIAMSON: Before I asked you,
5 okay, I see you've got this class of events you want
6 to identify, and I agree with your goal of identifying
7 them. But without a written directive, how would you
8 do the calculation to know that it's an error by more
9 than 20 percent?

10 And then, I asked you, if it's your intent
11 to have any administration of byproduct material,
12 whether correct or incorrect, to be a medical event if
13 there is no written directive, and you said yes. So
14 I've been the last five minutes making my -- my
15 discussion has assumed that's what you meant.

16 DR. HOWE: Yes. And you would -- we are
17 intending to add this to A2. A2 does not have that it
18 differs from what was prescribed. It says that you
19 have a dose that exceeds 5 rem or a dose that is
20 greater than 50 rem to an organ or tissue. This would
21 be -- so you don't have to decide whether it's
22 different from something in order to report it.

23 MEMBER WILLIAMSON: Correct. I understand
24 that. You know, the Part A is simply to identify a
25 threshold of dose delivery that's of medical or

1 clinical significance I guess. So you don't have a
2 lot of very, you know, tiny microsieverts
3 administrations being reported.

4 DR. HOWE: Right.

5 MEMBER WILLIAMSON: I understand that.
6 But the example I -- I think under -- unless I'm
7 really misunderstanding something, my impression is
8 you can have a perfectly adequately and correctly
9 delivered byproduct treatment, but have a technically
10 incomplete or incorrect written directive and it would
11 automatically be a medical event, because the written
12 directive did not exist because it was not filled out
13 completely or exactly correctly.

14 DR. HOWE: I don't think we're looking at
15 it not -- well, I mean, that's something that we could
16 discuss probably for hours.

17 MEMBER WILLIAMSON: I'm just asking how
18 you would put it in the regulation. I don't want to
19 dominate the conversation anymore. I think others --
20 if they don't think this is a problem, I'll just be
21 quiet.

22 DR. HOWE: Because we have ways of getting
23 to things if there is a written directive and it
24 exists. And we can get to whether, you know, it's
25 complete or not. But in this case nothing exists.

1 And, I mean, we could -- I mean, this obviously is
2 something that would be debated for a while, and we
3 could come up with final words that would satisfy
4 everybody. But this was really meant -- our intention
5 was to capture things in which there was no written
6 directive, not that it was --

7 MEMBER WILLIAMSON: Well, I could make a
8 motion, if the Chair would like.

9 CHAIRMAN MALMUD: Yes, thank you.

10 MEMBER WILLIAMSON: Yes. I move that the
11 ACMUI recognize that the staff has identified a valid
12 problem or shortcoming in the reporting criteria, and
13 that they, you know, consider approaches that could be
14 used to capture incorrect -- egregiously incorrect
15 treatments in combination with no written directive in
16 such a way as not to capture a large number of
17 clinically innocuous events.

18 CHAIRMAN MALMUD: Well --

19 MEMBER WILLIAMSON: This is not endorsing
20 their specific approach, but recognizing that they
21 have a problem and it needs to be worked on and that
22 we agree with working on it.

23 CHAIRMAN MALMUD: How about if we simply
24 state it as follows, that we recognize that current
25 regulation does not cover the accidental

1 administration of therapeutic doses to individuals
2 when there is an absence of a written directive, and
3 that we suggest that NRC develop a policy for this.

4 MEMBER WILLIAMSON: Well put. Much better
5 than my statement.

6 CHAIRMAN MALMUD: Well, I'm not sure that
7 it's better, but I hope it's just simpler.

8 MEMBER WILLIAMSON: Yes. I agree with it.

9 CHAIRMAN MALMUD: Then, I -- if I may,
10 I'll -- we'll entertain that motion?

11 MEMBER NAG: This is Dr. Nag. I support
12 that motion.

13 CHAIRMAN MALMUD: All right. We have --
14 it's been moved and seconded. Any further discussion
15 of that motion?

16 (No response.)

17 If not, all in favor?

18 (Chorus of ayes.)

19 Thank you. Once again, Dr. Howe, the
20 committee supports the spirit of your intention.

21 DR. HOWE: Thank you very much. Moving
22 right along to 16, 16 should be a simple one. We
23 found that people have had difficulty interpreting
24 35.3045(a)(3), because of the presence of "to an organ
25 or tissue." That appears twice.

1 And we are just recommending that we use
2 this phrase only once in this section, and that we
3 take the second one out.

4 MEMBER LIETO: This is Ralph Lieto. I
5 think it would change the entire meaning, because it
6 would read, "A dose to the skin or organ or tissue,
7 other than a treatment site, that exists 50 rem."
8 That's not the intent, because you could have -- that
9 means if your treatment exceeded 50 rem, then what you
10 really mean is to an organ or site.

11 So I think it would actually end up being
12 more confusing, and actually not capturing the
13 situations that you wanted to capture.

14 CHAIRMAN MALMUD: Any other comments? I
15 hear a voice.

16 MEMBER WILLIAMSON: Yes. It's Jeff
17 Williamson. I agree with both of you. I think it is
18 a little awkward, but it is clear now, to me at least,
19 so I -- I agree as well. I agree it's awkward, but I
20 agree it's clear now, and I am concerned with Dr.
21 Howe's specific modification. It wouldn't be clear
22 what the criteria -- the criterion of "exceed .5
23 sievert or 50 percent or more" would mean without it.

24 So perhaps if you use some pronoun or
25 indefinite specifier that clearly related back to that

1 long phrase of skin or an organ or tissue.

2 MEMBER VETTER: This is Dick Vetter. I
3 recommend you change the word "that" to a comma,
4 "which." And then it refers back to dose, so it's a
5 dose which exceeds 50 rem or 50 percent or more,
6 etcetera, to the skin or organ or tissue other than
7 the treatment site.

8 DR. HOWE: Okay. Let me see if I catch
9 you. So you're saying that what's existing in the
10 regulation now is where you would take -- versus that?
11 That exceeds -- the first one -- a dose to the skin or
12 an organ or tissue, other than the treatment site --

13 MEMBER VETTER: No, in your
14 recommendation.

15 DR. HOWE: Oh, in my recommendation.
16 Okay. In my recommendation, then I go that -- where
17 it says "a treatment site that exceeds" you would put
18 a comma.

19 MEMBER VETTER: Put comma, "which."

20 DR. HOWE: And "which."

21 MEMBER VETTER: And then, "which exceeds
22 by .5 sievert," etcetera, refers back to dose.

23 MEMBER LIETO: I think that's a good
24 grammatical device. Better than the original
25 slide 16.

1 CHAIRMAN MALMUD: Does that achieve the
2 purpose?

3 DR. HOWE: Right off hand, it looks like
4 it does. But, of course, this is something you will
5 see many times if it comes up for rulemaking.

6 CHAIRMAN MALMUD: Dr. Vetter, do you wish
7 to reiterate it, or --

8 MEMBER VETTER: Sure. I -- do you want me
9 to read the whole thing?

10 MEMBER VETTER: Yes, please.

11 MEMBER VETTER: I move that we recommend
12 revising 10 CFR 35.3045(3) by deleting the second "to
13 an organ or tissue" to read "a dose to the skin or an
14 organ or tissue, other than the treatment site, which
15 exceeds by .05 sievert (50 rem) and 50 percent or more
16 of the dose expected from the administration defined
17 in the written directive (excluding for permanent
18 implant seeds that were implanted in the correct site
19 but migrated outside the treatment site)."

20 CHAIRMAN MALMUD: Thank you. That's a
21 motion.

22 MEMBER SCHWARZ: Second the motion.

23 CHAIRMAN MALMUD: Seconded. Any further
24 discussion of the motion?

25 MR. ESSIG: Dr. Malmud, this is Tom Essig.

1 Just to clarify that that is 35.305(a)(3).

2 DR. HOWE: Sorry. I have a typo.

3 CHAIRMAN MALMUD: Thank you, Mr. Essig.

4 Thank you, Dr. Howe. All in favor of the motion?

5 (Chorus of ayes.)

6 Any opposed?

7 (No response.)

8 Any abstentions?

9 (No response.)

10 The motion carries unanimously. Thank
11 you.

12 Dr. Howe?

13 DR. HOWE: Okay. 17 is another problem
14 where we have -- we have had people that have thought
15 -- they haven't been able to interpret 35.3045(a)(3).
16 They have actually thought that if the dose to the
17 wrong -- dose to the wrong treatment site had to
18 exceed by 50 percent the dose that was expected to be
19 delivered to the right treatment site.

20 So if you are going for target A, and you
21 were going to give 1,200 rads, and you made a mistake
22 and gave 1,200 rads to the wrong treatment site, they
23 would say that wasn't a medical event until you went
24 to 2,400 rad. So we're trying to make this appear a
25 little more -- a little clearer by revising that

1 section to read "exceeds 50 percent or more of the
2 dose expected to that site from the administration, if
3 it had been given in accordance with a written
4 directive."

5 The whole part of 35.3045(a)(3) is "a dose
6 to the skin or organ or tissue, other than treatment
7 site, that exceeds by 50 rem or exceeds 50 rem or more
8 to the dose expected to that site of the
9 administration -- from the administration being given
10 in accordance with a written directive."

11 MEMBER WILLIAMSON: Would that fit with
12 Dr. Vetter's proposed change?

13 DR. HOWE: Well, Dr. Vetter's proposed --
14 if I were to follow his, then I would -- after
15 "treatment site" I would put a comma and put "which."

16 MEMBER WILLIAMSON: May I ask a more
17 general question?

18 DR. HOWE: Yes.

19 CHAIRMAN MALMUD: Please do.

20 MEMBER WILLIAMSON: Yes. As I recall this
21 -- a subcommittee of the ACMUI spent considerable
22 effort recently trying to draft a new -- develop a new
23 concept of medical event reporting.

24 THE COURT REPORTER: Excuse me. This is
25 the Court Reporter. I need the ID of the current

1 speaker.

2 MEMBER WILLIAMSON: I'm sorry?

3 THE COURT REPORTER: The ID of the current
4 speaker.

5 MEMBER WILLIAMSON: Williamson.

6 THE COURT REPORTER: Thought so. Thank
7 you.

8 MEMBER WILLIAMSON: Okay. So to repeat,
9 how do these proposed changes to the medical event
10 reporting rule cohere or fit with this prior effort to
11 more radically revise the regulation at least for the
12 case of permanent seed implants?

13 DR. HOWE: This is Dr. Howe. What we're
14 hoping will happen is that a commission -- well, a
15 commission paper has already gone to the Commission
16 where they have approved in concept that the
17 requirements for reporting medical events has changed
18 in accordance with what you had recommended
19 previously.

20 And we're hoping that will reach a
21 priority where we can start working on a proposed
22 rule, and the staff is hoping that some of these
23 changes will be addressed at the same time, so that
24 everything can be handled as a complete package.
25 That's our hope.

1 MEMBER LIETO: This is Ralph Lieto. So,
2 Dr. Howe, then, what you're saying is that this change
3 is consistent with the recommendations that the ACMUI
4 had made in revising the medical event definition. Is
5 that correct?

6 DR. HOWE: I guess what I'm saying is
7 we're hoping to add these at the same time those
8 changes are put forward as a proposed rule. And we
9 will make sure that they conform with those changes.
10 I don't know -- right now, I can't say these
11 specifically conform. I do believe that they can fit
12 in with those changes.

13 CHAIRMAN MALMUD: Does that answer your
14 question?

15 MEMBER LIETO: This is Ralph Lieto. I
16 take that was a definite maybe.

17 DR. HOWE: It's a definite maybe.

18 CHAIRMAN MALMUD: Thank you. Do we have
19 a motion on the floor?

20 MEMBER WILLIAMSON: No, I don't think we
21 do. I move that we accept Dr. Howe's proposal to add
22 the words "to that site" to 35.3045(a)(3). And this
23 is Jeff Williamson speaking again.

24 CHAIRMAN MALMUD: Thank you, Dr.
25 Williamson. That is a motion. Is there a second to

1 Dr. Williamson's motion?

2 MEMBER VETTER: This is Dick Vetter. I
3 will second that, assuming that he also meant to
4 include comma "which."

5 MEMBER WILLIAMSON: I certainly -- I
6 didn't because we've already approved that on a prior
7 motion, but --

8 MEMBER VETTER: Oh, you're correct. That
9 would include -- that would pick that up, yes. I
10 second the motion.

11 MEMBER WILLIAMSON: It would pick that up,
12 and I don't think -- I think we've already established
13 that there's no contradiction between the two motions.

14 MEMBER VETTER: Gotcha.

15 CHAIRMAN MALMUD: The motion has been
16 moved and seconded. Any further discussion?

17 (No response.)

18 All in favor, aye?

19 (Chorus of ayes.)

20 Any opposed?

21 (No response.)

22 The motion carries unanimously. Thank
23 you. Dr. Howe, you're back on.

24 DR. HOWE: Okay. The final one I had is
25 more of a question to the ACMUI to see if we should

1 proceed or not. And this was an issue that was
2 brought to our attention, and we have an OGC
3 interpretation.

4 When you look at the board certification
5 criteria in 3551(a)(2)(i) you find that the supervisor
6 -- that the work experience -- the work experience has
7 to be provided under the supervision of a medical
8 physicist who is certified in medical physics by a
9 specialty board recognized by the Commission.

10 It is -- we believe that that
11 certification board would be a board that would be
12 recognized under 3551, but that's not what the rule
13 says. The rule is written in such a way that it would
14 also include a specialty board -- a medical physics
15 specialty board that was recognized under -- and I
16 have a typo here -- not 35.500 but 35.50. So that
17 would include the diagnostic medical physics boards
18 that are recognized for RSO use in 3550.

19 And the question is: is it acceptable for
20 the medical physicists coming through the therapy
21 authorization pathway to have received their medical
22 physics training by someone -- by a medical physicist
23 that is board certified in a therapy physics -- I
24 mean, in a diagnostic physics certification that's
25 recognized by us under 3550, or should it be a board

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1 that's recognized under 3551?

2 CHAIRMAN MALMUD: So should it be either
3 or -- either/or?

4 DR. HOWE: Either/or.

5 CHAIRMAN MALMUD: Why don't we address
6 that question to members of the committee, first to
7 our physicists.

8 MEMBER WILLIAMSON: Well, thinking here in
9 a moment --

10 CHAIRMAN MALMUD: Dr. Williamson.

11 MEMBER WILLIAMSON: Yes. Jeff Williamson.
12 I believe it was not the intention when we drafted
13 this proposal to recognize physicists certified in
14 other areas of physics besides radiation oncology
15 physics as appropriate personages in this role.

16 I would need to go back and look at the
17 ABR eligibility requirements, which at least used to
18 state that an authorized -- a physician boarded in
19 therapeutic radiology or radiation oncology could also
20 play that role. And that would be an acceptable
21 marker of that kind of experience, that a physicist
22 worked in a practice supervised by a board certified
23 physician. So, you know, I would need to check that
24 out before I could render a complete opinion on this.

25 DR. HOWE: To clarify Jeff's comment, 3551

1 does allow for the two years of full-time practical
2 training and/or supervised experience in medical
3 physics to be under the supervision -- I think there's
4 -- in a clinical radiation facility. It doesn't say
5 "physicians," does it?

6 MEMBER WILLIAMSON: I'm looking now. So
7 this is actually --

8 DR. HOWE: Yes, it does not --

9 MEMBER WILLIAMSON: Can you tell me
10 exactly the paragraph where this appears?

11 DR. HOWE: 3551(a)(2).

12 MEMBER WILLIAMSON: (a)(2).

13 DR. HOWE: There is no provision for a
14 physician.

15 MEMBER WILLIAMSON: Yes.

16 DR. HOWE: Yes, there is.

17 MEMBER WILLIAMSON: Oh, there is. Okay.

18 DR. HOWE: For the physician who meets the
19 requirements of an authorized user and --

20 MEMBER WILLIAMSON: Oh, there is in part
21 double I.

22 DR. HOWE: Yes.

23 MEMBER WILLIAMSON: Okay.

24 DR. HOWE: 490 and 690.

25 MEMBER WILLIAMSON: Okay. Since that is

1 there, yes, I think that I'd like Ralph's opinion and
2 Dick's maybe, too. But I think that changing single I
3 in this way as you propose would be in accord with the
4 intention we had.

5 MEMBER LIETO: This is Ralph Lieto. I
6 would agree. I can't think of a situation where a
7 diagnostic physicist of sound mind and body would feel
8 comfortable in supervising brachytherapy type work.
9 And so I would agree that it was totally the intention
10 that the supervision be done by a physicist who had
11 commensurate training and experience.

12 MEMBER VETTER: This is Dick Vetter. Yes,
13 I agree with that.

14 CHAIRMAN MALMUD: So it sounds as if the
15 three physicists on the committee are in agreement.
16 Do we need a motion for that?

17 MEMBER WILLIAMSON: Can you help us out,
18 Dr. Howe? Jeff Williamson.

19 DR. HOWE: Yes.

20 MEMBER WILLIAMSON: Since you don't have
21 a slide, I don't know exactly what --

22 DR. HOWE: Yes, I didn't have a slide for
23 that, because this is -- was just recently added. I
24 think the change in concept would be to ensure that
25 the supervision of the medical physicists who are

1 certified medical physics recognized by special -- a
2 therapeutic medical physicist certified in therapeutic
3 medical physics or something recognized in the
4 section.

5 MEMBER WILLIAMSON: I think that's -- I
6 would agree that's a reasonable statement of the
7 motion.

8 CHAIRMAN MALMUD: Thank you. We'll accept
9 the motion from Dr. Williamson. Is it seconded?

10 MEMBER NAG: I am not clear what the
11 motion is. I'm sorry.

12 MEMBER LIETO: Could I make maybe a more
13 specific suggestion to Dr. Howe?

14 CHAIRMAN MALMUD: Thank you, Mr. Lieto.

15 MEMBER LIETO: It would be that 3551
16 parens --

17 DR. HOWE: (a)(1)?

18 MEMBER LIETO: -- (a)(1) be revised to
19 include that the supervision of the medical -- of a
20 medical physicist be -- or have commensurate
21 megavoltage and brachytherapy experience to the
22 individual being supervised.

23 DR. HOWE: So you are thinking of picking
24 up the terminology that we used in double I --

25 MEMBER LIETO: Yes.

1 DR. HOWE: -- and applying it to the
2 physicist?

3 MEMBER LIETO: To the supervising
4 physicist.

5 MEMBER WILLIAMSON: I think we could do it
6 in a simpler way by basically stating that it be a --
7 that the supervising physicist be certified in medical
8 -- by a specialty board recognized by the Commission,
9 you know, as an acceptable credential for being an
10 authorized medical physicist. That way we don't have
11 to define what is meant by "an acceptable board" twice
12 in the regulations.

13 MEMBER LIETO: You're still not -- it
14 still doesn't get to the problem that Dr. Howe has
15 identified of a diagnostic physicist versus the
16 therapeutic radiation oncology therapist.

17 MEMBER WILLIAMSON: But a diagnostic -- a
18 person only board certified in diagnostic or nuclear
19 medicine physics could never become -- could never
20 become an authorized medical physicist by virtue of
21 board certification in that area. It's not recognized
22 for -- under 3551 as an acceptable credential. It
23 would be under 3550, but that's not the matter.

24 But I think, you know, it's just a matter
25 of in double I here and --

1 MEMBER LIETO: Would it be better just to
2 change the word "medical physicist" to "authorized
3 medical physicist" -- in other words, just insert the
4 word "authorized" in front of "medical physicist" in
5 (ii)?

6 MEMBER WILLIAMSON: No, I --

7 DR. HOWE: That creates a problem for the
8 -- this is Dr. Howe. That creates a problem, since we
9 have issues with the agreement states, that they may
10 not be listing people as authorized medical
11 physicists.

12 MEMBER VETTER: This is Dick Vetter. The
13 words that Dr. Howe put in her Word document I think
14 actually meet the intent of what we're trying to
15 accomplish here. Those words are "under the
16 supervision of a medical physicist who is certified in
17 medical physics by a specialty board recognized for
18 this section by the Commission or an agreement state."

19 MEMBER WILLIAMSON: I think that's an
20 appropriate motion, yes. That gets to the point in a
21 very straightforward way.

22 CHAIRMAN MALMUD: We will accept that
23 motion. Is it seconded?

24 MEMBER LIETO: Second.

25 CHAIRMAN MALMUD: It has been seconded by

1 Mr. Lieto. Any further discussion?

2 (No response.)

3 All in favor of the motion?

4 (Chorus of ayes.)

5 Thank you. I think that completes your
6 items. Am I correct, Dr. Howe?

7 DR. HOWE: You are correct. We came to
8 the end, and we crossed the finish line.

9 CHAIRMAN MALMUD: In a timely fashion.

10 DR. HOWE: Yes. Thank you very much.

11 CHAIRMAN MALMUD: Thank you, Dr. Howe, for
12 a yeoman's job. Let's see. Are there any other items
13 to be discussed at this meeting?

14 MR. ESSIG: Mr. Chairman, this is Tom
15 Essig. Only if you wish to recognize any comments
16 from members of the public who may have been
17 participating.

18 CHAIRMAN MALMUD: We always are willing to
19 do so, since it's their interest we're concerned
20 about. Are there any comments from the members of the
21 public?

22 DR. CERQUEIRA: Yes. This is Manuel
23 Cerqueira.

24 CHAIRMAN MALMUD: Could you spell your
25 name, please?

1 DR. CERQUEIRA: C-E-R-Q-U-E-I-R-A. And I
2 guess the one item that really wasn't on the agenda,
3 which I thought was going to be on there, related to
4 the issue of an RSO and who can basically sign off for
5 an authorized user for the RSO experience. I mean, I
6 saw that on the agenda for an earlier meeting, and I
7 guess either it was already discussed or it hasn't
8 been discussed at all.

9 CHAIRMAN MALMUD: It wasn't on the agenda
10 for this meeting, and I must say that --

11 DR. CERQUEIRA: This would be for 290
12 users. And it was obviously the discussion about the
13 390 and who could sign off, but --

14 CHAIRMAN MALMUD: Well, may we hear your
15 opinion regarding the issue?

16 DR. CERQUEIRA: Well, again, I remember
17 several years ago when we had discussions about
18 radiation safety officers for 300 and higher uses
19 that, you know, we felt it was appropriate for people
20 to have specific training in the type of therapy that
21 was being used, and that not all, you know, medical
22 physicists would receive the whole spectrum of use,
23 and, therefore, we required that there be sort of
24 specific training in that area.

25 And somehow I -- in some of the earlier

1 agenda items there was a discussion as to whether --
2 and if you were going to be an RSO, could an
3 authorized medical user sign off on you -- in terms of
4 the training and the experience. And there was some
5 interpretation that this would only be done by another
6 RSO, which certainly for the cardiologists and some of
7 the other users is going to present a problem.

8 So I guess I would really like to I guess
9 get some idea of when this would come up on the agenda
10 next, if at all. And I would -- is Dr. Zelac still
11 on, or -- because I believe he was the one associated
12 with the item.

13 CHAIRMAN MALMUD: Ron Zelac, are you still
14 with us?

15 (No response.)

16 No.

17 MEMBER NAG: This is Dr. Nag. I think
18 since this is not on the agenda, and it is bringing up
19 a new issue, it should be discussed in a separate
20 meeting.

21 CHAIRMAN MALMUD: Yes.

22 MEMBER NAG: But it certainly -- you know,
23 it's certainly separate from what we have been called
24 for.

25 MEMBER VETTER: This is Dick Vetter.

1 CHAIRMAN MALMUD: Dr. Vetter?

2 MEMBER VETTER: This was actually
3 discussed at the last ACMUI meeting, and this is the
4 result of that slippery slope we began. Dr.
5 Cerqueira, you may remember how the ACMUI -- the
6 position the ACMUI took on these matters, and then the
7 issue of attestation came up. And more recently, as
8 I recall the discussion, the NRC added the requirement
9 that the attestation for an authorized user to be the
10 RSO must be provided by an RSO.

11 DR. CERQUEIRA: Yes, sir. I guess it
12 would -- it was discussed at the last face-to-face
13 meeting.

14 MEMBER VETTER: Yes. Right. And that is
15 problematic. It's even problematic for the RSO,
16 because in a large training program the RSO doesn't
17 have the opportunity to interact very much with the
18 physicians who are in training, but yet must attest
19 that they could be the RSO. So that is problematic.

20 DR. CERQUEIRA: Well, again, I really
21 defer to the committee's judgment and Dr. Nag that it
22 not be in a suitable form, but I think it really does
23 need to have some discussion, perhaps at subsequent
24 meetings.

25 CHAIRMAN MALMUD: May we bring this up as

1 an agenda item at the upcoming meeting, Mr. Essig?

2 MR. ESSIG: Yes, you may.

3 CHAIRMAN MALMUD: Would you please put it
4 on the agenda for us?

5 MR. ESSIG: Certainly.

6 CHAIRMAN MALMUD: Thank you. Dr.
7 Cerqueira, thank you for bringing it to our attention.

8 DR. CERQUEIRA: My pleasure.

9 MEMBER NAG: Dr. Nag. Since we are about
10 to end, can we confirm that our NRC meeting is still
11 scheduled for October 24 and 25? We were supposed to
12 find out if the meeting room, etcetera, were
13 available.

14 CHAIRMAN MALMUD: I think Mr. Saba would
15 have the answer to that.

16 MEMBER NAG: Can you confirm whether we
17 have availability for the room and whether the meeting
18 is still for October 24 and 25?

19 MR. SABA: Yes. Yes, it is still the same
20 date. I will confirm that with an e-mail soon.

21 CHAIRMAN MALMUD: And location, Mr. Saba?

22 MR. SABA: It's usually the same. It's
23 usually in this building in the same conference room
24 that we had before.

25 CHAIRMAN MALMUD: Back at the NRC?

1 MR. SABA: Rockville. And something else
2 I wanted to tell you that -- remind you. Please send
3 your timesheet. It's due by Friday.

4 CHAIRMAN MALMUD: Thank you very much for
5 that reminder.

6 Are there any other items from the members
7 of the public besides Dr. Cerqueira?

8 (No response.)

9 We do have with us Chris Gallagher from
10 the ASMC, Emily Wilson from Astro, and Mike Peters
11 from SNM. Any comments from any of you?

12 (No response.)

13 If not --

14 MR. GALLAGHER: I would say -- Chris
15 Gallagher with ASMC. I would echo I think Dr.
16 Cerqueira's comments about the radiation safety
17 officer issue. And ASMC is pleased that the ACMUI
18 will discuss it at their next meeting.

19 CHAIRMAN MALMUD: Thank you.

20 MEMBER LIETO: Dr. Malmud?

21 CHAIRMAN MALMUD: Yes, sir.

22 MEMBER LIETO: Could we ask Dr. Cerqueira
23 and Mr. Gallagher if they would be willing to maybe
24 provide some type of statement of the problem
25 specifically from their perspective as authorized

1 users? Because sometimes I think we medical
2 physicists kind of look at it from maybe a little bit
3 different side of the fence than the clinical side.
4 And if they could maybe give us some specifics, that
5 would be very helpful.

6 MR. CERQUEIRA: Happy to do that.

7 CHAIRMAN MALMUD: Thank you. And Dr.
8 Cerqueira knows how to address -- to whom to address
9 that I'm certain.

10 MR. CERQUEIRA: Yes.

11 CHAIRMAN MALMUD: For those of you who are
12 not familiar, Dr. Cerqueira preceded me as the
13 Chairman of this committee.

14 MR. CERQUEIRA: Five wonderful years.

15 (Laughter.)

16 CHAIRMAN MALMUD: Is there a motion for
17 adjournment?

18 PARTICIPANT: So moved.

19 PARTICIPANT: Second.

20 CHAIRMAN MALMUD: Thank you all, and thank
21 you for your participation. I thank staff for its
22 work and the members of the public for having been
23 present. Thank you very much.

24 (Whereupon, at 5:30 p.m., the proceedings
25 in the foregoing matter were adjourned.)