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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

+ + + + +

MONDAY,

MARCH 22, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met at 1:00 p.m.. in T10c2 of the Nuclear Regulatory Commission, 11545 Rockville Pike, Dr. Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D.

, Nuclear Cardiologist,

Chairman

LEON S. MALMUD, M.D., Health Care Administrator,

Vice Chair

DOUGLAS F. EGGLI, M.D., Nuclear Medicine Physician

NEKITA HOBSON, Patient Advocate

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1 RALPH P. LIETO, Medical Physicist, Nuclear Medicine

2

3 COMMITTEE MEMBERS:

4 RUTH McBURNEY, State Robinson

5 SUBIR NAG, M.D., Radiation Oncologist

6 SALLY WAGNER SCHWARZ, RPh., Nuclear Pharmacist

7 ORHAN H. SULEIMAN, Ph.D.

8 Food and Drug Administration Representative

9 RICHARD J. VETTER, Ph.D., Radiation Safety Officer

10 JEFFREY F. WILLIAMSON, Ph.D., Therapy Physicist

11 NRC STAFF PRESENT:

12 ROGER W. BROSEUS, CHP, Ph.D, NMSS/IMNS/RGB

13 SUSAN CHIDAKEL, OGC

14 THOMAS H. ESSIG, Designated Federal Official,

15 NMSS/IMNS/MSIB

16 DONNA-BETH HOWE, Ph.D., NMSS/IMNS/MSIB

17 SAMI SHERBINI, Ph.D, NMSS/IMNS/MSIB

18 ANITA TURNER, Ph.D., NMSS/IMNS/MSIB

19 SANDRA WASTLER, NMSS/IMNS/RGB

20 ANGELA R. WILLIAMSON, NMSS/IMNS/MSIB

21 RONALD E. ZELAC, Ph.D., NMSS/IMNS/MSIB

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Dr. Malmud

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

1:05 p.m.

1
2
3 MR. ESSIG: Okay. This is Tom Essig
4 from NRC. I'm Designated Federal Official, and I
5 have about 1:05 eastern time by my watch, and I
6 think we should go ahead. I've heard a number of
7 key people announce their presence.

8 So let me just start with my opening
9 remarks.

10 DR. NAG: Dr. Nag joining in.

11 MR. ESSIG: Okay. As Designated Federal
12 Official for this meeting, I am pleased to welcome
13 you to the publicly noticed conference call meeting
14 of the ACMUI.

15 As I said, my name is Thomas Essig. I am
16 the Branch Chief for the Materials Safety Inspection
17 Branch and have been designed as the Federal
18 Official for this Advisory Committee in accordance
19 with 10 CFR Part 7.11. This is an announced meeting
20 of the Committee, it is being held in accordance
21 with the rules and regulations of the Federal
22 Advisory Committee Act and the Nuclear Regulatory
23 Commission.

24 The meeting was announced in the March
25 10, 2005 edition of the *Federal Register*.

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

7 The NRC solicits the views of the
8 Committee and values them very much.

9 I'll request that whenever possible we
10 try to reach a consensus on the various issues that
11 we will discuss during this conference call, but I
12 also value minority or dissenting opinions. If you
13 have such opinions, please allow them to be read
14 into the record.

15 As part of the preparation for this
16 meeting, I have reviewed the agenda for members and
17 employment interests based on the general nature of
18 the discussion that we're going to have today.

19 I've identified the item related to St.
20 Joseph Mercy Hospital dose reconstruction as posing
21 a conflict for Committee member Ralph Lieto.
22 Because that hospital is Mr. Lieto's current
23 employer, I ask that he not participate in any of
24 the Committee's decision making activities, other
25 formal actions, recommendation or conclusions

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1 related to the dose reconstruction effort for the
2 St. Joseph Mercy Hospital case.

3 If during the course of our business,
4 other members determine that they have a conflict of
5 interest in matters before the Committee, please
6 state it for the record and recuse yourself from
7 that particular aspect of the discussion.

8 One administrative point which I would
9 like to raise concerns the need for clearly
10 identifying action items which are being proposed or
11 existing action items for which status information
12 is either sought or being presented. Clearly
13 calling out these items during our discussion will
14 facilitate a search of the transcript following the
15 meetings. The existing process for Committee
16 motions already does this. We would like to
17 establish a comparable process for action items.

18 At this point I would like to perform a
19 roll call of Committee members that may be
20 participating today.

21 Dr. Cerqueira, I believe I heard you
22 before?

23 DR. CERQUEIRA: Yes, I'm on.

24 MR. ESSIG: Dr. Malmud?

25 DR. MALMUD: Yes.

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1 MR. ESSIG: And Nekita Hobson?

2 MS. HOBSON: Yes.

3 MR. ESSIG: Ruth McBurney?

4 MR. MCBURNEY: Yes.

5 MR. ESSIG: Dr. Eggli?

6 DR. EGGLI: Present.

7 MR. ESSIG: Dr. Diamond, I understand a
8 medical emergency and will not be with us today.

9 And Dr. Nag?

10 DR. NAG: Yes.

11 MR. ESSIG: Sally Schwarz?

12 MS. WILLIAMSON: She was on earlier.

13 MR. ESSIG: Sally was on.

14 MS. SCHWARZ: I'm here.

15 MR. ESSIG: Oh, you are here. Okay.

16 MS. SCHWARZ: I'm here.

17 MR. ESSIG: All right.

18 Dr. Vetter?

19 DR. VETTER: Here.

20 MR. ESSIG: Dr. Williamson?

21 DR. WILLIAMSON: Present.

22 MR. ESSIG: Okay. Ralph Lieto.

23 MR. LIETO: Present.

24 MR. ESSIG: Okay. And Dr. Suleiman from
25 FDA? Okay. Not present.

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1 And Dr. Schenter, I believe you said you
2 here.

3 DR. SCHENTER: Yes.

4 MR. ESSIG: Dr. Van Decker? Who is our
5 other new member, a nuclear cardiologist.

6 And Mr. Ed Bailey? Okay. Who is our
7 new State Representative.

8 And I'll now ask the NRC staff to
9 identify themselves. So we could just go around the
10 room where I am and there may be others from NRC who
11 have dialed in from other locations.

12 As I mentioned, I'm Tom Essig. And I'll
13 go to my left.

14 DR. HOWE: Dr. Donna-Beth Howe in the
15 MSIB.

16 MS. WILLIAMSON: Angela Williamson,
17 MSIB.

18 MS. TURNER: Anita Turner, MSIB.

19 MS. WASTLER: Sandra Wastler, RGB.

20 DR. BROSEUS: Roger Broseus, Rule Making
21 Guidance Branch.

22 MS. CHIDAKEL: Susan Chidakel, Office of
23 General Counsel.

24 MR. ESSIG: Are there any other NRC
25 staff on the line? I'm sorry.

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1 MR. ZELAC: Ronald Zelac.

2 MR. ROSEN: Okay. You sound like you're
3 500 miles away, Ron.

4 MR. ZELAC: I'm using a headset. I'll
5 try to speak loudly.

6 MR. ESSIG: Okay. Thank you.

7 And as far as members of the public, I
8 know beforehand we had indicated that Dr. Carol
9 Marcus, who I've already heard is present, and Dr.
10 Jeffrey Siegel also is present.

11 Is Gerald White on? Rohsunda Drummond?

12 MS. DRUMMOND: Yes, I'm here.

13 MR. ESSIG: Okay. William Uffelman?

14 MR. UFFELMAN: I'm here.

15 MR. ESSIG: That was here?

16 MR. UFFELMAN: I'm here, yes.

17 MR. ESSIG: Okay. And Fairobent?

18 MS. FAIROBENT: Yes.

19 MR. ESSIG: Okay. And Cassandra Foens?

20 MS. FAIROBENT: No. Dr. Foens had an
21 emergency.

22 MR. ESSIG: Okay. I believe that that
23 takes care of the preliminary remarks.

24 And, Dr. Cerqueira, I will now turn it
25 over to you to open the meeting.

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1 DR. CERQUEIRA: Tom, do you have the
2 agenda?

3 MR. ESSIG: Well, we only have two items
4 on the agenda. One was related to a further
5 discussion of Part 35, specifically the T&E issue
6 and the 35.100. As you recall from our last noticed
7 meeting, we had deferred until the next conference
8 call issues that -- unfortunately Dr. Diamond
9 couldn't be with today because the reason for
10 deferring the issues is because I believe that Dr.
11 Nag had to leave early and Dr. Diamond was not able
12 to be present. And so we wanted to defer certain
13 issues to this call so that we could have the
14 opportunity of Dr. Nag and Diamond to both weigh in
15 on them.

16 The other item that we wanted to discuss
17 is the dose reconstruction issue, the status of the
18 Subcommittee for the St. Joseph Mercy Hospital case.

19 So basically it was those two agenda
20 items.

21 DR. NAG: Right. So the training and
22 experience with -- was now that just related to the
23 1,000 series?

24 MR. ESSIG: I know -- go ahead.

25 DR. BROSEUS: This is Roger Broseus.

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1 I'm understanding is we're actually
2 supposed to be talking -- the aim of the Committee
3 was to talk about 35.390 as it relates to radiation
4 oncologists training experience and qualifications
5 for --

6 MS. YAK: This is me, it's Frances Yak.
7 Sorry about that.

8 DR. BROSEUS: So you guys can correct me
9 if I'm wrong, but that was the significant T&E issue
10 from the last agenda and why the radiation
11 oncologists were to weigh in on the call.

12 DR. WILLIAMSON: This is Jeff
13 Williamson.

14 That is correct, I believe.

15 DR. CERQUEIRA: Yes, that was my
16 understanding, too. So, why don't we start with
17 that. And, Jeff, maybe you could lead us through
18 this.

19 DR. WILLIAMSON: Okay. Let me make a
20 couple of comments.

21 I did circulate a written proposal to
22 the group, so a little background. Prior to the new
23 Part 35 going into force in October, the radiation
24 oncology certification through the American Board of
25 Radiology was an acceptable credential for being an

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1 authorized user for radiopharmaceuticals, for which
2 a written directive is required.

3 The new Part 35 basically put in place
4 the old Part 35, or essentially put in place as
5 Board qualification criteria the alternate pathway
6 requirements, and among with perhaps other boards,
7 American Board of Radiology, our old certification,
8 couldn't meet those in part, because the way the
9 Board examine is structured.

10 So the ACMUI T&E Committee attempted to
11 try to rectify this, and you can see that is in the
12 first half of the proposal I circulated. And what
13 it essentially did was place the requirement for
14 supervised clinical experience with 12 different
15 cases distributed in 4 different categories at the
16 end of the T&E requirement, which would be a common
17 but separate requirement applying to those who are
18 qualifying as authorized users both by virtue of
19 Board certification and alternate pathway training.

20 So what I have done is, somehow I will
21 mention although I believe it was the intent of the
22 Subcommittee, the final proposal draft was sent
23 forward by the staff, you know, in the
24 Subcommittee's name did not have exactly this draft
25 proposal in place.

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1 So, as a follow up to the last meeting,
2 I attempted to rewrite 35.390 in the form that you
3 see before you. I hope you all have it. Would it be
4 helpful if I stepped through it bit by bit? Okay.

5 So the proposal reads as follows:

6 "Except as provided in Sec. 35.57, the licensee
7 shall require an authorized user of unsealed
8 byproduct material for the uses authorized under
9 Sec. 35.300 to be a physician who:

10 (a) Is certified by medical specialty
11 board whose certification process includes all of
12 the requirements in paragraph (b) of this section."

13 Let me make sure I'm reading the right
14 one. Yes, I am. Okay.

15 "Whose certification has been recognized
16 by the Commission or an Agreement State...To be
17 recognized, a specialty board shall require all
18 candidates for certification to:

19 1) Successfully complete a minimum of 3
20 years of residency training in a
21 radiation therapy program approved by
22 the Residency Review Committee of..."
23 so-and-so and so on. I won't belabor
24 all of that. "Or a training program in
25 nuclear medicine or a related medical

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1 specialty that includes 700 hours of
2 training and experience as described in
3 paragraph (b) of this section.

4 Okay. So notice how it's stated. It
5 basically says complete a 3 year residency in
6 radiation oncology, approved by such-and-so or
7 training in a nuclear medicine or related medical
8 specialty program that includes 700 hours of
9 training and experience as described as in paragraph
10 (b).

11 So the idea is that there two groups in
12 here. Radiation oncology who defines the
13 appropriate residency, experience by means of this
14 approval mechanism and the nuclear medicine
15 community who defines what constitutes a program by
16 reference to the alternative pathway requirements.

17 2) Pass an examination,
18 administered by diplomates of
19 the specialty board, which
20 tests knowledge and competence
21 in radiation safety,
22 radionuclide handling, quality
23 assurance, and clinical use of
24 unsealed byproduct materials;
25 quality assurance, and

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1 clinical use.

2 So I see that, you know, my version has
3 a mistake. The second line shouldn't say "includes
4 all the requirements of paragraph (b).

5 Then paragraph (b) is essentially
6 unaltered from the current regulation. It says "Has
7 completed 700 hours of training and experience" and
8 it goes through the classroom, the work experience
9 and lists, you know, the work experiences (A)
10 through (E), whatever they are.

11 What it does not list now are 12 cases.

12 Then (c) says, paragraph (c) says: "In
13 addition to meeting the requirements of (a) or (b)
14 of this section, an authorized user of byproduct
15 material authorized under 35.300:

16 (1) Must have experience, under
17 the supervision of an
18 authorized user, administering
19 dosages of radioactive drugs
20 to patients or human research
21 subjects involving a minimum
22 of three cases in each of the
23 following categories."

24 And then these categories (A) through
25 (D) are just like they are in the current paragraph

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1 (b) except they're now moved to this new paragraph
2 (c).

3 Okay. So (c)(1) has the 12 cases of
4 supervised experience. (c)(2) is:

5 "Have obtained written
6 attestation that the
7 individual has satisfactorily
8 completed the requirements in
9 paragraph (a) or (b) of this
10 section and has achieved a
11 level of competency sufficient
12 to function independently as
13 an authorized user for the
14 medical uses authorized under
15 35.300."

16 And it basically states the same
17 requirements for authorized user preceptor that is
18 in the current regulation. Basically requiring that
19 the preceptor be an actual 35.300 AU or I suppose
20 partially certified or recognized AUs might also be
21 acceptable.

22 So that's the proposal. So the essence
23 of it is is that radiation oncology doesn't have to
24 comply with the letter of everything that's in
25 paragraph (b), any other residency experience does.

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1 But no matter which of the two pathways you go
2 through, the board certification or the alternative
3 pathway, at the end there is requirement (c), which
4 is 12 cases plus preceptor stage.

5 MR. MCBURNEY: This is Ruth McBurney.

6 In the paragraph (a) you said that the
7 requirements in paragraph (b) did not apply?

8 DR. WILLIAMSON: Yes. What I should
9 have excluded, in paragraph (a) the second line
10 includes all the requirements of paragraph (b) in
11 this section. That should be deleted. I meant to
12 delete it. It's just a mistake on my part. I cut
13 and pasted this from the current regulation.

14 So that's what I intended to do, so if
15 you would make that correction in my proposal, I'd
16 appreciate it.

17 DR. CERQUEIRA: All right. Now, Roger,
18 are you on the line? I guess I have a couple of
19 sort of -- and it really relates to part (a) where
20 we actually are listing the boards.

21 DR. BROSEUS: Excuse me. Dr. Cerqueira?

22 DR. CERQUEIRA: Yes.

23 DR. BROSEUS: This is Roger Broseus.

24 We have a paper copy here that has about
25 five pages. And I wanted to make sure that we were

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1 all the same page.

2 I'm reading from page 3. It says
3 "Proposed 390 Language: Jeffrey F. Williamson." Is
4 that where you want us to be, Jeff?

5 DR. WILLIAMSON: Yes.

6 DR. BROSEUS: Thank you.

7 DR. WILLIAMSON: And we are talking
8 about the paragraph (a) under the second line, the
9 entirety of the second line as I see it on my screen
10 should be struck out.

11 DR. BROSEUS: Thank you, Dr. Cerqueira.

12 DR. CERQUEIRA: Okay. That clarified it
13 I guess for me as well.

14 All right. Questions for Jeffrey?

15 DR. EGGLI: Yes. Jeff, are you
16 intending to say that basically everybody but
17 radiation oncologists have to meet the 700 hour
18 training requirement? And if so, why?

19 DR. WILLIAMSON: Well, the 700 hour
20 requirement basically has inserted in it that the
21 individual supervising it has to be an AU. And, you
22 know, for the same reason that radiation oncologists
23 couldn't be qualified to be AUs, even for their own
24 modalities, it was because the board eligibility
25 process doesn't require or doesn't have a mechanism

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1 for having AUs and preceptor statements in it. So,
2 that's one reason for moving it out.

3 But I would say the underlying reason
4 is, is that -- and Dr. Nag can correct me. I'm
5 trying to represent his discipline now.

6 I would say overall about 40 percent of
7 radiation oncologists have a substantial practice in
8 radionuclide therapy. So it is it not radiation
9 oncologists. And they have very successfully pursued
10 it under the existing regulations which doesn't
11 require them to, you know, basically show any of
12 this. Just simply the board certification alone was
13 hardwired into the current regulation. So, what I'm
14 trying to do, I guess the underlying intent is to
15 create a pathway by which graduates of those
16 particular programs that do have clinical experience
17 can become authorized users for this modality and
18 not have an unduly high burden placed upon them.

19 So the compromise I'm suggesting is that
20 the detailed training and experience requirements,
21 which were deleted by the way from the HDR
22 brachytherapy and gamma knife T&Es, you know, be
23 struck from this and stated in more general form, as
24 I have done in the examine requirements. But then
25 have the clinical experience requirement as a sort

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1 of separate requirement that would allow those
2 individuals to pass through the system of
3 qualification of AU without significantly more
4 hassle than they have now.

5 DR. NAG: Yes. A simpler possibility
6 would be like if somebody is board certified in
7 radiation oncology, they just have to show that they
8 have done those three cases in those subjects, and
9 therefore a total of those 12 cases.

10 You know, if you have radiation oncology
11 board only limiting board and you show you had those
12 cases that were done, then you would qualify for the
13 1000. That would be a shorter way.

14 DR. EGGLI: Okay. Again, Jeff, the way
15 you have this written nuclear medicine physicians
16 who are the primary practitioners of 390 are held to
17 a different and higher standard than the radiation
18 oncologists. Because in the current system, again,
19 board certification in nuclear medicine without
20 specific documentation of these requirements is
21 adequate training to become a practitioner of 390.
22 And I'm not sure that it's reasonable to set up two
23 different classes of standards: One for radiation
24 oncology whose programs may or may not include all
25 of these requirements and one for nuclear medicine

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1 who, although their programs traditionally do
2 include all of these requirements, have never been
3 in the past required to document that. I don't
4 think it's reasonable to set up two different
5 classes of users.

6 DR. WILLIAMSON: Well, I'm open to that.
7 The only reason I left it that way is because I
8 thought your community was content for yourselves
9 the way the proposed regulation was written. So I
10 just left it intact so it's exactly the same way as
11 the regulation that was published in the *Federal*
12 *Register* in December, I guess.

13 DR. NAG: I guess from a sense of --

14 DR. WILLIAMSON: I mean, I have no
15 objection whatsoever to changing it and making it
16 more performance based for the nuclear medicine
17 community.

18 DR. EGGLI: Okay. I just think it's
19 unreasonable to have two different standards. And
20 that whatever the standard for training and
21 experience is, it should apply uniformly and not
22 discreetly.

23 DR. WILLIAMSON: I would accept that. I
24 think then, you know, there has to be an alternative
25 definition of what kinds of training programs are to

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1 be included in the scope of this regulation.

2 And, you know, the only reason I left it
3 as what I said in my preamble, is I had this perhaps
4 mistaken assumption that you all, meaning you in the
5 nuclear medicine community, were using these
6 alternative pathway requirements to define what were
7 appropriate residency programs rather than enumerate
8 them.

9 DR. NAG: Yes. What we can say, anyone
10 who has the nuclear medicine boards or the radiation
11 oncology boards and can show that they have the
12 preceptors in those qualifications will qualify.
13 That makes it: (1) nondiscriminate, or; (2)
14 simpler, and; (3) it ensures that they have, you
15 know, sufficient training and handling in
16 radioactive materials and they have the practical
17 experience as well. I mean I think that would be
18 one --

19 DR. WILLIAMSON: I certainly wouldn't
20 oppose that.

21 MR. McBURNEY: And just a question for
22 my own knowledge. The examination for the American
23 Board of Radiology in radiation oncology does
24 include unsealed radioactive materials handling?

25 DR. NAG: Yes, it does include that.

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1 But it does not go into each specific -- it does
2 require you know about both sealed sources, unsealed
3 sources, but it doesn't categorize and say you must
4 have 12 cases.

5 MR. MCBURNEY: Right.

6 DR. NAG: So that's why I want to put
7 those number of cases in there.

8 MR. MCBURNEY: Right.

9 DR. WILLIAMSON: Yes. I agree, in fact.

10 MR. MCBURNEY: No, I was just asking
11 about the examination and (a) (2).

12 DR. WILLIAMSON: Yes. In physics when
13 we have the didactic lectures to the radiation
14 oncology residents, yes, we have to include lectures
15 on radionuclide therapy, dosimetry, source handling,
16 prescription. So, you know, we cover it in the same
17 way we cover the didactic principles of
18 brachytherapy.

19 MR. MCBURNEY: Right. Okay.

20 DR. NAG: Yes. I think, you know, the
21 thing is there is also you have written up, it
22 belongs so long that at the end you try to figure
23 out, you know, what is what and what even it
24 capture. You keep it simple and say you need to
25 have a board certification in radiology and

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1 therapeutic radiology on implementing the system and
2 demonstrate -- it makes life a lot simpler and it
3 makes the board to be level --

4 DR. WILLIAMSON: Well, I certainly would
5 support that. You know, I gave you my reasons for
6 leaving it the way it was.

7 DR. NAG: Right. Right. I know.

8 DR. WILLIAMSON: And that I thought the
9 --

10 DR. NAG: Well, what I meant is if all
11 the other Committee members feel that would make
12 things simpler, we can just have it that way. Make
13 it a lot simpler.

14 DR. WILLIAMSON: I agree.

15 DR. CERQUEIRA: So, Doug and Leon, would
16 that satisfy your concerns?

17 DR. MALMUD: It would satisfy mine.

18 Dr. Eggli?

19 DR. EGGLI: Yes. Essentially. I could
20 go either way for either of the two routes, but I
21 think that they should be the same for all 390
22 practitioners. So, yes, that would satisfy me.

23 MR. LIETO: I seem to recollect from Dr.
24 Diamond that his concern was that some of the
25 specifics, in particular are listed in Jeff's page 4

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1 under sub item (2) where it lists the specific
2 things like ordering, receiving and unpacking and so
3 forth. His objection was the requirement for
4 generator elution, quality control so forth that
5 really they would never do or have reason to do in
6 radiation oncology. And I think that that was one of
7 the items that he was concerned about being a
8 requirement for radiation oncology program.

9 DR. WILLIAMSON: That is, indeed. I
10 mean, eluting generator systems, as I naively
11 understand it, has to do with keeping on hand large
12 stores of technetium-99m, I assume.

13 MR. LIETO: Right. It didn't have any
14 relevance --

15 DR. WILLIAMSON: Yes, it doesn't have
16 any relevance to this.

17 MR. LIETO: And so that was one of the
18 things that, if my memory serves right about his
19 concern, was that 700 hour piece.

20 I don't think there was an objection to
21 the 700 hour requirement.

22 DR. WILLIAMSON: Well, I think there are
23 several objections to it. One was missed by the
24 original ACMUI Subcommittee on this business. And
25 first of all, it says that it has to be under the

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1 supervision of an authorized user that meets the
2 requirements of 35.390(a). Okay. Now, that is not
3 going to fit with the ABR paradigm of doing things,
4 because even in brachytherapy and in gamma
5 stereotactic, which are in the province very
6 uncontroversially of radiation oncology, that
7 requirement couldn't be met.

8 MR. LIETO: Yes. I don't object to that
9 particular phrase being removed, Jeff. I think my
10 point was that just the 700 hour requirement itself,
11 I don't think there was an objection of that by --

12 DR. WILLIAMSON: Well, there is. If it's
13 understood that the 700 hours devoted exclusively to
14 radionuclide therapy. As I mentioned, at least half
15 of the radiation oncology training programs do not
16 have a significant component of this in their
17 training program. And so if you can make the case
18 that even one individual will be allowed to sit for
19 the boards without having all of this, then it
20 disqualifies the whole board from being a default
21 credential for this process. So you have to really
22 careful.

23 I think the proposal to get around the
24 requirements is a good one, which is let's not be so
25 prescriptive. Let's, you know, basically try to be

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1 more performance based and just basically say you
2 have to have this clinical supervised experience
3 plus you have to have the board certification, which
4 gives you a general and good training in
5 radionuclide handling. And that plus the case
6 experience will be enough for all applicants for
7 35.300 AU status, then we don't have to worry is
8 this a good requirement, but that one a bad one.
9 And simply leave paragraph (b) intact for the
10 alternative pathway.

11 DR. NAG: I think I would agree. I mean
12 I think we should make the simpler, easy to swallow
13 and also make sure we cover the bases but yet not be
14 too overly prescriptive.

15 MR. LIETO: So, Jeff, if I understand
16 you correctly, then what you're suggesting also is
17 that in your proposed paragraph (a)(1) that you
18 would remove that last couple of lines there stating
19 includes 700 hours of training and experience?

20 DR. WILLIAMSON: That's correct. So
21 what we would do is replace training program in
22 nuclear medicine or related medical specialty that
23 includes 700 hours of training and experience that's
24 described in paragraph (b) with some kind of
25 enumeration of the appropriate residency training

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1 experiences that, I guess, we will rely on Dr.
2 Eggli, perhaps, our nuclear medicine colleagues on
3 the Committee to supply. Because I don't know how
4 to do it.

5 MR. MCBURNEY: I think there's a ACGME
6 residency, I mean, for that as well.

7 DR. WILLIAMSON: Yes. So I think that
8 the good proposal is just to enumerate the
9 appropriate residency experiences; diagnostic
10 radiology, accredited residency would do as well as
11 however many different kinds of specific nuclear
12 medicine residency experiences there may be. Again-
13 -

14 MR. LIETO: What you're saying then,
15 though, that all the nuclear medicine and radiology
16 programs have to fit into the alternate pathway?

17 DR. WILLIAMSON: No, I'm not, at all.

18 MR. MCBURNEY: No.

19 MR. LIETO: Well, you're striking it out
20 of (a).

21 DR. WILLIAMSON: We're striking it out
22 of paragraph (a) entirely. So in paragraph (a)
23 there will be no reference to paragraph (b). That's
24 what Dr. Nag and Dr. Eggli's proposal amounts to.

25 MR. LIETO: Well, if I'm reading it

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1 right now, (a) (1) says: successfully completes a 3
2 year residency training in a radiation therapy
3 program approved so forth and so on. So where do
4 the other programs comes in?

5 DR. WILLIAMSON: Well, we're going to
6 have to come up with language describing each one of
7 them, like that. Okay. So all of the radiation
8 oncology AU descriptions all have this phrase in
9 there. They define themselves by using the words
10 radiation oncology and residency program approved by
11 the Residency Review Committee of the ACGME or Royal
12 College of Physicians, or Surgeons, whatever it is.
13 So we have to come up with a similar list for the
14 other nuclear medicine and related medical
15 specialties. And then, you know, they are no longer
16 going to be defined by a reference to paragraph (b).
17 And I think that's what Dr. Nag/Eggli proposal
18 amounts to.

19 And paragraph (b) would remain, maybe
20 with the removal of the elution of generators.

21 MS. SCHWARZ: I think that will be a
22 good idea.

23 DR. WILLIAMSON: For a definition of the
24 alternate pathway only. And so we would have then
25 the criteria for (a) (1) (2) would be the criteria for

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1 board recognition. Then paragraph (b) will be the
2 sort of equivalence training and experience for
3 alternate pathway. And then paragraph (c) is the
4 common requirement for documented and supervised
5 clinical experience with 12 cases plus preceptor.

6 And that way, you know, I think
7 certainly would I think satisfy the needs of the
8 radiation oncology community and allow my clinical
9 colleagues to remain in this practice.

10 DR. VETTER: I think I like that
11 proposal, but I have another question for Drs. Eggli
12 and Malmud.

13 I don't know if you know the history.
14 Where did three years of residency come from and is
15 that an appropriate amount of time? Do you really
16 need to be in a residency 3 years to use
17 radionuclide therapy safety?

18 MR. UFFELMAN: If I may intrude on the
19 Committee's discussion. In SNM's letter responding
20 to the rule, we pointed out that when in fact when
21 the radiation oncologists were added that the 3 year
22 just in order in which it appears, the 3 years of
23 radiation oncology got in there which made it appear
24 that the nuclear medicine physicians were in fact
25 subject to that, when in fact their residency is a

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1 two year residency. And so we had actually
2 suggested some alternate punctuation that made it
3 clear how it should have been when that was first
4 added by the ACMUI last summer.

5 MS. FAIROBENT: We did the same thing in
6 our letter from us and the other associations.
7 Basically it was to clarify that the 3 years
8 residency applied to radiation therapy, that there
9 was 2 years of nuclear medicine residency program
10 or, any other program in a related medical specialty
11 that includes the 700 hours.

12 One of the concerns in listening to this
13 discussion I have of completely taking out any tie,
14 and I throw this back to Dr. Cerqueira, I think that
15 if you take out any reference at all to another
16 related medical specialty including 700 hours, what
17 does that do for the nuclear cardiology?

18 DR. CERQUEIRA: Well, this is for 390.

19 MS. FAIROBENT: Okay.

20 DR. CERQUEIRA: So our people would not
21 really be involved in this.

22 MS. FAIROBENT: Okay.

23 DR. CERQUEIRA: And I guess the
24 endocrinologists would not be covered by this
25 because they're not using doses in this amount. Is

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1 that correct, Jeff?

2 MS. FAIROBENT: Yes, that would be the
3 80 training under 392 and 394.

4 DR. WILLIAMSON: Yes. They have their
5 own sort of single indication I-131 AU definitions.

6 DR. EGGLI: In response to the 3 year
7 residency issue, if that 3 year just were removed
8 altogether and it would be defined as a residency
9 program approved by ACGME, the Residency Review
10 Committee of the ACGME, then ACGME for radiation
11 oncology determines that the residency is 3 years,
12 for nuclear medicine 2 years, and is it necessary to
13 have a reference to the time or just to the fact
14 that the residency is approved by the Residency
15 Review Committee of the ACGME?

16 DR. NAG: I was going to add that
17 similar suggestion that let's not make one three
18 year and one two year. We know that the residency
19 program have their own standards. And so it let it
20 be what the residency standards are and so long as
21 they're are board certified, they are board
22 certified. Let the board certification. Now
23 radiation oncology 4 years. So we don't need to say
24 how many years.

25 DR. WILLIAMSON: I agree with Dr. Nag's

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1 suggestion. I think there's no reason. In fact,
2 the requirement is now for 4 years of radiation
3 oncology.

4 MS. DRUMMOND: This is Roshunda Drummond
5 with ASTRO.

6 And I just wanted to point out that in
7 the joint comment letter we also highlighted that
8 point that the radiation oncology residency program
9 far exceeds what's already stated in 35.390. So we
10 also support that contingent that the 3 years just
11 be taken out altogether and just to say what the
12 program actually requires, the residency program
13 already requires.

14 DR. CERQUEIRA: So it seems like the
15 general agreement, yo know, leaving it up to the
16 programs, the ACGME accreditation, would be the
17 appropriate way to do it. And does anybody object
18 to do doing it that way, to not specifically state a
19 time period?

20 DR. MALMUD: I don't object, but I have
21 one or two questions.

22 The first one is this: Is board
23 certification a requirement or eligibility for
24 board certification adequate?

25 DR. WILLIAMSON: It's board

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1 certification.

2 DR. MALMUD: So we agree it's board
3 certification?

4 DR. WILLIAMSON: Yes. I mean, there's
5 two requirements; having the residency and passing
6 the examine.

7 MR. McBURNEY: That's the A path, yes.

8 DR. MALMUD: All right. So then if
9 that's the case, then under 35.390 subheading (a)
10 and under that subheading (b) and then under (b)
11 number (1) that should read: "To successfully
12 complete ACGME board certification in radiation
13 oncology, nuclear medicine, or a program in related
14 medical specialty..." etcetera. Is that the wording
15 that is discussable?

16 DR. WILLIAMSON: I think that in this
17 definition you can't have the word "related medical
18 specialty." I think it has to be more specific.

19 DR. NAG: Yes. I believe that, too.
20 Because, you know, radiation oncology and nuclear
21 medicine we know that they do cover all of this.

22 DR. WILLIAMSON: And radiology, too.

23 DR. NAG: Yes. If you say and related
24 specialty, someone may say well, I am in thyroid
25 disorders and it's a related specialty and so I

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1 claim a background.

2 So, the word related becomes very vague.

3 DR. MALMUD: Fine. What is the wording
4 that is preferred? Could someone read subheading
5 (b) paragraph (1) to me so that I can agree or
6 disagree with it?

7 DR. WILLIAMSON: I suppose successfully
8 complete a residency training program in a radiation
9 therapy program approved by X, Y or Z. I guess, no.
10 A radiation oncology, nuclear medicine, or radiology
11 program approved by blah, blah, blah. But it may not
12 be able to be so simple. I think you might have to
13 have a separate phrase for each one, because I'm not
14 sure necessarily all the nuclear medicine, radiology
15 and radiation oncology programs are approved by the
16 same entity.

17 DR. EGGLI: I think it actually is
18 pretty much similar.

19 DR. WILLIAMSON: Okay.

20 DR. EGGLI: There's a ACGME, there's the
21 Royal College of Canada, and there's the osteopathic
22 group for nuclear medicine.

23 DR. WILLIAMSON: Okay.

24 DR. EGGLI: And I believe they're quite
25 similar for diagnostic radiology as well.

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1 DR. WILLIAMSON: Okay. Well, if that's
2 so, then it could read --

3 MS. FAIROBENT: My only concern is
4 trying to identify these, I'm looking back at the
5 original language in subpart (a)(4) this type of
6 stuff. And because, in fact, the certification
7 titles have changed over the years, I'm a little
8 concerned that if we start specifying and calling
9 out certification areas, that we may in fact
10 disenfranchise some people who have older
11 certification titles.

12 In subpart (j) --

13 DR. WILLIAMSON: But hold on, Lynne.
14 We're not enumerating certifications. We're
15 enumerating residency experiences that are eligible
16 that make a certification process eligible.

17 MS. FAIROBENT: Okay. But if you looked
18 up in the old language under subpart (g), the ABR
19 certifications were in radiology, therapeutic
20 radiology or radiation oncology.

21 DR. WILLIAMSON: But those are the
22 certifications.

23 MS. FAIROBENT: I would assume the
24 residency programs pretty much back at those times,
25 went along with it.

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1 DR. CERQUEIRA: This probably falls into
2 the area of grandfathering. I think what we're
3 proposing is basically applicable to people who are
4 starting training or currently in training. In some
5 of these other issues, what do we do in terms of
6 people who are currently practicing? But shouldn't
7 they already be qualified, Jeff?

8 MS. FAIROBENT: They may not be on a
9 license.

10 DR. WILLIAMSON: But, Lynne, why then
11 aren't the 600 and 400 rules also subject to that
12 criticism, and ACR never commented on that?

13 MS. FAIROBENT: The 600 and 400 was only
14 the -- in fact, we did comment in the past on those,
15 Jeff.

16 DR. WILLIAMSON: But it does say, it
17 uses the word "radiation oncology residency" to
18 define them. So why would it be wrong to use the
19 word radiation oncology residency in 300 if we use
20 it in all the other regulations?

21 MS. FAIROBENT: I'm not questioning on
22 the oncology side. I'm trying to be sure we're all
23 inclusive on the diagnostic radiology and nuclear
24 medicine side. And just saying simply nuclear
25 medicine, I don't think we are all inclusive for ABR

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1 radiologists that are also certified and authorized
2 users under 300.

3 DR. WILLIAMSON: So it probably means a
4 little research needs to be done.

5 MR. ESSIG: Okay. You going to do it,
6 Jeff?

7 DR. WILLIAMSON: Well, I thought the NRC
8 had a staff?

9 DR. CERQUEIRA: Tom, any staff that can
10 help Jeff out on this?

11 MR. ESSIG: Is the question whether or
12 not we can do the -- I wasn't quite sure what Jeff's
13 reference was to.

14 DR. WILLIAMSON: Well, I think the
15 concern is that some research needs to be done to
16 identify all of the types of residency experiences
17 on the nuclear medicine side that we would want to
18 put in the scope of this regulation. And --

19 DR. NAG: Well, one question is that,
20 you know, they always have the alternative pathway
21 to provide. If they are only going to be, you know,
22 one or two or very few numbered, they can always use
23 the alternative pathway.

24 DR. WILLIAMSON: Well, I think it's a
25 legitimate question that Lynne raises. I think,

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1 though, I'm basically a therapy physicist. I don't
2 know the details of nuclear medicine certification
3 and programs. So I think that this is a much better
4 question for our representatives on the nuclear
5 medicine side of the table to opine on.

6 DR. EGGLI: I mean, basically there are
7 a limited number of certifications that effect
8 nuclear medicine. There is American Board of
9 Nuclear Medicine, there is the Canadian equivalent,
10 which is the Royal College of Surgeons, there's an
11 osteopathic equivalent. And that's straight nuclear
12 medicine.

13 I think what Lynne was addressing was
14 diagnostic radiology. But again, in diagnostic
15 radiology, there's the American Board of Radiology
16 certificate in diagnostic radiology. There is the
17 certification in diagnostic radiology for the Royal
18 College of Physicians and Surgeons.

19 MS. FAIROBENT: Right.

20 DR. EGGLI: And there's also a
21 certification in diagnostic radiology for the post
22 graduate training of the American Osteopathic
23 Association.

24 So I think if diagnostic radiology is
25 listed, then the only issue is to go backwards to

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1 deal with the historical titles which have changed.
2 And, again, I think the issue raised was maybe the
3 grandfathering process takes care of that. And if
4 the person hasn't practices in a time frame that's
5 old, they may have to retrain anyway.

6 DR. BROSEUS: Dr. Cerqueira?

7 DR. WILLIAMSON: That's correct.

8 DR. BROSEUS: Dr. Cerqueira, there's a
9 hand raised here by Roger Broseus. May I be
10 recognized?

11 DR. CERQUEIRA: Yes.

12 DR. BROSEUS: One of the things that we
13 tried to do when we were writing the proposed rule
14 is to be less specific and use language that was
15 nonprescriptive and general enough that would
16 capture different areas.

17 And so the idea that I have is it
18 sufficient, and this is a target maybe that I'm
19 throwing up, to say radiation therapy and not say
20 radiology and radiation oncology and a whole bunch
21 of qualifiers that limits things overly? Is it
22 sufficient to say that?

23 DR. WILLIAMSON: Well, remember that
24 what has to be qualified in this paragraph (1)(a) is
25 not the name of the certification and not really the

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1 specialty that the practitioner is in, but it's the
2 residency experience that you do have to delineate.

3 DR. BROSEUS: Okay. Thank you.

4 MS. FAIROBENT: Right.

5 DR. WILLIAMSON: So that's the key
6 issue. So it's basically, you know, who approves
7 residency programs for radiology and nuclear
8 medicine, and within the 7 year time frame are there
9 any ones that are left out?

10 I do think the argument that if they're
11 more than 7 years old, it should be a nonissue.

12 DR. MALMUD: May I go back to a very
13 concrete issue, and I'll try and reread section (b)
14 line (1) again? About to successfully complete
15 ACGME board certification or equivalent
16 certification by the Canadian, British or
17 Osteopathic Board for residence training in
18 radiation oncology or nuclear medicine training
19 program, or a program in a medical specialty that
20 includes the 700 hours of training experience as
21 described.

22 Now, it is true that ones that argue
23 that an unrelated field may say it's related, but
24 they would still have to document the 700 hours.

25 DR. WILLIAMSON: Maybe it's better to

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1 have some sort of an out for a new program that
2 might come along. I mean maybe, who knows,
3 urologists of the future will find radionuclide
4 therapy becomes a central modality in their field
5 and --

6 DR. MALMUD: Well, they have qualified.

7 DR. WILLIAMSON: Yes. And then this
8 provides then if they can show that it does have
9 this amount of activity, 700 hours, then they could
10 qualify.

11 DR. GOLDBERG: I think --

12 DR. MALMUD: Excuse me, but what I
13 wanted to say is that if they are urologists and
14 they are ACGME approved, and they can document that
15 they've had 700 hours, they will qualify under this
16 hypothetical in the future.

17 DR. WILLIAMSON: Okay. I think so. But
18 you know the intent was to not have the nuclear
19 medicine radiology or radiation oncology programs
20 have to have -- live up to the letter of paragraph
21 (b).

22 DR. MALMUD: The nuclear medicine
23 residence training programs exceed the 700 hours of
24 training.

25 MR. MCBURNEY: Right.

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1 DR. MALMUD: So the nuclear medicine
2 programs are not threatened by it. What we were
3 concerned about as practicing or former nuclear
4 medicine physicians is NRC not become prescriptive
5 in demanding training requirements for board
6 certifications, since that is a board certification
7 issue and not an NRC issue by tradition.

8 DR. WILLIAMSON: Right. I think that's
9 a reasonable point.

10 So I think your language with the
11 exception of maybe adding in radiology would be a
12 point appropriate.

13 DR. CERQUEIRA: Is that a motion, Jeff?

14 DR. WILLIAMSON: Yes. I guess with the
15 addition of diagnostic radiology, I move that we
16 accept Dr. Malmud's rephrasing of paragraph (a)(1).

17 DR. CERQUEIRA: Do I have a second?

18 MS. SCHWARZ: I second the motion.

19 DR. CERQUEIRA: Okay. And any further
20 discussion?

21 MR. LIETO: I thought Dr. Malmud's,
22 correct me if I'm wrong, I thought you were say was
23 B as in boy (1) that you were rephrasing?

24 DR. WILLIAMSON: No. No. Successfully
25 complete a residency training program approved by

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1 the Residency Review Committee of the ACGME or Royal
2 College of Physicians and Surgeons of Canada or the
3 Osteopathic one in radiation therapy, nuclear
4 medicine or diagnostic radiology. Period. I think
5 you have to say, and then or in any related medical
6 specialty that includes the 700 hours of training
7 and experience as described in paragraph (b) of this
8 section.

9 MR. MCBURNEY: There you go.

10 DR. WILLIAMSON: So that's a separate
11 sentence.

12 DR. MALMUD: That is correct, Dr.
13 Williamson.

14 DR. WILLIAMSON: So that's how he has
15 stated it, I think.

16 Yes?

17 MR. MCBURNEY: I think that will work
18 because their certification still has to include it
19 to be accepted item (2) as well.

20 DR. WILLIAMSON: That's correct. So
21 item (2) then, (a) (2) is: "Pass an examination,"
22 which basically then lists these things in a more
23 sort of generic fashion.

24 MR. MCBURNEY: Right. To be accepted as
25 the board --

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1 DR. WILLIAMSON: I should say, in a less
2 descriptive fashion kind of lists all the things
3 that are covered in a very prescriptive fashion in
4 paragraph (1) (b).

5 DR. MALMUD: That is correct. I did
6 want to specifically ask Mr. Eggli as a practitioner
7 of nuclear medicine whether he's in agreement with
8 this?

9 DR. EGGLI: Yes, I am.

10 DR. VETTER: I have a question. The
11 residency program in diagnostic radiology, does it
12 currently include radiation therapy using unsealed
13 radioactive materials?

14 DR. MALMUD: The answer to your question
15 might come best from a member of the ABR, but my
16 understanding is that in the past and even into the
17 future no fewer than 3 months would have been
18 required. Is that correct?

19 DR. VETTER: Well, I think their
20 rotation through nuclear medicine is changing to
21 three months. I think that is correct.

22 DR. MALMUD: Yes.

23 DR. VETTER: Now will that include all
24 of these therapies?

25 DR. WILLIAMSON: Well if it doesn't,

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1 they'll fail to qualify on part (c) then. Okay.
2 Remember (a) or (b) and (c). So if the individual
3 does not actually have the 12 cases of documented
4 and supervised experience, that individual won't.
5 But if any radiologist who presents their board
6 certification certificate in evidence of a preceptor
7 statement and the 12 cases, will then a AU.

8 DR. MALMUD: At our institution, which
9 is not meant to be a template for the country, we
10 are requiring that the residents document and keep a
11 record of the specific cases with which they were
12 involved in order to meet the requirement.

13 DR. EGGLI: We do exactly the same thing
14 with radiology residents. We provide in diagnostic
15 radiology residency all this subpart (b)
16 requirements. And then it's up to the individual to
17 determine whether they want to garner all the
18 necessary cases to demonstrate the direct case
19 related experience in subpart (c).

20 And so I think that the statement is
21 correct that you need that subpart (c) experience as
22 well, and that's where different radiology residents
23 within a residency program choose whether or not to
24 participate in the unsealed source therapies.

25 MS. FAIROBENT: Dr. Vetter, that's my

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1 understanding from my discussion with the nuclear
2 medicine board trustees from the American Board of
3 Radiology as to what the diagnostic radiologists
4 are, pardon the pun, exposed to during their nuc med
5 rotation. And I do think that you need a
6 preposition between (a)(1) and (a)(2), Jeff, in your
7 draft. You did not have an "and," and I believe
8 that you mean paragraph (a)(1) and (a)(2) to reply.

9 DR. WILLIAMSON: That is correct.

10 MS. FAIROBENT: Okay. So I think you
11 are missing an "and" there.

12 DR. WILLIAMSON: Well, I'm an amateur
13 rule writer.

14 DR. CERQUEIRA: A little qualification.
15 It's 3 months of nuclear medicine now.

16 MS. FAIROBENT: That is what they're
17 going down to, which is roughly the 700 hours.

18 DR. CERQUEIRA: Okay. Three months of
19 nuclear medicine total for everything. Okay.

20 All right. Any further discussion on
21 this?

22 DR. VETTER: I'm satisfied with that
23 answer. I think that takes care of the concern I
24 had about -- I was a little concerned that the 3
25 months residency would not include these therapies

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1 but, in fact, if a resident wants to include them,
2 he simply has to make arrangements to include them.

3 MS. FAIROBENT: And provide the
4 documentation.

5 DR. CERQUEIRA: And provide the
6 documentation.

7 DR. VETTER: Right. Yes. I think that's
8 reasonable.

9 DR. CERQUEIRA: Shall we call the
10 question?

11 All in favor of the motion by Jeff.

12 ALL: Aye.

13 DR. CERQUEIRA: Opposed? So it's
14 passed.

15 All right. We've spent 56 minutes on
16 this one item.

17 DR. BROSEUS: There's a virtual hand
18 here from Roger Broseus.

19 One of the questions that the Commission
20 directed us to ask when we published the proposed
21 rule, are the changes being proposed adequate -- I'm
22 going to paraphrase -- to protect health and safety?
23 And I personally feel that it would be useful to
24 make sure that I understand for the record of these
25 deliberations the ACMUI people who are speaking, the

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1 members of the Committee feel that there is adequate
2 health and safety protection built into the training
3 programs, the certification programs, the residency
4 programs that AUs are getting sufficient training as
5 well as being tested on this. That would be a
6 useful sort of thing to discuss very briefly for the
7 record, I believe.

8 DR. MALMUD: The 700 hours is adequate
9 from my perspective. The testing, of course, is
10 variable from institution to institution but is
11 consistent at the time of sitting for the boards.

12 DR. NAG: I think while we were
13 discussing all this, we were keeping in our minds
14 about the safety and the training be enough. So I
15 think I'm satisfied.

16 MS. SCHWARZ: I do have one question
17 about the training. Jeff had raised it earlier. I
18 don't know that it's an issue, but it might be
19 something is to take off (H) under the training
20 section.

21 DR. BROSEUS: Who is speaking, please?

22 MS. SCHWARZ: Sally Schwarz.

23 MR. ESSIG: Sally, this is Tom Essig.

24 The only thing that I know our previous
25 discussion focused on generators for technetium-99m,

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1 but then we were wondering if there aren't other
2 generators that might come into play, and even those
3 that may be tagged some other compounds, some other
4 radiolabeled compounds that may be other than
5 diagnostic.

6 I was only raising it because that (H)
7 may be broader than just the normal technetium-99m
8 generators.

9 DR. MALMUD: Sally?

10 MS. SCHWARZ: Yes.

11 DR. MALMUD: May I address the issue? I
12 agree that it's a technique which is not used in
13 many departments today. However, with the future
14 being uncertain as to what will be coming down the
15 pike, including other generators, it is practical to
16 send the resident for several sessions to a
17 radiopharmacy house to witness and participate in
18 the experience of eluding a generator for those the
19 departments that now receive unit doses and don't
20 have resident generators any longer.

21 It is something which few of us have
22 done since our years of training, but I think the
23 experience will resonate in our minds as to what we
24 did and by participating in it at the time.

25 MR. LIETO: I would like to support

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1 Sally on removing that section (H) from the
2 radiopharmaceutical therapy training and experience.
3 If I need to make a motion, I will.

4 My reasoning is that the generators are
5 more important for the training experience for
6 diagnostic and imagining uses. And really I think,
7 at least the impression I got also from Jeff, was
8 that really is not apropos for radiation oncology.
9 And I think that is the section that it's under.

10 MS. SCHWARZ: Excuse me. I just wanted
11 to mention, I do agree that there are generators in
12 the pipeline essentially for therapeutics. But they
13 are much different in terms of operational capacity
14 than -- not much different, they are different.

15 But I think that the focus on the
16 training is really the comment on safety issues,
17 seems better addressed time wise not necessarily
18 involve eluting generators, but I mean I think that
19 belongs in diagnostic.

20 That was my thought.

21 DR. WILLIAMSON: Yes. I agree, too. I
22 think that if we were to put such a requirement in
23 there, it must be made much more generic and somehow
24 refer to appropriate packaging and preparation of
25 the radionuclides.

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1 MS. SCHWARZ: Right.

2 DR. WILLIAMSON: Rather than -- this is
3 sort of -- you know, really obsolete sort of
4 requirement and I agree with Sally. I think the
5 time could be better spent in didactic or practical
6 training with real radioactive drug preparation.

7 DR. CERQUEIRA: I support those comments
8 as well. But I think do we need a motion to remove
9 it?

10 DR. WILLIAMSON: Well, maybe we could
11 amend the motion that we have on the floor, which is
12 essentially to remove what is called paragraph
13 (b) (2) (H).

14 DR. MALMUD: I have a question for
15 Eggli.

16 Eggli, do you agree with removing it?

17 DR. EGGLI: Yes. I really think that the
18 generator stuff is -- and we still use generators in
19 my practice. That's 200 series and at the current
20 time there's certainly nothing in 300. And I think
21 it might be appropriate, as Dr. Williamson
22 suggested, to modify the statement to include a
23 training in the preparation that's appropriate for
24 the therapeutic radiopharmaceuticals.

25 DR. MALMUD: Oh, it's covered under

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1 (2) (c). (2) (C) says: "Calculating, measuring and
2 safely preparing patient or human research subject
3 dosages." So I think that covers it.

4 DR. EGGLI: Yes, I think you're right,
5 Jeff.

6 So I fully agree with removing (H).
7 That's a 200 issue.

8 DR. MALMUD: I remove my objection.

9 DR. WILLIAMSON: Okay.

10 So then if it's removed, so perhaps --

11 DR. HOWE: You have a virtual hand
12 raise.

13 DR. MALMUD: -- would be helpful if I
14 may summarize what the regulation now says. So (a)
15 says it's certified by a medical specialty board
16 whose certification process has been recognized by
17 the Commission or an Agreement State. To be
18 recognized, a specialty board shall require all
19 candidates for certification to:

20 (1) Successfully complete a
21 residency training program in
22 radiation therapy, nuclear
23 medicine or diagnostic
24 radiology approved by the
25 Residency Review Committee of

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1 the ACGME, Royal College of
2 Physicians and Surgeons of
3 Canada or the Committee on
4 Post-Graduate Training of the
5 American Osteopathic
6 Association; or alternatively
7 a residency training program
8 in a related medical specialty
9 that includes 700 hours of
10 training and experience as
11 described in paragraph (b) of
12 this section, and" and then
13 (a)(2) is unmodified.

14 And then paragraph (b) is unmodified
15 with the exception of deleting paragraph (2)(H).

16 And otherwise it reads as I have written
17 it. So I think that's the motion.

18 DR. CERQUEIRA: Okay.

19 DR. HOWE: Dr. Cerqueira?

20 DR. CERQUEIRA: Yes.

21 DR. HOWE: This is just kind of an
22 historical. I think (H) was put in there by the
23 group that wrote the rule so that it was clear that
24 the 35,300 physicians had training and experience in
25 preparing radiopharmaceuticals and therefore could

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1 be recognized as someone that could prepare
2 radiopharmaceuticals under 100 or 200. Because the
3 old Part 35, the 300 physicians were specifically
4 excluded from preparing radiopharmaceuticals because
5 their training was only 80 hours.

6 So I don't know how that's going to fit
7 into your elimination of (H).

8 DR. CERQUEIRA: Jeff, do you care to
9 comment?

10 DR. WILLIAMSON: I would prefer to defer
11 to those with more expertise.

12 I'll only say that, you know, it seems
13 that the specific technical requirement is really
14 irrelevant to the modern practice of
15 radiopharmaceutical therapy.

16 DR. HOWE: I don't think --

17 DR. WILLIAMSON: And the staff should
18 perhaps come back with a more up to date phraseology
19 or requirement that captures their concern.

20 DR. CERQUEIRA: Donna-Beth?

21 DR. HOWE: I think one other point was I
22 don't think (H) was specifically for the technetium-
23 99m generators. I think they were talking about the
24 other generators that were coming down the line for
25 therapy.

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1 MR. LIETO: No. That's just taken right
2 out of the old requirement. There was, I don't
3 think, anything to do with -- it's nice that you
4 would think that we had all this future foresight,
5 but that wasn't really the intention. This was just
6 a rephraseology of the old requirements.

7 DR. WILLIAMSON: I don't think that the
8 word generator is appropriate for the way, you know,
9 even fairly complex preparations are done.

10 MS. SCHWARZ: I agree with that.

11 DR. WILLIAMSON: I mean, it makes no
12 sense. It refers specifically to a mother/daughter
13 radioactive decay manufacturing process, as I
14 understand it.

15 DR. CERQUEIRA: Does anyone support
16 keeping that language in there from the Committee?

17 DR. EGGLI: I do not support keeping the
18 language in there.

19 MS. SCHWARZ: I don't think it's
20 necessary at this part of --

21 MR. MCBURNEY: If there's a concern
22 about that they know how to actually measure and
23 test for the purity and the nuclides measurements
24 and safety prepare the dosage, if taking out age is
25 a concern to staff, maybe if they could modify (c)

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1 to include whatever concerns were there.

2 DR. WILLIAMSON: But I'm trying to think
3 of the radioactive, the radiopharmaceuticals I've
4 had contact with in radiation therapy. If there's
5 any where, you know, where there was a purity test
6 that's part of the state of practice?

7 MS. SCHWARZ: Currently there aren't any
8 that are available.

9 DR. WILLIAMSON: Yes. So any it's too
10 speculative a requirement.

11 MR. MCBURNEY: Okay.

12 DR. WILLIAMSON: I mean, I'm trying to
13 think. And I certainly haven't had the broadest
14 experience, but we did use seven or eight
15 radionuclide preparations.

16 MR. MCBURNEY: And the tagged antibodies
17 are not --

18 MS. SCHWARZ: Typically it's iodinated
19 antibodies and the iodine is not produced as part of
20 the generator system.

21 MR. MCBURNEY: Right.

22 MS. SCHWARZ: So, I mean, yttrium, those
23 are not available as generator products
24 radionuclides.

25 DR. EGGLI: Not only is a throwback to

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1 technetium generator, but it's a throwback to the
2 early day of technetium generators when there was an
3 issue with radiochemical purity of what came off the
4 silica column. And, again, even with modern
5 generators, that's almost never a problem. We teach
6 our residents about it for historic interest only.

7 MS. SCHWARZ: And really the wording
8 here is and processing elute with kits to prepare
9 labeled radioactive drugs. And I really don't
10 think it will be useful in therapy at this point in
11 time.

12 DR. CERQUEIRA: I think you've got the
13 sense of the Committee that there is not much
14 support for keeping this here and for their reasons.
15 Given the time, I suggest we call the question with
16 Jeff's new proposal.

17 MR. ESSIG: Call the question. Go ahead.

18 DR. CERQUEIRA: All in favor?

19 ALL: Aye.

20 DR. CERQUEIRA: Opposed? Anyone
21 abstaining?

22 Okay.

23 MS. WILLIAMSON: Dr. Cerqueira?

24 DR. CERQUEIRA: Yes.

25 MS. WILLIAMSON: There's going to be a

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1 phantom person named Mary-Beth on the transcript
2 now.

3 MR. MCBURNEY: Donna-Beth.

4 DR. CERQUEIRA: Oh, I'm sorry. I've
5 done that before. Okay. Sorry, Donna-Beth.

6 DR. WILLIAMSON: Okay. I have edited
7 this document, so I will send it forward then so the
8 staff has something to -- and the Committee members
9 to look at to determine whether this is -- it keeps
10 a detailed record of what we voted on.

11 DR. CERQUEIRA: Okay. That's good.

12 MR. ZELAC: Dr. Cerqueira?

13 DR. CERQUEIRA: Yes?

14 MR. ZELAC: This is Ronald Zelac. Could
15 I just interject for the previous from the Advisory
16 Committee about the fallout of taking out the
17 generator elution aspects of the 390 requirements.
18 Currently, as Donna-Beth pointed out, one can become
19 an authorized user after 290 if in fact they are
20 authorized user under 390.

21 And I've heard several statements to the
22 effect that although it's not as normal these days
23 or as prevalent, there is still some aspects of
24 generator elution that's important for diagnostic
25 work.

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1 So what I'm really saying is that the
2 fallout of removing the elution requirements of 390
3 is going to put into question the ability for
4 someone who is recognized under 390 now be
5 recognized as an authorized user under 290 if
6 generator elution still has relevance for diagnostic
7 work. I'd just like some feedback if possible from
8 the Committee on this issue, which is a secondary
9 issue to the one that's just been discussed.

10 DR. CERQUEIRA: Well, I guess one way to
11 phrase that is should it be taken out of 290?
12 What's the Committee's feeling on that?

13 MS. SCHWARZ: No.

14 DR. CERQUEIRA: Sally says no. Okay.

15 MS. SCHWARZ: Well, no. I'm thinking
16 about that statement, actually.

17 And as far as taking it out of 390, I
18 mean if it's an historical problem, maybe it just
19 needs to be reworded.

20 DR. WILLIAMSON: Well, now are you
21 speaking with respect to 290 or 390, Sally?

22 MS. SCHWARZ: Well, I'm trying to see
23 what kind of confusion he's talking about people not
24 being able to be licensed in 290.

25 DR. WILLIAMSON: Well, the issue is that

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1 now apparently somebody who qualifies for 300 can
2 automatically qualify for 200, which is imagining
3 with localization.

4 MR. ZELAC: That's correct.

5 DR. WILLIAMSON: That's the way it's
6 structured now. I guess that's a question I would
7 have to defer to the nuclear medicine community on.

8 DR. VETTER: I think we have just
9 created an inconsistency between 390 and 290.

10 DR. WILLIAMSON: Well, not necessarily.
11 I mean, the localization and imagining could
12 potentially pose different safety --

13 DR. BROSEUS: Oh, it's true. It does. It
14 does. But if we require that anyone authorized under
15 290 -- or that the training authorized for 200 under
16 290 -- the training requires eluting generator
17 systems, then why would we allow anyone else to be
18 authorized under 200 who hasn't had that training.

19 MR. LIETO: Would going back to that
20 subitem (c) under part (b) (2) would in guidance
21 space could we say that calculating measuring and
22 "safely preparing patient or human research subject
23 dosages must involve the elution process of
24 measuring and preparing."

25 MS. CHIDAKEL: And from a legal

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1 standpoint we can't make any requirements in the
2 supplementary information that are not in the rule.
3 We cannot say any "musts" unless they're supported
4 the regulations.

5 MR. LIETO: No. What I'm just saying is
6 that safety preparing dosages in guidance space
7 would be described as including eluting and
8 preparing dosages from a generator.

9 DR. WILLIAMSON: I think that that's
10 unreasonable. We've just said that for 300 uses,
11 that's not a reasonable requirement. So I think the
12 question is now if some proaction of the community
13 that, say, a radiation oncologist might be a good
14 example. So are there any radiation oncologists who
15 are going to be disenfranchised by virtue of doing
16 radio oncology rather than say passing the examine
17 and doing 12 cases, and then they're going to be
18 unhappy that they can't do nuclear medical
19 localization and imagining because their program
20 didn't including eluting a generator?

21 This is really the issue, I guess. Maybe
22 there are other examples that perhaps Dr. Zelac can
23 give.

24 DR. BROSEUS: The relevant item in
25 35.290 includes requirements in 35.390. And one

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1 could fix the problem at issue by saying 390 and
2 incorporating in this paragraph by reference 290(g)
3 which includes eluting generator systems appropriate
4 blah, blah, blah.

5 DR. WILLIAMSON: So 290 basically refers
6 to the 390 paragraph (b)(1), is that correct.

7 DR. BROSEUS: That's correct.

8 DR. WILLIAMSON: Oh, I didn't realize
9 that.

10 DR. BROSEUS: It refers to 390. And if
11 one incorporates a back reference to the experience
12 -- the work experience eluting generators in 35.290,
13 I believe that would fix your problem.

14 DR. CERQUEIRA: Jeff, are you in
15 agreement that it would?

16 DR. WILLIAMSON: I guess so. Yes. I
17 mean, I'm a little out of my area here. I haven't
18 actually read the 290 one for a long time.

19 DR. CERQUEIRA: Dr. Eggli, would that be
20 acceptable? Would it solve the problem?

21 DR. MALMUD: I think that it would.

22 DR. VETTER: I think it would also.

23 MS. FAIROBENT: Dr. Cerqueira. I just
24 want to be sure I kept the right tie from Roger.

25 Roger, you suggesting then under

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1 35.290(b) to add a statement? As currently written
2 it is "As an authorized user under section 35.390,
3 or, before October 24, 2000, section 35.920 or a
4 group equivalent --"

5 DR. BROSEUS: No.

6 MS. FAIROBENT: --"and" paragraph and
7 then it was would be (c)(1)(ii)(GG)?

8 DR. BROSEUS: I was referring to the
9 last paragraph in 35.290. We might have to go back
10 and look at paragraph (G) also.

11 I think that for the purposes of our
12 rule writing, if the ACMUI were to indicate that by
13 way of motion that this is their intent that we
14 could look at the rule language and adjust it
15 appropriately to make sure that the inclusion of
16 35.390 authorized users with experience eluting
17 generation systems as enumerated in 35.290 now would
18 qualify them.

19 DR. WILLIAMSON: Yes. Here's what it
20 says under 290 now, as I understand it. Is that
21 except as provided in the -- the licensee shall
22 require authorized user of byproduct material for
23 35.200 to be a physician who is certified by a
24 medical specialty board or (b) is an authorized user
25 of 35.390 or equivalent Agreement Statement

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1 requirements or (c) (1) has completed 700 hours of
2 training.

3 That's the one you're concerned about?

4 DR. BROSEUS: Well, it's in two
5 locations. In paragraph (b) and in paragraph
6 (c) (2).

7 MS. FAIROBENT: Yes. Roger, under
8 paragraph (c) (2) I say where you're at. I think that
9 the incorporation by the reference to paragraph
10 (c) (1) (ii) (G) is going to have to go into both
11 places if that's what ACMUI is requiring. Because I
12 think you're going to have to have a preceptor
13 authorized user from 390 be somebody who has the
14 experience with eluting the generator.

15 So I think you've got to look at it at
16 both places. That's why I was asking for where you
17 were sticking it, because I was looking at the other
18 place.

19 DR. BROSEUS: Thank you.

20 MS. FAIROBENT: You're welcome.

21 DR. CERQUEIRA: All right. So, Jeff,
22 where do you go with this next?

23 DR. WILLIAMSON: Okay. Are we through
24 with this or -- well, this seems awfully
25 complicated. And since even for nuclear medicine

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1 imagining, doubts have been raised about the
2 relevance of this requirements. Maybe the nuclear
3 medicine representative should consider a proposal
4 to strike it from 35.200.

5 DR. EGGLI: Although there are fewer
6 now, there are still processes which use generators,
7 including mine. So I'm reluctant to strike it from
8 the 200 series.

9 MS. SCHWARZ: I agree. It should not be
10 struck from the 200 series for certain. I'm just
11 concerned now that having it taken it out of 390,
12 that it's a bigger problem than it solved.

13 DR. CERQUEIRA: And from the perspective
14 of the nuclear cardiologists, nearly all of the new
15 unit dose pharmacies which really generators are
16 usually not part of the normal practice setup. So
17 for that group it is not a big requirement.
18 Currently most of them will go a radiopharmacy and
19 spend some time there, you know, getting the
20 exposure. But in their daily practices, it's not
21 something that they have to do.

22 DR. MALMUD: We agree it's something
23 they don't have to do, but we certainly believe that
24 it is something that should remain with the 200, do
25 we?

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1 MS. SCHWARZ: Yes, I agree.

2 MR. MCBURNEY: I agree that it needs to
3 stay as part of the training in 200. The old
4 generator type, the technetium or the new one coming
5 on board and a lot of facilities still use them.

6 DR. MALMUD: Right.

7 DR. CERQUEIRA: Okay. Then that's fine.

8 We should probably move on.

9 Now, Tom, let me get some clarification.
10 What's the duration of the conference call? this
11 thing could go on forever?

12 MR. ESSIG: Until 3:00 p.m. eastern. So
13 another 40 minutes.

14 DR. CERQUEIRA: Okay. All right.

15 So what's the next item on the agenda
16 that you would like our input on?

17 MR. ESSIG: Roger needed to raise one
18 question.

19 DR. BROSEUS: Dr. Cerqueira, was there a
20 motion from the Committee on the issue of eluting
21 generators?

22 DR. CERQUEIRA: I don't think there was
23 a motion. There was general agreement that it should
24 be kept in 200, and we have -- and essentially we
25 were just the 390. Do we need a motion on it? Or I

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1 think you've got the feeling on the Committee. I was
2 the only one who had any sort of objection, and
3 nobody else supported it. So I think there's pretty
4 much uniform agreement.

5 MS. WILLIAMSON: So you're saying there
6 is a motion to eliminate an (H)?

7 DR. WILLIAMSON: Yes, we've passed a
8 motion to eliminate H from 35.390.

9 DR. BROSEUS: I understand that the
10 remaining question was for nuclear medicine
11 physicians to be qualifying under 390 if the
12 striking from 390 of that paragraph (H), if that's
13 still is a problem that needs to be addressed in the
14 final rule.

15 DR. VETTER: I have a motion. Be it
16 resolved that the ACMUI wishes to include under 200
17 the requirement that any authorized user who
18 qualifies must have had experience in eluting
19 generators. End of motion. And then the NRC can
20 put in whatever words are necessary to accomplish
21 that.

22 DR. CERQUEIRA: So do we have a second
23 on the motion?

24 DR. WILLIAMSON: Second.

25 DR. CERQUEIRA: Okay. Further

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1 discussion? There being on, I call the question.

2 All in favor?

3 ALL: Yes.

4 DR. CERQUEIRA: Opposed? Okay. So that
5 passed And it's an official motion.

6 DR. BROSEUS: Thank you.

7 DR. CERQUEIRA: So what next?

8 MR. ESSIG: Yes. The only other item
9 that we had on the agenda was to briefly discuss the
10 Dose Reconstruction Subcommittee efforts and
11 basically a status report where they are. this is
12 in conjunction with the St. Joseph Mercy Hospital
13 dose reconstruction.

14 Right now we're marching toward a
15 milestone of having the Subcommittee complete its
16 effort and provide a report by March 30th to the
17 full Committee. I should say not later than March
18 30th, to clarify that. And then the full Committee
19 not later than April 9th provide its report which
20 considered the Subcommittee's report to the staff so
21 that we can act on it and replay to the incoming
22 letter from the Society of Nuclear Medicine
23 President.

24 So at this time it might be appropriate
25 for Dr. Malmud to provide us a status of the

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1 Subcommittee efforts and if he is on track to
2 getting a report to the full Committee by March
3 30th.

4 DR. MALMUD: Thank you.

5 I have sent a memo to Dr. Williamson and
6 copied it to the other members of the Committee.
7 And I invited comments from the members of the
8 Committee regarding the memo. I hope that all the
9 members of the Subcommittee on the call now did
10 receive did receive my memo and also Dr.
11 Williamson's response to it, and Dr. Nag's comment.

12 ALL: Yes.

13 DR. MALMUD: Okay. And so it looks as
14 if, and I then sent a follow up note to Dr.
15 Williamson indicating that I appreciated his
16 comments and additions or deletions in both cases,
17 to my recommendation. And if I may, I'll read the
18 memo as amended by Dr. Williamson's comments. Is
19 that okay?

20 DR. NAG: Is that the one from March
21 17th?

22 DR. WILLIAMSON: As amended earlier
23 today.

24 DR. MALMUD: Yes. As amended earlier
25 today. And in the chaos of this meeting, I lost

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1 that memo. Hold on a second. I had it right in
2 front of me at the beginning of this call.

3 It begins with the following: "The
4 calculations derived by Dr. Williamson estimate the
5 range of radiation exposure to the patient's
6 daughter, a "member of the public" to be forward to
7 diagram in a best case-worst case scenario. The
8 methodology is summarized in the slides presented by
9 Dr. Williamson but does not include an additional
10 radiation burden from the urine bag, whose radiation
11 burden was presumed not to be additive.

12 Even at the lowest estimate, that is the
13 best case, of 4 rem the radiation burden exceeded
14 the 100 rem allowed.

15 Paragraph two: The calculations of 4 to
16 9 rem that Dr. Williamson submitted to the
17 Subcommittee of the ACMUI would mean that the NRC
18 Regional office overestimated the exposure to the
19 daughter by 3.75 to 1.67 times Dr. Williamson's
20 calculations.

21 Paragraph three: The reasons for the
22 differences in the estimated radiation burden has to
23 do with the assumptions of the time and distance of
24 exposure of the daughter to the patient.

25 Paragraph four."

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1 DR. NAG: I hear a lot of wind or some
2 other noise. Is that the same for everybody?

3 ALL: Yes.

4 DR. MALMUD: It sounds like somebody's
5 breathing really heavily. Breathing heavily into
6 our phone. I didn't mean the call to be anything
7 but serious business.

8 We now move to paragraph number four:

9 "There was agreement among members of the Committee
10 that the calculations performed by the regional
11 office of the NRC which produced a radiation burden
12 of 15 rem were overly conservative because they
13 assumed extended close contact between the patient
14 and the daughter at an unrealistically close
15 distance and ignored the use of local shielding.
16 More specifically, the use of Monte Carlo simulation
17 to reconstruct the bedside measurement distance came
18 up with an unrealistically short distance for mean
19 patient center-to-daughter surface distance."

20 I'll reread that: "The use of Monte
21 Carlo simulation to reconstruct the bedside
22 measurement distance came up with an unrealistically
23 short distance for mean patient center-to-daughter
24 surface distance. And the use of continuous decay
25 would lower the dose estimate by about 10 percent.

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1 Most importantly, the license post-
2 incident interviewers and dose reconstruction lead
3 to a different scenario regarding the use of body
4 shields and daughter dwell time distribution than
5 that derived from the Region III interview. The
6 Subcommittee strongly feels that these differences
7 should have been outlined in the inspection report
8 and used to define lower and upper exposure bounds."
9 In other words, a range.

10 Paragraph five: "Perhaps prompt
11 contemporaneous notification to the NRC regional
12 office of the unwillingness of a member of the
13 public to comply with the directions of the RSO
14 would have had the desirable effect of assisting in
15 the better documentation of the event.

16 Paragraph six: A concern of the
17 committee is how such a similar situation in the
18 future might be handled in a more optimal matter for
19 both the public and the licensee. Therefore, the
20 Subcommittee recommends that the ACMUI recommend to
21 the NRC one of several options:"

22 First one: "That the NRC develop an
23 information notice regarding contemporaneous
24 notification of the regional NRC office of
25 noncompliance by a member of the public despite the

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1 best effort and advice of the licensee."

2 Second bullet --

3 DR. WILLIAMSON: Well, there is an
4 addition I made there.

5 DR. MALMUD: Oh, I'm sorry. "That the
6 IN should summarize all available guidance on
7 exposure limits and licensee options when a family
8 insists on attending a radioactive patient."

9 DR. WILLIAMSON: I meant to say "family
10 member."

11 DR. MALMUD: All right. "That the IN
12 should summarize all available guidance on exposure
13 limits and licensee options when a family member
14 insists on attending a radioactive patient." And
15 the word "member" will be inserted between "family"
16 and "insists."

17 Next bullet: "That a modification
18 process be developed by the NRC to allow the
19 enforcement policy to grant exemptions based on
20 humanitarian grounds, thus when a licensee after
21 having made a best effort to inform and enforce the
22 regulations is unable to do so (such as for
23 humanitarian reasons), that the licensee might have
24 recourse in collaboration with the NRC for dealing
25 with the issue and without unduly alarming a member

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1 of the public regarding the consequences of
2 exceeding the allowable radiation burden when
3 exceeding the limit is deemed not to have serious
4 medical consequences." In other words, we remain
5 concerned about the psychological well being of the
6 public as well as its physical well being by unduly
7 making them anxious.

8 That is the recommendation of the member
9 of the ACMUI Subcommittee which was circulated. The
10 comments of Dr. Williamson were then incorporated.
11 And those of you who have received his comments,
12 will see the gray lining in addition to the text
13 that I sent to him.

14 And we present that to the Subcommittee
15 for its recommendation to the Committee.

16 So, if I may, I will present as a motion
17 of the Subcommittee. May I do that.

18 DR. NAG: Yes.

19 DR. MALMUD: Yes.

20 DR. NAG: One thing. Did you want to
21 just briefly mention what I had -- the comment I
22 made about having a signature something akin to a
23 patient going out on their own will against medical
24 advice?

25 DR. MALMUD: Yes. Did you all receive a

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1 copy of Dr. Nag's memo?

2 MS. SCHWARZ: Yes, I did.

3 DR. MALMUD: All right. I only heard
4 one yes, so let me read it to you if I may. It's
5 dated March 17th and it was emailed to me.

6 "I am not a member of the Subcommittee,
7 however one suggestion regarding item six reproduced
8 below is to treat the matter similar to the way we
9 treat patients who leave the hospital against
10 medical advice. I suggest that the licensee have the
11 patient's relatives sign a form indicating that they
12 have been warned that the time spent in proximity to
13 the radioactive patient is likely to exceed the
14 amount permissible under current regulations, that
15 they are voluntarily exceeding the permissible
16 amount against medical advice.

17 We may have to design a suitable form to
18 paraphrase this in simple language. This could be
19 placed in the patient's chart."

20 MR. MCBURNEY: Excuse me. I'm going to
21 need to leave for another conference call. Thanks.

22 DR. MALMUD: Okay. Thank you, Dr.
23 McBurney.

24 DR. VETTER: What happens when the
25 patient's relatives refuses to sign. Could we

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1 accomplish the same thing by simply dictating a note
2 in the chart that the patient has eloped, and prior
3 to that of course during patient instructions they
4 were given this information?

5 DR. NAG: Yes. Basically like a patient
6 who is a hardship risk who we ask them to sign, but
7 if they don't sign, we cannot tie them down.

8 DR. VETTER: Right.

9 DR. NAG: If a patient leaves the
10 hospital, we say this is what we told them.

11 DR. VETTER: Right.

12 DR. NAG: Similar thing.

13 DR. VETTER: Okay.

14 DR. MALMUD: Any other discussion of
15 this recommendation by Dr. Nag?

16 DR. VETTER: I think it's a good
17 characteristic or a good concept to tie into the
18 Committee's report. I'm not exactly sure about the
19 words, but the concept I think is good.

20 MS. SCHWARZ: I do agree with that.

21 DR. MALMUD: Any other comments
22 regarding the spirit of the paragraph, though we'd
23 have to refine the words a bit?

24 DR. EGGLI: I agree with it
25 conceptually.

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1 DR. MALMUD: So, Dr. Nag, shall we
2 accept that as a motion?

3 DR. NAG: Yes, I think we can make that
4 a motion and make the comment part of the
5 Subcommittee report. Because this will be dispersed
6 in the whole Committee and, you know, this can be
7 added, this paragraph would be modified. I'll leave
8 it to you to modify it and add it as part of the
9 amended Subcommittee report.

10 DR. MALMUD: Dr. Williamson, did I hear
11 you getting ready to say something?

12 DR. WILLIAMSON: Oh, no, I agree with
13 that. I'm wondering, though, whether this report
14 fulfills completely our mandate. You know, I
15 thought we had three mission. One mission was to
16 review Mr. Marcus' and Siegel's letter and the NRC
17 dose calculation for being overly conservative,
18 etcetera.

19 DR. MALMUD: We did that.

20 DR. WILLIAMSON: Which, we did. Okay.
21 The third one was to make recommendations about the
22 future management of patient's relatives who insist
23 on being present with their relatives and receiving
24 more than the 100 or 500 mR exposure limit they are
25 allowed.

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1 And the second one, which I don't think
2 we've done, was actually to give some more general
3 advise to the NRC to follow in future dose
4 reconstruction efforts so that, you know, scientific
5 credibility or loss of confidence doesn't occur
6 again.

7 DR. NAG: And I think -- because you
8 have to inject the feature there should be minimum
9 and maximum and legal range rather than one and two
10 say that the NRC should -- you know, real-case
11 scenario rather than being overly conservative. You
12 did mention all those points in your letter that I
13 saw.

14 DR. WILLIAMSON: Yes, in my letter that
15 I saw, they're not -- you know. It just might be
16 necessary to summarize them as a separate set of
17 bullets in our final report.

18 DR. NAG: Yes, I think I agree with
19 that. I think, you know, many of the points that
20 you made that I looked at this afternoon were points
21 that should be brought up to the whole Committee's
22 notice.

23 DR. MALMUD: When the Committee met in
24 Washington, we discussed the concept of a best
25 case/worst case/most likely case scenario. And some

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1 of us felt that when data, though calculated
2 precisely are based upon estimates, that there
3 should be a presentation of the results based upon
4 three different scenarios; the most likely, the
5 least likely and -- well, best case/worst case and
6 intermediate situation.

7 And I think that, Jeff, you incorporated
8 that in your bullet two under paragraph four. But I
9 will take your advice and more specifically tease
10 that out into a separate item.

11 DR. WILLIAMSON: Yes. I think that one
12 thing especially that the major source of
13 discrepancy between my lower limit estimate and that
14 of the NRC regional office actually had to do with a
15 very distinct difference in opinion between the
16 licensee and the NRC inspectors who, both groups did
17 interview to some extent the same group of people
18 and they came up with different conclusions. And I
19 thought that the final report should have reflected
20 these differences and that these different
21 assessments of who was where when behind what should
22 have been used to form upper and lower limits.

23 DR. MALMUD: Thank you. Any other
24 comments for addition or deletion of this
25 Subcommittee report to the Committee.

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1 DR. MARCUS: This is Dr. Marcus.

2 Dr. Cerqueira, may I make a comment?

3 DR. CERQUEIRA: Yes, please.

4 DR. MARCUS: I think the Committee or
5 the Subcommittee has done a very good job making
6 suggestions to the NRC how to more accurately do the
7 calculation to the daughter's upper arm. But this
8 is not really a trunk dose, and it's the trunk dose
9 of the true whole body dose that is really used for
10 risk assessment.

11 And in situations where the dose to the
12 upper arm is not indicative of the dose to the whole
13 body, there needs to be an additional calculation at
14 least done that is to be used for risk assessment.
15 Because the dose to the whole body is really what
16 you want know and what you want to use for risk
17 assessment and is going to be a lower number.

18 DR. SIEGEL: Yes. Before everybody
19 responds, I'd like to commend the Committee and
20 Jeff's report. It was terrific. And up until the
21 point of regulatory definition of TEDE, that's
22 right. We went beyond the regulatory definition
23 because in terms of a risk assessment, one needs
24 more than a regulatory value. One needs a value
25 more reflective of the situation, and that's how we

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1 got from 4 down to 1 because the trunk and the arm
2 were different distances, plus there's more
3 attenuation in the truck.

4 So I'd like the ACMUI to contemplate --

5 OPERATOR: Your conference is scheduled
6 to end in 15 minutes.

7 DR. SIEGEL: Oh, thanks. To
8 contemplate, yes, one needs to based on NRC
9 regulatory requirements to calculate the one
10 centimeter DDE, that's true. But if this value is to
11 be used for risk assessment at some point, is it or
12 is it not appropriate, especially in this case, to
13 use that value?

14 DR. MALMUD: Okay. Thanks, Jeff.

15 Dr. Williamson?

16 DR. WILLIAMSON: Well, you know, I
17 certainly can't disagree with that. In my initial
18 report to the spring ACMUI meeting I did calculate
19 that by Monte Carlo simulation. I don't have the
20 figure in front of me, but I think it would drop
21 these estimates by an additional factor of four if
22 one averaged the exposure over the daughter's entire
23 body.

24 And I agree for medical risk assessment
25 where there is a question of stochastic or

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1 nonstochastic injury to the daughter, that would be
2 appropriate. And that's worth pointing out. But in
3 terms of addressing the sort of narrow regulatory
4 issue that we were asked to address, that is not
5 really relevant.

6 I mean, we have the definition of TEDE
7 in Part 20, and that's the regulatory conclusion
8 will be based upon. And I think at this level, even
9 if it is 15 rem, that is I don't think anybody was
10 claiming that there was an enormous or any
11 significant risk a bodily injury to the daughter
12 based on even the highest estimate.

13 DR. SIEGEL: Well, with respect that's
14 exactly the point. In the Adams' document, a
15 medical consultant wrote back that essentially there
16 was very small medical consequences. But in order
17 for that expert to have made that assessment, I
18 would think it would be important for that medical
19 consultant to know that a 15 rem was to the arm as
20 opposed to 15 rem was to the total arm.

21 DR. WILLIAMSON: Well, I'd certainly
22 agree with that, and you know like I said, that was
23 definitely one of my comments to the full Committee.

24 DR. MALMUD: And we should add another
25 bullet to our letter in that there seems to have

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1 been a lapse in fully informing the medical
2 consultant?

3 DR. WILLIAMSON: Well, I don't know if
4 there really was a lapse. But I certainly think
5 that it is a good piece of advice, and yes. If the
6 NRC is going to ask a medical consultant was there
7 any medical risk to this patient by virtue of the
8 exposure, it certainly is appropriate to supply them
9 with a more relevant physical endpoint than the
10 regulatory TEDE. It's only common sense. Even
11 though it has in this context no regulatory
12 significance.

13 DR. NAG: Yes. I agree that as a
14 clinician I would like to have an estimate of the
15 total body combined exposure for me to make any
16 decision about the medical -- any of the medical
17 degree.

18 DR. MALMUD: An other comments?

19 Reporting as the chair of the
20 Subcommittee to the Committee, and we will clean up
21 this document and get it out to the Committee
22 members today, to Subcommittee members today so they
23 can review it and then make a final report to the
24 Committee based upon a draft and the additions as a
25 result of today's discussion.

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1 Is that acceptable?

2 ALL: Yes.

3 DR. MALMUD: Are there any other
4 comments that anyone wants to make about this.

5 DR. EGGLI: Yes.

6 DR. MALMUD: Yes.

7 DR. EGGLI: I didn't get those whole
8 exchange of emails, although I agree with everything
9 that you read and was discussed. Could you send me
10 this whole chain?

11 DR. MALMUD: Certainly.

12 DR. EGGLI: Thank you.

13 DR. MALMUD: Okay. Any other comments?

14 MR. LIETO: Dr. Malmud?

15 DR. MALMUD: Yes.

16 MR. LIETO: It was my understanding that
17 the second charge that was described earlier by Jeff
18 of the ACMUI regarding this matter was something
19 that was going to be done and completed in the
20 future, which was to come up with I thought a
21 specific --

22 OPERATOR: Your conference is scheduled
23 to end in 10 minutes.

24 MR. LIETO: We'd come up with specific
25 suggestions for guidance to the NRC. Are we saying

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1 that our charge regarding that is completed with
2 this Subcommittee report?

3 DR. WILLIAMSON: I think that Dr. Malmud
4 said he was going to take another pass at it, break
5 out a set of bullets that address the problem more
6 generally.

7 MS. SCHWARZ: Dr. Malmud, when you do
8 complete your bullets, will you then mail us a copy
9 of your --

10 DR. MALMUD: Yes. I want to get the
11 amended report out to each of you so that we can
12 present it as a Subcommittee to the full ACMUI.

13 MS. SCHWARZ: Right.

14 DR. MALMUD: But simply an ad hoc or
15 subcommittee of the ACMUI.

16 And let me just review with you before
17 we sign off, what tasks you have given me at the
18 moment. And that is point out that a major source
19 of discrepancy existed between the licensee
20 calculation and the NRC inspectors, that was one
21 point.

22 And the other one was that if the NRC
23 would ask the consultant to look at the medical
24 risk, then that consultant should be given relative
25 data, than simply the TEDE. They really need the

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1 whole body.

2 Does that cover the additional items
3 that you wanted me to include?

4 DR. WILLIAMSON: Yes, I believe so.

5 There's a small change about having to
6 do with the urine bag. That's I don't think quite
7 accurate. I didn't take an explicit count of the
8 radioactivity that was in this urine bag, but
9 assumed it was included in the bedside readings and
10 one meter readings that I did work with. So it was
11 implicitly included. So I'll have to make a little
12 comment about that.

13 DR. MALMUD: What I said, Jeff, is that
14 you had mentioned that at the meeting, and that what
15 you had done was to assume that because the urine
16 bag was hanging there, that it was part of the
17 activity that was monitored at a distance?

18 DR. WILLIAMSON: Correct.

19 DR. MALMUD: And you are consistent. You
20 did say that then, and you are reiterating it now.

21 DR. WILLIAMSON: Right. But I think
22 that the point one makes it seem like I ignored.
23 And, you know, I don't think that's quite true,
24 either. But it wasn't independently considered as a
25 source, but it was assumed to -- I didn't think

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1 there was enough information available to separately
2 treat it as a source.

3 DR. NAG: I think if you would just put
4 back as an amendment note

5 DR. WILLIAMSON: Yes, I think when we
6 revise it, we can edit this a little.

7 DR. MALMUD: We can just add on to that
8 sentence which ends "Whose radiation burden was
9 presumed not to be added exclusively, but included
10 in the moderate dose."

11 DR. WILLIAMSON: Correct. That would be
12 perfect.

13 MR. ESSIG: Mr. Malmud, this is Tom
14 Essig. I need to raise one other administrative
15 issue relative to the receipt and action by the full
16 Committee on the Subcommittee's report.

17 I think what we'll have to do so that
18 there is a formal acceptance of the report by the
19 full Committee is we'll have convene another
20 conference call, perhaps in two weeks after the full
21 Committee has received the report and had a chance
22 to read it. And then we will for the record have
23 amotion to accept the report of the Subcommittee and
24 forward it to the NRC.

25 DR. CERQUEIRA: Leon, is that fine with

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1 you?

2 DR. MALMUD: That's fine with me. We
3 could even do that next week if you wish to. I'm
4 going to be out of town and then unavailable for a
5 bit. But we'll do it whatever time is convenient.
6 Because I think that Jeff and I could probably
7 polish this up today if he has a few minutes.

8 MR. ESSIG: Okay. If the full Committee
9 can review the report in a fairly timely fashion,
10 we're up against a noticing procedure, however, and
11 we've got to allow two weeks for the *Federal*
12 *Register* notice. So even if we manage to get the
13 *Register* notice out tomorrow, I think the earliest
14 we could have the call is April 6th. That would be
15 two weeks from tomorrow.

16 OPERATOR: Your conference is scheduled
17 to end in five minutes.

18 DR. MALMUD: All right. May I read this
19 to you and see how this sounds to you?

20 "Under item six we another bullet which
21 says that we recommend to the consultant that the
22 medical risk be evaluated based upon whole body
23 exposure rather than using the TEDE." Is that
24 acceptable?

25 DR. WILLIAMSON: Yes.

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1 DR. MALMUD: Okay. That's one line.

2 The other line would refer to the fact
3 that the data, that when there is a discrepancy
4 between the licensee's report and the NRC's report,
5 that both sets of data are presented for evaluation
6 to the -- who are they presented? The NRC?

7 DR. WILLIAMSON: Well, I mean, I think
8 that the discrepancy should be described in the
9 final inspection report and basically unless there's
10 some real reason, clear reason for discrediting one
11 or the other, the two alternative reconstructions
12 should be used to bracket the two exposure to be
13 used for defining upper and lower limits.

14 DR. MALMUD: Discrepancy should be
15 described in the final report and a high dose/low
16 dose estimated from the two variables.

17 DR. WILLIAMSON: Right.

18 DR. MALMUD: Okay. Does the Committee
19 wish to move on this? We'll get you the final
20 wording today, but you've got what I'm going to be
21 saying.

22 MR. LIETO: Quick question?

23 DR. MALMUD: Yes.

24 MR. LIETO: Jeff, would it be
25 unreasonable to put in what the ratio or the facts

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1 of difference between the TEDE and the whole body
2 from a risk standpoint to an individual?

3 DR. MALMUD: Who is speaking?

4 MR. LIETO: I'm sorry. This is Ralph
5 Lieto.

6 DR. WILLIAMSON: I mean it certainly
7 could go in there. I have no problem putting it
8 there.

9 DR. VETTER: That may work for this
10 case, but the ratio would be potentially different
11 for any other case.

12 DR. WILLIAMSON: And one involving much
13 larger distances, it might be fairly minor
14 contributing factor or for a little hotter
15 radiation.

16 DR. SIEGEL: Excuse me. That's exactly
17 why you do a dose reconstruction in a specific case,
18 because no two cases are the same.

19 DR. WILLIAMSON: That's correct. So,
20 yes, I mean in the context of this particular
21 incident, you know, I think that even the highest
22 exposure estimate was well below any threshold for
23 medical injury to the patient. And I think putting
24 a factor of four in the general discussion of what
25 the recommendations should be is inappropriate,

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1 because it only applies to this case.

2 DR. MALMUD: But that the discrepancy
3 should be described in the final report. The
4 discrepancy, if any, should be described in the
5 final report and presented in a manner which
6 provides a high dose/low dose burden estimate?

7 DR. WILLIAMSON: Yes, I think that's
8 reasonable.

9 DR. CERQUEIRA: Gentlemen, we're going
10 to have to end soon.

11 DR. MALMUD: As the Chair to the
12 Subcommittee, do these sentences meet with the
13 Subcommittee's approval.

14 MS. SCHWARZ: Yes, I think they do.

15 DR. MALMUD: Does someone on the
16 Subcommittee want to make a motion.

17 DR. WILLIAMSON: Okay. So moved.

18 DR. MALMUD: So moved, is there a
19 second.

20 OPERATOR: Your conference is scheduled
21 to end in one minute.

22 DR. MALMUD: All in favor?
23 Subcommittee?

24 ALL: Aye.

25 DR. MALMUD: Any opposed?

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1 MR. ESSIG: We don't know what the
2 motion was, Jeff, that you said I so move. The
3 record won't show what your motion was.

4 DR. MALMUD: The motion was the memo
5 that sent back to me by Jeff, dated March 17th
6 referring to the conference call of March 15th.

7 DR. WILLIAMSON: Well, Leon, I think the
8 time has run out and we really can't present this to
9 the full Committee for a vote. I think the simplest
10 thing is to basically send it to all of us.

11 OPERATOR: Your conference time has now
12 expired. Thank you.

13 DR. MALMUD: Thank you, all. We will
14 send it by email, Jeff.

15 DR. WILLIAMSON: Okay. Thank you.

16 (Whereupon, at 3:00 p.m. the meeting was
17 concluded.)

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