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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

5 (ACMUI)

6 + + + + +

7 MEETING

8 + + + + +

9 TUESDAY,

10 MARCH 2, 2004

11 + + + + +

12 ROCKVILLE, MARYLAND

13 + + + + +

14 The Advisory Committee met at 8:00 a.m.

15 in the Auditorium of the Nuclear Regulatory
16 Commission, 11545 Rockville Pike, Dr. Manual
17 Cerqueira, Chairman, presiding.

18 COMMITTEE MEMBERS:

19 MANUEL D. CERQUEIRA, M.D. Nuclear Cardiologist,

20 Chairman

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

22 Administrator,

23 Vice Chair

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

25 Physician

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1 COMMITTEE MEMBERS: (cont.)

2 NEKITA HOBSON Patient Advocate

3 RALPH P. LIETO Medical Physicist,

4 Nuclear Medicine

5 RUTH McBURNEY State Robinson

6 SUBIR NAG, M.D. Radiation Oncologist

7 SALLY WAGNER SCHWARZ, R.Ph. Nuclear Pharmacist

8 ORHAN H. SULEIMAN, Ph.D. Food and Drug

9 Administration

10 Representative

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

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

13

14 NRC STAFF PRESENT:

15 THOMAS ESSIG Designated Federal

16 Officer

17 NMSS/IMNS/MSIB

18 PATRICIA K. HOLAHAN, Ph.D. NMSS/IMNS

19 DONNA-BETH HOWE, Ph.D. NMSS/IMNS

20 CHARLES L. MILLER, Ph.D. NMSS/IMNS

21 ROBERTO J. TORRES NMSS/IMNS

22 ANGELA R. WILLIAMSON NMSS/IMNS/MSIB

23

24

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

(8:05 a.m.)

CHAIRMAN CERQUEIRA: Good morning. My name is Manuel Cerqueira, and I'm the Chairman of the ACMUI, and this is a preparation -- now is this an open or closed meeting?

MR. ESSIG: This is open.

CHAIRMAN CERQUEIRA: It's open. Okay. So one of the agenda items this morning between now and when we meet with the Commissioners is really to go over the Commission briefing. So maybe, Tom, since the NRC Staff is going to be doing the initial portion of it, maybe you want to review that first? Part 35 Licensing and Inspection under the New Part 35 Pamela Henderson. Are you going to go over any of that with us or preview it with the Committee, or is this --

MR. ESSIG: It would be my suggestion that we could best utilize the time here to provide Ralph any insights that might be needed in his presentation. I mean, it's kind of our hour to do with what we please.

CHAIRMAN CERQUEIRA: Sure. Okay.

MR. ESSIG: Certainly, you're welcome to copies of the slides of the other presentations, but I don't know if at this point -- we can't change the

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1 slides. They've already gone to the Commission, so
2 they would be for information only. We can certainly
3 do that.

4 CHAIRMAN CERQUEIRA: I guess the one thing
5 that may be of some help is the sense, we're going to
6 be talking about the review of method of NRC
7 Reconstruction. It might be worthwhile to see Dr.
8 Sherbini's presentation so we at least have some --

9 MR. ESSIG: Well, it's actually going to
10 be mine.

11 CHAIRMAN CERQUEIRA: Oh, it's going to be
12 your's. Okay. So what does the Committee feel?
13 Would it be of some help to have Tom go over his
14 presentation so we could --

15 DR. NAG: I think we went over that
16 yesterday.

17 DR. VETTER: Yes. I personally would like
18 us to discuss Part 35 issues.

19 CHAIRMAN CERQUEIRA: Okay.

20 DR. VETTER: Unless we're all comfortable
21 with whatever information he has, and he could review
22 that for us, and then go from there.

23 DR. WILLIAMSON: Yes. I would like to
24 hear that sort of data, at least a summary of the
25 content.

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1 CHAIRMAN CERQUEIRA: Ralph.

2 MR. LIETO: I'm here to serve the
3 Committee.

4 CHAIRMAN CERQUEIRA: Excellent. So how do
5 you want to do it? Do you have your slides?

6 MR. LIETO: I think they're in the handout
7 right here. Starting with the second slide, just a
8 summary of the proposed rulemaking dates, when things
9 started, involvement of the ACMUI with Staff and the
10 discussion sessions, and just identify that there's
11 these three major issues -- topics that I wanted to
12 present. One was about board certification, probably
13 a lengthier part of it has to do with the Preceptor
14 Statement, and then some transitional issues that have
15 been brought up by the Committee, make a comment that
16 the --

17 CHAIRMAN CERQUEIRA: Now, Dick, is this
18 what you want, or do you want Ralph to maybe just kind
19 of go through this?

20 DR. VETTER: This is fine.

21 CHAIRMAN CERQUEIRA: This is fine. Okay.
22 Good.

23 MR. LIETO: And then transitional issues.
24 I mean, if you want I could go through the whole
25 thing, I mean, just go through the presentation as

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1 sort of a warm-up, and then just kind of -- we could
2 do that too.

3 MR. ESSIG: Are there copies of the --

4 DR. VETTER: Yes.

5 CHAIRMAN CERQUEIRA: We have the slides.

6 MR. ESSIG: It's interesting the Committee
7 has them and we don't. We got them this morning. Oh.

8 DR. VETTER: Are they right in front of
9 you there?

10 DR. NAG: That's the one Angela gave this
11 morning.

12 MR. LIETO: Just to introduce myself and
13 thank the Committee or the Commission for the
14 opportunity to comment on proposed rules. Then to
15 indicate that the NRC published the proposed rule on
16 December 9th seeking comments on the revision of the
17 training and experience requirements, and that these
18 training and experience requirements affect authorized
19 users, authorized medical physicists, authorized
20 nuclear pharmacist and radiation safety officer, and
21 that the authorized medical physicist is a new
22 designation.

23 The NRC proposed amendments to training
24 and experience which affect the approval of these
25 authorized individuals via both the current mechanisms

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1 which are recognition of board certification and the
2 alternate pathway.

3 The proposed rules involve significant
4 work by the ACMUI with the NRC Staff, and from
5 discussion sessions with representatives from the
6 affected board and the professional societies.

7 On behalf of the ACMUI we wanted to bring
8 to the Commissioners' attention some issues relating
9 to the proposed rule. There are three particular
10 aspects that we feel should be commented on. These
11 have been raised in ACMUI meetings since the Advisory
12 Committee last met with the Commission, and also were
13 raised during the drafting of the proposed rule.
14 These three aspects of the proposed rule involve board
15 certification, a preceptor statement, and transitional
16 issues in going from current regulation to the
17 proposed.

18 One of the questions raised during the
19 comment period in the proposed rule asked should the
20 word "attestation" be used in place of the word
21 certification and preceptor statements? The ACMUI
22 would like to strongly re-affirm its recommendation to
23 use the term "attest or attestation" in Part 35.

24 It should be noted that the comment period
25 ended last week on February 23rd. Also, I'll state

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1 that there may be individuals from the ACMUI that may
2 have some additional comments on issues affecting the
3 proposed rules and its future implementation.

4 The criteria for board certification to be
5 recognized and listed in Part 35 is the crux of the
6 proposed rulemaking. The importance of board
7 certification cannot be emphasized enough. However,
8 it needs to be understood that board certification
9 provides a mean to assess and document the
10 comprehension of a body of knowledge and/or basic
11 skills. It does not determine the training program
12 content or adequacy, nor does it determine competency
13 to supervise safety programs.

14 If the NRC expects that medical events can
15 be related to board certification, this is a
16 misunderstanding of the board process. Inadequate
17 radiation safety training is a reflection of an
18 individual's training program, not their board
19 certification.

20 DR. WILLIAMSON: Can we comment?

21 CHAIRMAN CERQUEIRA: Yes, please.

22 DR. WILLIAMSON: Are you sure you want to
23 say that? You know, they're making certain
24 assumptions about board certification which maybe we
25 should just --

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1 MR. LIETO: I took that largely from the
2 Minutes.

3 CHAIRMAN CERQUEIRA: Maybe we could move
4 that since it's not being --

5 DR. WILLIAMSON: I mean, I know it's
6 perhaps in the initiative, but there's a certain sense
7 in which that's true, but there's also -- I'm sorry
8 that it's in the Minutes. I'm sure that's what the
9 boards themselves say, so at a certain level I think
10 it's true, but at a certain level it's also
11 misleading. I think that as a tool for calling out
12 experienced and reasonably well-trained professionals,
13 board certification has served us well for many
14 decades now. And I think to sort of attack that
15 connection serves no useful purpose.

16 CHAIRMAN CERQUEIRA: Dick.

17 DR. VETTER: I think the whole
18 misunderstanding here revolves around the word
19 "competence". Boards certainly do demonstrate that
20 you have the knowledge and skill to perform your
21 professional duties. The issue is are you competent,
22 and competence is demonstrated on a day-to-day basis.
23 And that goes back to this whole issue of requiring
24 preceptors to sign a preceptor statement for people
25 who are board certified.

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1 MR. LIETO: Do you want me to strike the
2 whole sentence or do you want me to replace
3 "inadequate radiation safety training with competence?

4 DR. VETTER: Competence. Personally, I
5 think that's the issue, it's competence.

6 CHAIRMAN CERQUEIRA: Yes. Why don't you
7 read the original and then the revised statement?

8 MR. LIETO: I think it was the last
9 sentence, which was "inadequate radiation safety
10 training is a reflection of an individual's training
11 program, not their board certification." And their
12 suggestion was replace "competency" is a reflection,
13 or radiation safety competence is a reflection of the
14 training program, not certification.

15 DR. VETTER: What were the first few
16 words?

17 MR. LIETO: "Inadequate radiation safety
18 training."

19 DR. VETTER: Why are you assuming that
20 anyone is getting inadequate radiation safety
21 training?

22 MR. LIETO: Well, that was the -- I think
23 relating to board certification and tying board
24 certification to medical events.

25 DR. VETTER: But there is no - - there has

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1 been no tie.

2 MR. LIETO: No. But that's been one of
3 the issues that's been raised at least in the last
4 meeting with the Commission --

5 DR. VETTER: Where the Commission has that
6 opinion.

7 MR. LIETO: Right.

8 DR. VETTER: I don't know where they get
9 it.

10 MR. LIETO: What I guess I'm trying to
11 reflect is that our agreement is that it doesn't. And
12 that was the reason for the --

13 DR. WILLIAMSON: I'm not sure I'd agree
14 with that. You know, honestly I think that's sort of
15 a level of train -- it's very speculative whether it
16 does or doesn't. But my hunch is, is that somebody
17 that -- a group of persons who have passed the boards
18 probably overall would do better at radiation safety
19 practices than an equivalent group that has not.

20 MR. LIETO: Then I'll just end it with
21 that.

22 DR. WILLIAMSON: So I see no point, and I
23 think we're just asking -- you know, we don't want the
24 rule as its broadly formed now to be overturned, and
25 so I don't think that it's --

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1 MR. LIETO: So I'll just end it with --

2 DR. WILLIAMSON: Yes, it's very
3 speculative one way or the other. I would just drop
4 it.

5 DR. EGGLI: I would like to take a
6 slightly contrarian approach. Not all training
7 programs across all groups of authorized users
8 emphasize radiation training to the same degree. And
9 there are training programs where -- and there are
10 generic categories of training programs where
11 radiation safety is significantly de-emphasized at the
12 training program.

13 DR. WILLIAMSON: That could be, but what
14 useful purpose is served by drawing their attention to
15 that fact?

16 DR. EGGLI: Public safety.

17 CHAIRMAN CERQUEIRA: But do you have any
18 data to support that?

19 DR. EGGLI: There is an organization
20 called SCANS, which is Society of Chiefs of Academic
21 Nuclear Medicine Departments who collected data on
22 this kind of training, and over several years tried to
23 influence the training in nuclear medicine. And it
24 was the strong opinion of this group that there were
25 categories of trainees where radiation safety was in

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1 fact de-emphasized.

2 CHAIRMAN CERQUEIRA: But again, that's
3 certainly not information that I was familiar with,
4 and I'm just not certain what purpose that --

5 MR. LIETO: It's obviously quite
6 controversial, and so I'll just strike that sentence.

7 DR. WILLIAMSON: What is your sort of
8 underlying purpose? What are you trying to achieve
9 with these comments? I mean, what were you --

10 MR. LIETO: Well, basically, this is a
11 reflection of what the Committee has discussed since
12 we last met with the Commissioners on the proposed
13 rulemaking, and what went into the proposed rule. I
14 mean, that's what I thought the purpose of this was,
15 to give them sort of a status report on things that
16 have happened since.

17 DR. MALMUD: The SCANS report I'm familiar
18 with. I think it would be wisest to simply address
19 the issue of board certification as indicating that
20 when one is board certified, what the director of the
21 training program indicates is that we have received
22 the requisite fund of knowledge and are familiar with
23 it in order to practice whatever our specialty is. I
24 don't think we should touch the word "competence".
25 That's something that is achieved and improved upon

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1 with experience, but simply state that the board
2 certification is an indication that the individual has
3 the requisite fund of knowledge necessary to practice
4 his or her specialty. That's what it is. Don't you
5 agree?

6 DR. WILLIAMSON: I do. I think it tests
7 basically a breadth and to some extent depth of
8 knowledge. It has in addition to that certain
9 prerequisites that limit or mandate a certain type of
10 training. I agree it may not be followed ideally as
11 it should in all cases, but I think we've argued in
12 the past that board certification is an important
13 mechanism and has served the community well in
14 general, and so I don't see any mileage in trying to
15 undermine that view.

16 DR. MALMUD: And in fact, just for the
17 record, and in fact, most boards require more training
18 hours than does the NRC recommend. The issue of the
19 differences among the boards, which is I believe what
20 you're addressing, is an issue which I don't think it
21 would serve us well to bring before that Committee at
22 this time, because that would open up another issue
23 for discussion which is not the issue on the table at
24 the moment, even though there is evidence that the
25 number of training hours differs among the programs.

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1 That's just my personal opinion.

2 CHAIRMAN CERQUEIRA: So how do we want to
3 word this now?

4 MR. LIETO: I think it's best just to
5 strike it out. It's obvious -- because it will, I
6 think, give them maybe a misunderstanding of what the
7 Committee's intention is. And I've already got a
8 statement about that board certification is a means to
9 assess and document comprehension of a basic body of
10 knowledge and skills.

11 CHAIRMAN CERQUEIRA: So comprehension,
12 certainly nothing about competency.

13 MR. LIETO: Right.

14 CHAIRMAN CERQUEIRA: Something softer
15 would be "exposure", which is really a non-committal
16 sort of term.

17 DR. WILLIAMSON: And it does also carry
18 with it some limitations or expectations for a kind of
19 a training, because it does have an important role
20 shaping, I would say, minimum requirements for
21 training, and the nature of the experience you have to
22 have.

23 CHAIRMAN CERQUEIRA: Right. And we've had
24 quite a discussion when the boards actually came here,
25 you know, and Dr. Hendee from the ACR. And again,

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1 there were issues about program directors versus
2 authorized users. I don't think this is the forum to
3 necessarily get into those kind of issues. So is
4 everyone comfortable with the statement that Ralph is
5 going to make?

6 MR. LIETO: Forget I said it.

7 CHAIRMAN CERQUEIRA: Okay.

8 MR. LIETO: The next point has to do with
9 Section 35.50 which addresses training and experience
10 for radiation safety officers. Repeatedly during the
11 rule revision process, the ACMUI stated that the
12 training and experience revisions must not exclude
13 existing recognized boards. In paragraph specifically
14 50(d)2(i), there's a new paragraph added to allow
15 medical physicists to serve as RSOs if they are
16 certified by a specialty board and the certification
17 process has been recognized by the Commission or an
18 agreement statement.

19 It appears to be intended to authorize as
20 an RSO board certified medical physicists who are not
21 AMPs. However, as stated, the proposed rule
22 disqualifies certain certification categories in the
23 American Board of Radiology and the American Board of
24 Science and Nuclear Medicine from which many currently
25 certified medical physicists serve as RSOs.

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1 Well, this may be unintentional by the
2 NRC. It must be rectified before the final rulemaking
3 process is published, or the final rulemaking you
4 should say is published. Process for a board to be
5 recognized and listed in the NRC website is an
6 entirely new concept and requirement. This will
7 require formal application process by the boards,
8 regardless of the length of time that they have
9 existed. ACMUI suggests that the notice also go to
10 major societies whose members comprise the various
11 board diplomats. And I'll just list the boards.

12 DR. WILLIAMSON: I'll make a suggestion.
13 The RSO issue you raised I think is a really important
14 one, so I think to add a line indicating what the
15 consequences will be if these individuals, for
16 example, board certified nuclear medicine physicists
17 are excluded from the process be appropriate.

18 DR. VETTER: Relative to that issue,
19 Ralph, do you know specifically what's excluding them?

20 MR. LIETO: It's the requirement in
21 Section A that has to do with the documented years of
22 applied health physics. I think it's three or five,
23 depending on how, I guess, it's read exactly. But in
24 those categories since they're all master's
25 candidates, I think it's the three year piece that

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1 does it. I've heard conflicting comments that the
2 American Board of Science and Nuclear Medicine has two
3 years -- and someone else says no, it does have the
4 three years -- but I do know that they did sign, I
5 think in a letter in the comments that went to the
6 Commission, that they supported that aspect. So I'm
7 assuming that they feel that that affects the --

8 DR. WILLIAMSON: Yes. I think so. Now
9 just to clarify further, I think there are two kind of
10 classes of RSO that are implicitly defined by that
11 rule, 35.50. One is the kind of unrestricted RSO
12 where the content of services offered by the licensee
13 is not limited by the personal work experience of the
14 RSO. And the second category is RSO whose sort of
15 scope of RSO duties is limited to those modalities
16 which the individual has some work experience. And I
17 think the category that we're disputing now is the
18 second category, so what is not at issue are the basic
19 requirements for being an unrestricted RSO, but being
20 the RSO of a smaller operation where, in fact, the
21 board certified radiological or nuclear medicine
22 physicist may be by far the most appropriate skilled
23 and knowledgeable person to serve as RSO for a small
24 licensee.

25 CHAIRMAN CERQUEIRA: Dick, go ahead.

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1 DR. VETTER: I think we need to identify
2 what the fix is, and maybe later when we come back we
3 have to make a motion or something, but just to throw
4 out the fact that there's a problem, I'm not sure
5 that's adequate. I mean, perhaps here that's all we
6 need to do, unless we know it's a very, very easy fix
7 and we specifically identify it. But at some point in
8 time today, this Committee is going to have to
9 identify the fix in order to give the NRC some
10 guidance.

11 DR. WILLIAMSON: It's not a very
12 straightforward fix.

13 MR. LIETO: Yes. I agree with you, Dick.
14 There was in the slide originally what I thought was
15 a fix, and staff looked at it, and they did not feel
16 it was the fix. So I guess it was a little bit more
17 convoluted than I thought.

18 DR. WILLIAMSON: So can we put that as a
19 discussion item for this afternoon?

20 CHAIRMAN CERQUEIRA: Right. We can do
21 that.

22 DR. WILLIAMSON: Talk about fixes, what
23 the staff's attitude is towards this matter.

24 MR. LIETO: The next was just simply in
25 terms of the process for listing, that the NRC plans

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1 to notify the boards by a letter and/or notice, but
2 that in addition, when the process is established, a
3 work shop with the stakeholders should be held for the
4 purpose of addressing the specifics to finalize the
5 process for broad listing by providing a two-way
6 dialogue with the NRC and the affected groups or
7 boards.

8 The next slide, the discussion about the
9 preceptor statement. This is one aspect of the
10 revision that has envisioned training and experience
11 rulemaking that has been the NRC maintaining this
12 requirement for preceptor based on input from the
13 ACMUI. The requirement for a preceptor statement was
14 decoupled from the board certification pathway to meet
15 the NRC directive. This is a new regulatory
16 requirement for both board certified and alternate
17 pathways for obtaining NRC authorization, so now each
18 applicant bears the burden for obtaining a preceptor
19 statement.

20 The ACMUI believes that the definition of
21 the preceptor will greatly impact the implementation
22 of this requirement. The current definition is, and
23 then I'm just going to read it right off the slide --
24 emphasizing the articles, an individual and directs
25 the training.

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1 A comment that the preceptor statement
2 must be a flexible, practical, and document that
3 minimizes implementation burden, and allow the
4 preceptor who is not necessarily the one providing the
5 training and experience.

6 An example here would be a program
7 director who may not be an authorized user or
8 authorized medical physicist, but oversees the overall
9 training of the individual and can document the
10 performance and comprehension of that individual
11 during the training program.

12 It should also possibly provide for the
13 input of multiple preceptor statements. Now a
14 suggestion from the ACMUI for NRC consideration might
15 be that to modify the definition to "an individual who
16 provides or directs training and experience, or more
17 directly an individual who provides, directs, or can
18 verify the training and experience." But again, these
19 are just suggestions for consideration to address the
20 implementation.

21 DR. WILLIAMSON: So one issue you're
22 taking on is the connection between preceptor and
23 having to be AMP or AU on agreement state or NRC
24 license. One might argue that's sort of a lost cause
25 to argue that. I've lost that battle.

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1 MR. LIETO: Well, I think it was something
2 that we really discussed last time, and it was quite,
3 I think, strongly felt by the Committee as a whole
4 that they may be the best person to comment on their
5 comprehension, and skill, and knowledge base.

6 DR. WILLIAMSON: The -- sorry.

7 DR. VETTER: Can we come up with a very
8 concrete example of where that would be a problem?
9 For example, if you get HDR, is there a physician that
10 comes in and trains the physicians on the use of HDR,
11 and then certifies that those new physicians will be
12 competent? Because that's what the language says.

13 MR. LIETO: I could see where it might
14 happen, Dick, would be say in a radiation oncology
15 program where they get their training with unsealed
16 radiopharmaceuticals in their medicine department.
17 And so there would be a nuclear medicine director
18 and/or maybe authorized user that would be able to
19 document that training and experience; yet, their work
20 with other sealed sources would be an entirely
21 different --

22 DR. WILLIAMSON: That's addressing the
23 multiple person. I think that's uncontroversial and
24 something they will do. But coupling this from the
25 preceptor being an AU or AMP I think is a more

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1 controversial and difficult issue.

2 CHAIRMAN CERQUEIRA: It's more
3 controversial, and the way we ended up going in this
4 direction was I think when the ACR came in, Dr. Hendee
5 didn't feel that the person signing the statement
6 would necessarily be an authorized user for an AU.
7 And if we go back four or five years when we first
8 started this process, I mean, it was felt that we
9 really needed somebody to assume responsibility. And
10 it was felt that for radiation safety that the
11 authorized user should be that individual or an
12 appropriate AMP-type.

13 DR. VETTER: But the problem is when a
14 physician, when a licensee gets a new type of use,
15 there is no one at the institution who is an
16 authorized user.

17 CHAIRMAN CERQUEIRA: Yes. No, I
18 understand in that situation, but we're talking more
19 for the general individual, radiologist and nuclear
20 medicine physician or cardiologist who's had training,
21 who can sign off.

22 DR. WILLIAMSON: So I think --

23 DR. VETTER: But the regulation is
24 all-encompassing. It must cover all circumstances.
25 And I think it's going to be problematic.

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1 DR. WILLIAMSON: So my suggestion would
2 be, is I think we're going to lose the battle. You
3 know, we've already talked them into decoupling
4 preceptorship from the board eligibility requirements
5 just for this exact reason, because they insisted on
6 retaining the connection between preceptor and being
7 a named person on a license. So I think a more
8 effective, winnable strategy is to negotiate about the
9 details of the definition of what the preceptor does.
10 So my suggestion would be that --

11 MR. LIETO: Well, I think that's the point
12 here.

13 DR. WILLIAMSON: Yes. Well, no. You're
14 attacking the connection between preceptor and being
15 a named person on a license. I don't think we're
16 going to win that. My suggestion would be we try to
17 fix the definition of preceptor so it's broader. And
18 one suggestion I would have is, has knowledge of the
19 competence and skills of the applicant. Okay? So
20 this would then allow colleagues who haven't been
21 directly involved in the primary training, but who
22 have been in a position to observe or supervise the
23 individual, to attest to that individual's competence,
24 so that's the kind of fix I think that could be sold.
25 I don't know what the staff's opinion is.

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1 CHAIRMAN CERQUEIRA: Not attest to
2 competence. I mean, I don't think anybody has ever
3 gone in that direction. Doug had a --

4 DR. EGGLI: Again, I think there are
5 situations where a general training director is not
6 the person with any knowledge of the level of training
7 the individual has received. And there are some
8 situations where it is beneficial to have an
9 authorized user, an authorized medical physicist, and
10 RSO, in fact, be the preceptor for those individuals.
11 And I do think in some situations there's a public
12 safety issue. And I think that public safety issue
13 overrides the inconvenience of this being broadly
14 applied.

15 DR. NAG: If I remember the discussion
16 we've had when the board people were here, one of the
17 major problems would be that a change in the
18 preceptor, that preceptor who actually taught the
19 authorized user, trained this person is no longer
20 there, so the training director serves de facto as the
21 one who is going to sign off. And the training
22 director -- all the paperwork that is there in an
23 institution is in the name of the training director.
24 And even if that training director leaves, the
25 paperwork will still be there, so the new training

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1 director can sign off on their behalf.

2 DR. EGGLI: I disagree with that. Anybody
3 who finishes a training program should walk out of
4 that training program with their preceptor statement.
5 There should not be an issue of having to come back
6 five years later and ask for a preceptor statement.
7 We keep copies of every preceptor statement that we
8 write in the institution. If somebody loses their
9 preceptor statement, we can file a copy for them. But
10 if you get your preceptor statement before you walk
11 out the door, this is a non-issue.

12 DR. WILLIAMSON: That's not realistic for
13 radiation oncology, your approach.

14 CHAIRMAN CERQUEIRA: This may not be
15 applicable across the board. But, Leon, you've been
16 patiently waiting.

17 DR. MALMUD: I thought that Jeff's
18 description would be applicable and encompassing; and
19 that is, that the training program director or his
20 designee has the knowledge, and rather than using the
21 term "competence", has knowledge of the training and
22 skill of the preceptee. Is that acceptable? Has
23 knowledge of the training and skill of the preceptee.

24 MR. LIETO: Well, I think the controversy
25 here is they have to be a person that has been

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1 approved on the license or approved in the broad
2 scope.

3 DR. MALMUD: That's why I said or his
4 designee. In other words, I may be the chairman of
5 the department, but I may not be the director of
6 residency training. In fact, in our department, which
7 is not meant to be a universal example, the chairman
8 is not the training program director. There is always
9 a designated training program director. And in many
10 departments that is the case, so that if it is the
11 director or his designate having knowledge of the
12 training and skill of the preceptee, I think it covers
13 most situations. Any further comment?

14 CHAIRMAN CERQUEIRA: Dick.

15 DR. VETTER: I think the regulations will
16 allow the NRC in guidance space to accommodate your
17 view of who the preceptor is. But the regulation also
18 says, this is very explicit, that the preceptor must
19 attest to the competency of that individual.

20 DR. WILLIAMSON: That's not what it says.
21 I'll read what it says for radiation safety, for
22 example.

23 DR. VETTER: Radiation safety is a little
24 different.

25 DR. WILLIAMSON: Okay. Let's go to the

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1 other one.

2 CHAIRMAN CERQUEIRA: Go to the authorized
3 user, or the physician.

4 DR. WILLIAMSON: "Has obtained written
5 certification signed by a preceptor authorized nuclear
6 pharmacist that an individual has satisfactorily
7 completed the requirements in Paragraph B(1) of this
8 section, and has achieved a level of competency
9 sufficient to function independently as an authorized
10 nuclear pharmacist." Let's see if the physician one
11 is the same.

12 CHAIRMAN CERQUEIRA: I mean, this is the
13 issue. I think the Commissioners consistently have
14 wanted the word "competency", because it basically
15 puts some liability on the training programs and the
16 person signing the statement, and no matter how many
17 times we've gone to them with this, they have
18 basically balked and been very steadfast. The
19 problem, the boards when they made their
20 presentations, they did not want to attest to
21 competency, and so I don't think we've really resolved
22 this. Ruth.

23 MS. MCBURNEY: That's probably why it was
24 decoupled, that the boards do not do that. It still
25 has to be another preceptor doing it.

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1 DR. MALMUD: One way of dealing with this
2 may be to recognize that competency is not a constant
3 throughout life. And, therefore, that the individual
4 could attest to the competency of the trainee at the
5 completion of the program. That does not mean that
6 the trainee is competent one year later, which would
7 deal with the legal liability; namely, when I trained
8 you, you were competent. Well, what happened to you
9 in a year, I can't speak to that.

10 CHAIRMAN CERQUEIRA: Jeff, and then Subir.

11 DR. WILLIAMSON: I wanted to correct
12 something I just said. I was reading out of the Part
13 35 as currently published. I'm now going to read what
14 it says.

15 CHAIRMAN CERQUEIRA: This is the revision
16 from our subcommittee?

17 DR. WILLIAMSON: Let me try to make it
18 clear. I'm doing my best here. The original Part 35
19 that -- I read out of the Part 35 that took effect in
20 October. The current rule which discussion just
21 closed states as follows -- this is for the 35.690.
22 It says, "As obtained, written certification that the
23 individual has satisfactorily completed the
24 requirements in Paragraphs A or B of this section, and
25 has achieved a level of competency sufficient to

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1 function independently as an authorized user for each
2 type of therapeutic medical unit for which the
3 authorized user -- individual is requesting authorized
4 user status. The written certification must be signed
5 by a preceptor authorized user who meets the
6 requirements in 35.690".

7 MS. McBURNEY: It still says
8 certification.

9 DR. WILLIAMSON: It does say competence in
10 here. It says, "Has achieved a level of competency
11 sufficient to function independently as an authorized
12 user." So I suggest that maybe we want to say level
13 of skill and knowledge.

14 MR. LIETO: I don't want to get into that,
15 because that -- what you're talking about there is
16 changing requirements of the individual for authorized
17 user status or whatever, and that's not what I'm
18 presenting right here. This is the precept, dealing
19 with who can be a preceptor, so to speak, by
20 definition.

21 DR. WILLIAMSON: Okay.

22 CHAIRMAN CERQUEIRA: Dick.

23 MR. LIETO: So I guess the question is,
24 the controversy I still don't have any resolution on
25 is we want to state that it may not be an authorized

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1 user or authorized --

2 DR. WILLIAMSON: I think that's the most
3 controversial thing of all.

4 MR. LIETO: If there's not consensus, I
5 won't state --

6 CHAIRMAN CERQUEIRA: And the committee has
7 not come to a consensus, and I think for this
8 afternoon's agenda, that --

9 DR. WILLIAMSON: That's not quite true
10 either. We had a very clear consensus that that
11 person, this preceptor need not be an AU. So right
12 now I'm arguing a tactical point that we've lost that
13 battle, and what percentage is there in renewing the
14 war.

15 CHAIRMAN CERQUEIRA: Dick.

16 DR. VETTER: I think Jeff is exactly
17 right. I think this is going to become problematic
18 when it comes to implementation. For example, when a
19 licensee gets an HDR, some new type of use, the
20 individual comes in and trains them is not an
21 authorized user on that license. They can't be,
22 unless you want to hire them to come in, so there are
23 some practical issues that will become problematic
24 that we'll have to sort out. But we're not going to
25 win this battle if we bring it up again.

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1 CHAIRMAN CERQUEIRA: I agree with you, and
2 this is probably not th forum to try to argue it. I
3 mean, if the Commissioners have questions, they can
4 ask it. But what --

5 MR. LIETO: Do you want me just to stay
6 away from that specific prepositional phrase, if you
7 will, and just -- and if it comes up and they bring it
8 up, bring up these examples that there's going to be
9 some problematic implementation of this if it has to
10 be authorized user or authorized RSO?

11 CHAIRMAN CERQUEIRA: I think that's the
12 most legitimate way to do it.

13 DR. NAG: I think although we seem to have
14 lost a couple of times before, I think it's still very
15 important that the ACMUI puts forward the view that
16 yes, we put this before you, you didn't agree, but it
17 builds some of the problems that will exist if we
18 allow -- I mean, if the preceptor has to be the
19 authorized user, you know, these problems do exist.
20 We have to again -- you know, sometimes they may not
21 accept the first time, second time, but you keep on
22 haggling three, four times, at some point they may
23 have to give up.

24 CHAIRMAN CERQUEIRA: All right. Dick.

25 DR. VETTER: I guess my suggestion would

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1 be that we identify it as a continuing problem, that
2 it may be problematic during implementation, that
3 ACMUI is here willing to work with the staff to
4 resolve those issues.

5 CHAIRMAN CERQUEIRA: I think that's the
6 best way to put it, because as we've observed from
7 this discussion, we have not resolved it within our
8 own ranks, so I think the verbiage that you used was
9 appropriate, the language. So, Ralph, did you --

10 MR. LIETO: Yes. I'll just say an example
11 would be a program director who has the knowledge of
12 the applicant's skill and training experience.

13 CHAIRMAN CERQUEIRA: That's
14 implementation.

15 MR. LIETO: There are some other issues
16 that we need to bring up.

17 DR. WILLIAMSON: I think another example
18 that's really worth mentioning, it is important, is a
19 practitioner who acquires a new modality where there
20 isn't -- that wasn't reflected in the original
21 residency training of the individual, and for which
22 there is no authorized user for that modality that can
23 sign a preceptor statement. Now how is that to be
24 handled?

25 CHAIRMAN CERQUEIRA: Yes, but this isn't

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1 the forum to get into these specific examples. I
2 think --

3 DR. WILLIAMSON: Yes, I think it is. I
4 think he has to define the problem that we need to
5 work on.

6 CHAIRMAN CERQUEIRA: All right. But he --

7 MR. LIETO: If you let me go on, I'm going
8 to get into the specifics about preceptor issues.

9 CHAIRMAN CERQUEIRA: Okay.

10 MR. LIETO: And the questions that have
11 been raised. It's on the next couple of slides.

12 DR. WILLIAMSON: I think the solution is
13 messy, but the problem is clear.

14 CHAIRMAN CERQUEIRA: Go ahead, Ralph.

15 MR. LIETO: Obviously, several questions
16 and concerns have been raised, have arisen in ACMUI
17 discussion on implementing this preceptor statement
18 requirement. The ACMUI does not expect to obtain
19 answers at this meeting with the Commission, but
20 wishes to express these issues for resolution during
21 the final rulemaking process. For example, who can be
22 a preceptor? What documentation is required for an
23 individual to be recognized by the NRC as a preceptor?
24 What information does that preceptor need or require
25 to make an attestation for training and experience?

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1 What are his or her recordkeeping requirements to
2 document this decision? And grandfathering with
3 respect to Section 35.50, for example, when changing
4 from one license to another licensee, does another
5 preceptor statement need to be submitted for this
6 individual? Must it be updated every seven years to
7 satisfy recentness of training rule if that experience
8 - - the licensee changes licenses. How is it handled
9 if a preceptor is unwilling to provide a statement
10 because of personal reasons, or perceived liability
11 concerns? What liability concerns does that preceptor
12 bear, especially if NRC is looking at a relationship
13 between medical events and training experience. How
14 would it be handled if the preceptor is unavailable
15 due to death, training program termination, or some
16 other cause in which the length of time between the
17 training and experience and the applicant makes their
18 request for authorization.

19 Ideally, a generic statement form would be
20 the most acceptable and practical; however, can this
21 be done such that the statement language is
22 appropriate for an authorized user and RSO, a medical
23 physicist, a nuclear pharmacist, and/or for applicants
24 who have not yet completed board certification.

25 There may arise situations where an

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1 individual may receive multi-modality training at
2 different institutions or facilities, or most training
3 was received at one facility or one licensee, and then
4 completed under a second licensee. Will multiple
5 preceptors be acceptable, or does one preceptor have
6 to address the full training and experience?

7 The ACMUI feels if it's the latter case,
8 this would be very problematic for an individual to
9 get a preceptor statement and would support the
10 acceptance of multiple preceptor statements.

11 Another issue lies, and this I'm not
12 really strong on a comment, but another issue is
13 licensee's whose radiation safety committees are
14 authorized to approve authorized users or medical
15 physicists. They currently enjoy an expedited
16 process, approval process mechanism, but with the
17 preceptor statement implementation may incur delays in
18 that approval process.

19 DR. NAG: Can you go over that, what you
20 mean by that?

21 MR. LIETO: I'm thinking like broad-scope
22 programs and some specific programs where the
23 radiation safety committee can authorize the user or
24 medical physicist, and so they may incur delays in
25 their process to approve that user on to their license

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1 or whatever because of delays in getting the preceptor
2 statement information.

3 CHAIRMAN CERQUEIRA: I would probably try
4 to keep it simple again, because we're probably going
5 into too much detail that we're not going to really be
6 able to resolve.

7 MR. LIETO: Obviously, we raised many
8 questions and concerns that the preceptor statement
9 could create a bureaucracy of its own. Based on past
10 experience with Part 35 licensing, many problems arose
11 with regulatory guidance become de facto regulations.
12 The preference is that if it is required, it should be
13 in Part 35. However, we suggest that implementation
14 of preceptor statement occur in guidance space and
15 with the use of the frequently asked questions on the
16 NRC website to allow flexibility in addressing these
17 many issues.

18 And then in the next slide we talk about
19 some of the transitional issues that have been brought
20 up in going to the revised Part 35. There are a few
21 issues of concern that licensees and other members of
22 the regulated community have raised. One has to do
23 with individuals currently in training programs. They
24 have not had the opportunity to document their
25 training experience because it was not a requirement;

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1 yet these individuals in training need to have the
2 opportunity to document their training and experience.

3 A possible recommendation for
4 consideration is maybe the training and experience
5 requirement should be applied to individuals who are
6 entering training programs now, or after some specific
7 date in the year 2004.

8 The authorized medical physicist is a new
9 definition which did not exist previously. It's come
10 to our attention that some agreement states do not
11 explicitly list physicists on the license. In order
12 to assure that the current shortage of authorized
13 medical physicists is not made worse, a mechanism is
14 needed to ensure that not only an initial pool of
15 authorized medical physicists is not compromised, but
16 also to provide as a source of preceptors for new
17 authorized medical physicists.

18 Another transition issue involves nuclear
19 medicine authorized users. Before Part 35 was
20 revised, I-131 authorization was based on therapy
21 versus diagnostic applications, rather than the
22 activity thresholds, which current regulations follow.

23 In other words, an authorized user --
24 users were authorized under Part 200 to use I-131 for
25 diagnostic imaging and localization studies which

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1 exceeded 30 microcuries. These were essentially
2 studies for assessing thyroid cancer in patients that
3 were going to be treated, but did not exceed a few
4 millicuries. Now it requires that that physician need
5 the training and experience for therapy applications
6 requiring a written directive, which is Section 392,
7 so some method needs to be found so that authorized
8 users currently providing this study to patients are
9 permitted to continue.

10 Because the comment period has just
11 closed, additional issues may be raised before the
12 final rulemaking process. The ACMUI can provide
13 valuable assistance in this regard, and will make
14 itself available during the review and implementation
15 of these changes. Again, on behalf of the committee,
16 we take the opportunity to provide comment on this
17 critical change. That's it.

18 CHAIRMAN CERQUEIRA: Good. Jeff. Dick.
19 Sally, okay?

20 MR. LIETO: The latter half is more non-
21 controversial.

22 CHAIRMAN CERQUEIRA: Roger, do you want to
23 make a comment since you --

24 DR. BROSEUS: Excuse me, because this is
25 really your part of the meeting, but I would observe

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1 that in my view, that many of the points that Dr.
2 Lieto went over fall into -- they're not new problems,
3 and many of them are not related specifically to the
4 changes for T&E for recognition of boards. Many of
5 them are implementation problems, and I think they're
6 being dealt with now. For example, multiple preceptor
7 statements. I spoke with Pam when I saw your comment
8 about that, and that's handled now. There are
9 exceptional cases where you need more than one person
10 to attest, I'll use that word today, to the
11 competency, so that's just an observation I have about
12 the content of many of your -- the character of many
13 of your comments from my point of view.

14 DR. EGGLI: And I can attest to the
15 multiple preceptors. Right now for when I train a
16 cardiology fellow, I do their clinical experience.
17 They get their basic didactic experience elsewhere, and
18 they submit to NRC two preceptor statements, and none
19 of them have had trouble getting licensed.

20 CHAIRMAN CERQUEIRA: That's true. Dick.

21 DR. WILLIAMSON: Roger, if I may ask, how
22 do you handle the situation where a practice acquires
23 a gamma knife, and none of the physicians at this
24 facility are authorized users for gamma knife. Who
25 signs their preceptor statement?

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1 DR. HOWE: We had gamma knife physicians
2 in the past, and so there are gamma knife authorized
3 users available.

4 DR. WILLIAMSON: Yes, but none of them
5 have been involved in the training of the individual,
6 so if Hospital X, which has three radiation
7 oncologists, none of whom are authorized for gamma
8 knife, gets a gamma knife -- if they go through the
9 one-week vendor-supported training course, you know,
10 these other authorized users across the country don't
11 know these people from Adam. Who signs their
12 preceptor statement?

13 DR. HOWE: I think we look at it as a
14 case-by-case, and you're getting to some of the issues
15 that we do with the emerging technology where you're
16 in the beginning, so we have to give some leeway on
17 the very first people.

18 CHAIRMAN CERQUEIRA: Ruth, do you want to
19 comment?

20 MS. MCBURNEY: The way we did in Texas and
21 probably some of the other agreement states is for
22 certain modalities to have that person go to another
23 facility and observe about three cases, two to three
24 cases involving the use of that modality, if it's like
25 HDR something like that. For some of the other

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1 emerging modalities, if they've been authorized for
2 something similar in that modality, we will authorize
3 them.

4 DR. WILLIAMSON: Well, I think you know
5 Ralph's point can be reduced to the concern that we
6 want the rule language to be consistent with the level
7 of flexibility that would allow the medical director
8 of say this one-week training program who presumably
9 is an AU for gamma knife, to be able to sign those
10 preceptor statements.

11 MS. MCBURNEY: Yes, and that's what we
12 allow.

13 CHAIRMAN CERQUEIRA: I would try to avoid
14 specifics, because if it's authorized user or medical
15 physicist, there's going to be unique things. And I'm
16 not sure it's necessarily productive for the meeting
17 with the Commissioners to get into those specific
18 implementations.

19 DR. WILLIAMSON: I think enough examples
20 have to be given to indicate what the nature of the
21 problem is. Otherwise, it's too abstract. I don't
22 think we need to argue each individual case, but just
23 to give some examples of what the problems might be I
24 think is a very useful strategy, since we're not
25 advocating a general solution at this time.

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1 DR. NAG: Yes. I think we do have to
2 point out some of the problems that implementation of
3 a straightforward statement that the authorized user
4 be the one who is certifying that these are the
5 problems that you are going to create. And unless we
6 -- we have already been blamed that we put forward a
7 rule not knowing the problems it's going to create.
8 Here we know that these are the problems we are going
9 to create and that may allow the Commissioners to give
10 you the flexibility, that let's not create these
11 problems.

12 CHAIRMAN CERQUEIRA: Ralph, go ahead.

13 MR. LIETO: I was just going to add that
14 I thought in reviewing the Minutes, or I should say
15 the transcripts from the last couple of meetings, that
16 obviously it was recognized, we're not going to change
17 this preceptor requirement. But I think that as we
18 look at its implementation, a lot of issues have been
19 raised by both this committee and others, the newness
20 and the details of this is really going to affect
21 licensees, the states and regions that have to approve
22 users and medical physicists and RSOs. And we need to
23 be prepared for that type of issue.

24 CHAIRMAN CERQUEIRA: Lynne, you have a
25 comment?

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1 MS. FAIROBENT: Yes. Dr. Cerqueira, I
2 just want to clarify for the record, you accredited
3 Bill Hendee with the American College of Radiology.
4 Dr. Hendee was actually speaking on behalf of the
5 American Board of Radiology, ABR. And I just wanted
6 to be sure that that was adequately reflected in the
7 transcript.

8 CHAIRMAN CERQUEIRA: You're correct.
9 Okay. All right. Tom.

10 MR. ESSIG: May I suggest we move on to
11 the other --

12 CHAIRMAN CERQUEIRA: I was just going to
13 do that.

14 MR. ESSIG: If it helps, I could quickly
15 run through the slides that I have, because I'll be
16 going on before you. It's just a single sheet of
17 paper. I'll pass it out. There are only six slides,
18 and I think there are some left over for the audience,
19 as well. And, of course, it's captioned "The NRC
20 Method of Dose Reconstruction" but it's specifically,
21 we're going to be talking about the exposure that
22 occurred at St. Joseph Mercy Hospital. And I'm just
23 noting that we conducted a special inspection in
24 October of 2002, a female patient in July of that year
25 had been administered 285 millicuries of I-131 for

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1 treatment of thyroid cancer. And that her patient,
2 during her stay in the hospital, her patient's adult
3 daughter was observed to be frequently at her mother's
4 beside. The first day no one was allowed in the room,
5 and then after that the visitation restrictions were
6 relaxed and days two through four, or 50 percent of
7 the time days five and six, the daughter was in the
8 room essentially all but four hours based on
9 interviews with her. Then the patient died on July
10 7th, after being admitted on July 1st.

11 The inspection report documented the
12 daughter may have received a total effective dose
13 equivalent of 15 rem. The licensee did not collect a
14 bioassay sample from the daughter; thus, the total
15 effective dose equivalent explicitly assumes no
16 internal exposure. Approximately 20 other members of
17 the public were exposed. Of these, 10 received doses
18 between 100 and 500 millirem, and the remaining 10
19 received less than 100 millirem.

20 On May 7th, the second bullet on the
21 action slide here, the letter from Regional III
22 Regional Administrator imposed a civil penalty to the
23 licensee of \$6,000. The civil penalty consisted of
24 two parts; first, for licensee activities which caused
25 members of the public to receive doses in excess of

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1 public dose limit of 100 millirem per year. And
2 second, for the failure of the licensee to investigate
3 and implement corrective action when it became known
4 that a relative of the patient was not following the
5 licensee's radiation safety practices.

6 And as far as other actions to date on
7 slide 3, the NRC in December 2003 received a letter
8 from the President of the Society of Nuclear Medicine
9 and the President of the American College of Nuclear
10 Physicians which forwarded a critique of the dose
11 evaluation which was in the Region's inspection
12 report.

13 The critique which was authored by Doctors
14 Carol Marcus and Jeffrey Siegel offered that the NRC's
15 dose evaluation was as much a factor of 17 higher than
16 it should be. We have conducted a preliminary
17 evaluation of that critique and have addressed the
18 five principal issues raised in it. And we will
19 finalize our evaluation once we receive the ACMUI's
20 views.

21 On slide 4, on January 12th, a letter from
22 Chairman Diaz to the presidents of SNM and ACNP noted
23 that the ACMUI has been tasked to provide an
24 independent analysis and recommendations, if
25 appropriate, regarding the alternate dose

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1 reconstruction offered by the SNM and ACNP.

2 The subcommittee was established within
3 the ACMUI on January 29th, 2004 to review the dose
4 evaluation contained in the inspection report and the
5 critique of it prepared by Doctors Marcus and Siegel.
6 The subcommittee was specifically requested to review
7 each aspect of dose evaluation, and offer a critique
8 -- and the critique offering alternative methodology,
9 and to determine whether or not it agrees with the
10 approaches and why.

11 And slide 5, we are expecting ACMUI's
12 report later this month, but are sensitive to the
13 committee's need for additional discussions and the
14 time to assess the additional information. And we
15 plan to use the Region III assessment, our own
16 evaluations, the ACMUI report and form our conclusions
17 regarding the merits of the SNM critique, and will use
18 the results of this evaluation to inform future
19 evaluations of this type.

20 And lastly, a report will be prepared
21 detailing staff's findings and conclusions for the
22 chairman's signature which will be appended to the
23 final response letter to the Society of Nuclear
24 Medicine and the American College of Nuclear
25 Physicians. That's my presentation. I ran through it

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1 rather quickly.

2 DR. MILLER: Tom, based upon our
3 discussions yesterday, the comments about we're
4 expecting the report later this month, I thought we
5 agreed yesterday that it would take about four more
6 weeks.

7 MR. ESSIG: That's still later this month.

8 DR. MILLER: Well, we're into March. That
9 will get us into April.

10 MR. ESSIG: Okay.

11 DR. MILLER: Maybe if you could just
12 modify this comment slightly to say in about a month?

13 MR. ESSIG: Okay. We can do that. Sure.

14 DR. MILLER: Give flexibility to it.

15 MR. ESSIG: Sure.

16 DR. MILLER: If that's okay with the
17 committee.

18 MR. ESSIG: No problem. I was just going
19 on Jeff committed to have it within four weeks.

20 (Simultaneous speech.)

21 DR. WILLIAMSON: That depends on the staff
22 producing some data in a timely fashion. If we get
23 the data the day before the report is due, that will
24 be problematic.

25 MR. ESSIG: I understand.

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1 DR. WILLIAMSON: I'm saying, I was told it
2 may not be simple to obtain said data.

3 CHAIRMAN CERQUEIRA: I hate to play
4 musical chairs, but would it be more appropriate to
5 have your presentation dovetailed into Leon's?
6 Because you're going to do your --

7 MR. ESSIG: Yes.

8 CHAIRMAN CERQUEIRA: We'll be at the table
9 at different times.

10 MR. ESSIG: Yes.

11 CHAIRMAN CERQUEIRA: The staff will give
12 its presentation the way the Commission does it, and
13 you will leave the Commission table and then ACMUI
14 will go to the Commission table and make your
15 presentation.

16 MR. ESSIG: The Commission has been
17 informed that this is the order that we're going to
18 go.

19 CHAIRMAN CERQUEIRA: And that can't be
20 modified? I mean, just in terms of -- I mean, you're
21 going to do your presentation --

22 MR. LIETO: Leon and I switch order?

23 CHAIRMAN CERQUEIRA: Pardon me?

24 MR. LIETO: Could Leon and I switch order?

25 In other words, Leon go before me.

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1 DR. MILLER: To keep the continuity.

2 CHAIRMAN CERQUEIRA: Yes. Otherwise, it's
3 going to be disjointed.

4 DR. MILLER: I think you can propose that
5 when you get to the table to keep the continuity. I'm
6 sure the Commission will accommodate.

7 MR. ESSIG: Yes. I think as part of your
8 opening remarks you can say --

9 DR. MILLER: Well, actually you're going
10 to -- I'm going to make some initial opening remarks,
11 and I'm going to talk about the fact that there will
12 be two speakers from the staff today and I'll
13 introduce Pam to speak, and then Tom will speak. At
14 that point in time, Dr. Paperiello will say the staff
15 has completed its presentation. The Commission will
16 ask questions of the staff. When that's done, then
17 the staff will leave the table, and ACMUI will go to
18 the table. Maybe, Dr. Cerqueira, in your opening
19 remarks you might say to keep continuity we'd like to
20 address those deconstruction issues first, and then
21 we'd go into Ralph's presentation.

22 CHAIRMAN CERQUEIRA: Now in terms of
23 whoever is controlling the slides, we should get some
24 idea ahead of time whether we can do that.

25 DR. MILLER: Yes. They're usually

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1 controlled from the back room.

2 MR. ESSIG: Yes, we control them. SECY
3 does not offer that service, so Angela will be in the
4 slide --

5 CHAIRMAN CERQUEIRA: There you go, as long
6 as Angela can do that.

7 MR. ESSIG: I have to inform Angela that
8 that's what we'll be doing though.

9 DR. VETTER: I have a philosophical
10 question for Tom.

11 MR. ESSIG: Yes.

12 DR. VETTER: In your fifth slide you ended
13 by saying "form conclusions regarding the merits of
14 the SNM critique." Why don't you concluding regarding
15 the current methodology for dose reconstruction that
16 the NRC uses?

17 MR. ESSIG: We can certainly --

18 DR. VETTER: You see the difference.

19 MR. ESSIG: Yes, I see --

20 DR. MILLER: I think there's an outgrowth
21 to that. I think that's where we want to ultimately
22 get to. But what Tom's addressing is the tasking that
23 was specifically given by the Commission.

24 MR. ESSIG: And that's why it was focused
25 on --

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1 DR. VETTER: All right. I understand
2 then.

3 DR. MILLER: I think a natural outgrowth
4 of that is to do exactly what you said.

5 MR. ESSIG: Yes. And the issue would have
6 never arisen, most likely, had we not received this
7 report, so that's why it has such a major focus.

8 CHAIRMAN CERQUEIRA: All right. Dr.
9 Malmud, do you want to go over your's?

10 DR. MALMUD: My presentation is rather
11 brief. I'll just introduce myself. I'm Leon Malmud,
12 a board certified nuclear physician and Dean Emeritus
13 of Temple University School of Medicine, serving as a
14 representative of health care administration on the
15 ACMUI. The chairman of the ACMUI, Dr. Cerqueira,
16 appointed a subcommittee consisting of a patient
17 advocate, a medical physicist, radiopharmacist, a
18 therapy physicist and myself as chair to review
19 material relating to radiation dose estimates in the
20 St. Joseph Mercy Hospital incident.

21 Briefly, a patient with metastatic thyroid
22 cancer who was also in renal failure was treated on an
23 in-patient basis with 285 millicuries of I-131. The
24 renal failure is relevant because in patients with
25 impaired renal failure, the administered dose of I-131

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1 is retained longer in the patient's body than would
2 otherwise be the case.

3 The patient succumbed to her illness six
4 days following the I-131 treatment. During that six
5 day period the patient's daughter, whom we are told
6 was given radiation protection guidelines in order to
7 minimize the radiation dose that she would receive
8 from exposure to her mother, chose to ignore the
9 guidelines so that she could be physically close to
10 her terminally ill mother. As a result of the
11 daughter's non-compliance, she received a higher than
12 allowed radiation burden to herself.

13 The NRC's methodology for calculating the
14 radiation burden to the daughter is being called into
15 question, not the fact that in this instance that the
16 radiation burden to the daughter, even in the best
17 case scenario, exceeded the 100 millirem limit for a
18 member of the public per the guidelines.

19 We're still in the process of collecting
20 data and questioning the assumptions presented. For
21 example, did the daughter sit by the patient's bed for
22 12 hours a day for three days with her arms on the
23 bed, and then do so for 20 hours a day on days five
24 and six? What was the real half-life of the I-131 in
25 the patient? How was it measured? These are just a

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1 few questions.

2 In the absence of adequate contemporaneous
3 records, what assumptions should be made before
4 calculating the radiation burden to the daughter? How
5 should a similar situation be addressed in the future?
6 What guidelines would be helpful to RSOs and licensees
7 in addressing non-compliance by public visitors?
8 Would more timely notification of the Regional Office
9 have been appropriate?

10 We hope to have a final report available
11 within four weeks for both the ACMUI and the NRC.
12 Thank you.

13 CHAIRMAN CERQUEIRA: Brief and sweet. Any
14 comments?

15 MR. ESSIG: I just had one. Dr. Malmud
16 you said impaired renal failure?

17 DR. MALMUD: Impaired renal function. I
18 think I said function.

19 MR. ESSIG: I thought I heard failure.

20 DR. MALMUD: I read it incorrectly, but I
21 wrote function.

22 DR. WILLIAMSON: You did say impaired
23 renal failure.

24 DR. MALMUD: Did I? All right. Thank
25 you.

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1 MR. ESSIG: I was listening.

2 DR. MALMUD: And I wasn't reading my own
3 writing.

4 CHAIRMAN CERQUEIRA: Sally.

5 MS. SCHWARZ: I just wanted to ask one
6 question that really doesn't have to do with your
7 presentation at the moment, but for the subcommittee
8 -- the article that was written by Marcus and Siegel.
9 I don't believe that we ever received the full actual
10 calculations that they performed. We just received
11 the first several sheets as part of the committee,
12 kind of a summary of the work. Is there a way that as
13 part of what was faxed to the committee members,
14 subcommittee members, we could get the actual
15 calculations so we could review those too?

16 MR. ESSIG: We will certainly give you
17 what we have, which is about a 12, 16-page -- I'm
18 sorry. It's 17 pages.

19 MS. SCHWARZ: That would be good, because
20 we didn't receive that.

21 MR. ESSIG: Oh, you didn't receive that.
22 Something happened in the --

23 DR. MALMUD: What happened -- you're
24 correct. I didn't realize that you hadn't received it
25 either. I had received an abbreviated copy, and then

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1 I did receive the full copy. So you didn't receive
2 the full copy, perhaps -- I have a full copy here.

3 MR. ESSIG: We can take care of that.

4 DR. MALMUD: We can take care of that
5 right now.

6 MR. ESSIG: I didn't realize that.

7 DR. WILLIAMSON: I think I have a full
8 copy but there weren't detailed calculations in there
9 particularly.

10 DR. MILLER: We don't have those either.

11 DR. WILLIAMSON: No. I mean, I don't
12 think there are any detailed calculations by anybody.

13 MR. ESSIG: Not from Marcus and Siegel.

14 DR. WILLIAMSON: There is the inspection
15 report, and it's addenda that the Region prepared, nd
16 then there is the manuscript as submitted and reviewed
17 by Dick, the journal part of Dr. Marcus' --

18 MS. SCHWARZ: And the manuscript does have
19 the detailed calculation.

20 DR. WILLIAMSON: No, it doesn't -- it as
21 a critique and statements that it's off by this or
22 that. Some of which, you know, are not exactly true.

23 MS. SCHWARZ: The assumptions that they
24 made were part of the --

25 DR. NAG: The assumptions made were in

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1 there.

2 DR. WILLIAMSON: The fact is nobody has
3 the basis for a critique because we haven't seen any
4 data, nor have they.

5 DR. MALMUD: Did the other members of the
6 committee also not receive the full article which is
7 17 pages?

8 DR. EGGLI: I did not.

9 CHAIRMAN CERQUEIRA: I think it's really
10 important for the subcommittee to define the material
11 that they need to make a full evaluation, and we
12 should make certain that all of the, certainly the
13 subcommittee members. Did the rest of the ACMUI wish
14 to receive copies, as well? I don't think there's any
15 -- I certainly don't. I think the subcommittee --
16 Tom, I think it's important to get it out, complete
17 records of everything that you have that they need.

18 MR. ESSIG: What I would suggest is
19 shortly after everyone returns to their office, we'll
20 schedule a conference call with the subcommittee, and
21 you can voice whatever needs you have, and we'll --

22 CHAIRMAN CERQUEIRA: I think it would be
23 best to define the material that they need and get it
24 out to them as soon as possible. And then set up the
25 conference calls. But, you know, the fact that some

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1 of the committee got part of the material and others
2 didn't, the subcommittee, I think is a problem. Jeff.

3 DR. WILLIAMSON: I think there's an issue
4 with claiming we're going to be done in four weeks,
5 because obviously, we're going to be meeting you know,
6 without -- we're going to be having unnoticed
7 meetings, and the subcommittee will formulate its
8 recommendations. But my understanding of the Sunshine
9 Law requirements are, is that this report has to be
10 deliberated in public by the full committee before
11 this report can be submitted to the staff.

12 CHAIRMAN CERQUEIRA: That's right.

13 DR. WILLIAMSON: So I think that it's
14 optimistic to say that's going to be done in four
15 weeks.

16 MR. ESSIG: That will be done by a noticed
17 phone call, conference call. I mean, we're not
18 proposing getting the full committee together to
19 deliberate on the report.

20 CHAIRMAN CERQUEIRA: If you're to get it
21 to the commissioners in four weeks, then we should set
22 that up now. Otherwise, it's not going to happen.

23 DR. WILLIAMSON: I think it's kind of
24 optimistic to think we're going to have all these --
25 that's my worry, because we do have to have a noticed

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1 meeting.

2 MR. LIETO: Can I have a clarification?
3 I'm trying to understand which topic we're talking
4 about with this four-week period. I thought there
5 were two tasks, two short-term tasks of the
6 subcommittee. The one was going to be the calculation
7 reassessment and critique which is going to be done in
8 four weeks. The second one that Dr. Malmud is
9 referring to in his presentation, that was going to be
10 passed too, and I didn't - - are we saying that we're
11 going to have both of them done in a month? I mean,
12 that's what it sounds like to me, and I'm thinking
13 that maybe the one that Dr. Malmud is referring to
14 might take a little bit longer.

15 DR. MALMUD: Excuse me. By the second
16 task, do you mean how we should deal with this issue
17 in the future?

18 MR. LIETO: Right.

19 DR. MALMUD: That really I don't think is
20 a major task, in that these are recommendations which
21 would just be helpful to RSOs in general. I think
22 that the current guidelines probably give us adequate
23 means of dealing with this. But it would still be
24 very helpful to the RSOs and to the licensees to know
25 specifically what do we do in situations such as this,

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1 when a member of the public in a tragic situation such
2 as this, refuses to cooperate. This is not a
3 stranger. This is a --

4 DR. WILLIAMSON: Well, that's not the only
5 issue. I think the issue is how to manage patients
6 whose family members request exemption from the 100 or
7 500 mR limit for compassionate rationale.

8 DR. MALMUD: You're correct.

9 DR. WILLIAMSON: Not just those who
10 disobey the instructions of the -- so I think you're
11 making --

12 CHAIRMAN CERQUEIRA: We're going to need
13 to go upstairs to be on time for the Commission
14 briefing. But before we leave, we need to make sure
15 that the charge to the subcommittee is clearly written
16 and distributed to all the committee members. And that
17 should be done by the end of this week.

18 You know, Charles, we have to give some
19 idea of when we're going to have this to them. And,
20 obviously, that's of concern to you -- what are we
21 going to way, four weeks?

22 DR. MILLER: I think for the purposes of
23 the Commission meeting it's safest to say that the
24 subcommittee will try to complete its activities in
25 four weeks, an we will convene a conference call of

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1 the full committee as soon as possible thereafter.

2 CHAIRMAN CERQUEIRA: Yes. I think that's
3 the right language, because when we reconvene again we
4 need to set these timelines.

5 DR. WILLIAMSON: And then, you know, we'll
6 set these timelines at the meeting this afternoon to
7 go forward. I don't want to box you into four weeks,
8 because if we give the Commission a finite timeline,
9 Commissioner McGaffigan will push to get it done
10 especially in that timeline.

11 DR. MALMUD: So I'll change my last
12 sentence to say that we hope to have a final report of
13 the subcommittee available in four weeks for review by
14 the ACMUI.

15 CHAIRMAN CERQUEIRA: Yes.

16 (Whereupon, the proceedings in the
17 above-entitled matter went off the record at 9:18 a.m.
18 and went back on the record at 12:49 p.m.)

19 CHAIRMAN CERQUEIRA: The transcription
20 service is now available, so if people would like to
21 get started we can.

22 And a couple of people have asked me to
23 maybe add a couple of things sort of immediately when
24 we're getting started and one is the -- I guess we
25 really need Tom and Trish here. The whole issue of

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1 the inventory and the process and what's been going on
2 and what the ACMUI can do to help. Maybe we'll wait
3 for Tom to come back.

4 The other thing that Ralph asked that
5 perhaps we do is to just sort of review the charges,
6 if any, that were put to the Committee by the
7 Commissioners.

8 DR. MILLER: Mr. Chairman, if I can, I
9 want to caution all of us. We heard what the
10 Commissioners said at the table today. Now what
11 they'll go back and do from the meeting is they will
12 deliberate on what they call a Staff Requirements
13 Memorandum. That's the official guidance that we'll
14 get. So to jump from anything that they said
15 verbally, I think you can anticipate some of the
16 things that may be coming, but the jump from anything
17 that they said verbally we have to be cautious on.

18 They'll deliberate how they want to direct
19 the guidance to be done and sometimes that takes two
20 or three iterations of discussions amongst the
21 Commission offices to make that happen. We did hear
22 from some of the Commissioners verbally on their
23 views.

24 We have to do the bidding of the whole
25 Commission once they make up their mind. So what

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1 we'll do is as soon as we get the SRM, that will give
2 us the guidance of what we have to charge ACMUI with
3 doing.

4 CHAIRMAN CERQUEIRA: Ralph, is that --

5 MR. LIETO: I don't have any objection
6 with that. I just thought that there were a couple of
7 things that, like for example, regarding the sealed
8 source information that Commissioner McGaffigan very
9 politely, but sternly, encouraged us to get those
10 inventories in, so to speak.

11 CHAIRMAN CERQUEIRA: Yes.

12 MR. LIETO: And I was thinking that maybe
13 we might want to go back to various organizations that
14 might be affected by this, so that their membership,
15 if they're contacted, you know, this is what you need
16 to do and maybe just to get the word out there so that
17 people start something along that line.

18 CHAIRMAN CERQUEIRA: Sure.

19 MR. LIETO: The other thing was about the
20 implementation of Part 35 this morning. I have some
21 I guess this going to be a surprise, I have some
22 strong opinions about certain things, that I think --
23 just want to kind of put out on the table. I don't
24 know if we're going to go anywhere with it, but I
25 think it would have been helpful if we had some input

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1 on -- not input, but some advance notice on what was
2 being presented. Because I think there's reasons why
3 some of that stuff is currently out there.

4 And I think some of the guidance that NRC
5 is giving us, I personally have some reservations.
6 Those are the kind of things that I thought maybe
7 might be good to kick around and discuss a little bit.

8 CHAIRMAN CERQUEIRA: So do you want to
9 initiate that?

10 DR. MILLER: I think that's reasonable to
11 have a discussion. I am just cautioning everyone with
12 regard to the official capacity of what the Committee
13 would do at the Commission's direction.

14 MR. LIETO: I guess just to start off on
15 the first issue having to do with the sealed source in
16 the IAEA charge, if you will, to the NRC, is that
17 there's this -- I won't say necessarily a reluctance,
18 but maybe lack of due diligence in responding to the
19 NRC inquiry for their inventories that I agree the
20 point that Dick made earlier that getting an e-mail
21 from somebody is not -- that doesn't have some kind of
22 official imprimatur kind of bothers us all.

23 In fact, this is the second time it's
24 happened to me. And so I myself will also admit that
25 I didn't respond either. And it's not a very simple

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1 inventory to respond to either, request.

2 But be that as it may, I think that we can
3 have sort of the -- maybe if Trish or Tom can help us
4 with sort of -- if you have questions who to go to
5 type of a thing. There are various listservers that
6 we could put this out on that businesses interact with
7 as well as -- I think mainly it's going to affect the
8 therapy end of the community because that's where the
9 high activity sources lie and maybe going to
10 representatives of those organizations to say if
11 you've been contacted and you have not responded, you
12 need to do this. It's important that you follow up on
13 this. And have the societies also, the professional
14 societies encourage the individual licensees that they
15 need to complete this inquiry.

16 CHAIRMAN CERQUEIRA: Can I ask you a
17 couple of questions, maybe both you and Dick? Did you
18 receive the official letter from NRC?

19 DR. VETTER: No.

20 CHAIRMAN CERQUEIRA: No.

21 DR. VETTER: I don't remember receiving a
22 letter. Just a cold e-mail.

23 DR. MILLER: That's the first step of the
24 problem, if that was an oversight or if it ended up
25 some place else in the organization and never got to

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1 you.

2 MR. LIETO: I don't recollect one. I'll
3 be honest.

4 DR. MILLER: The second issue is then how
5 to follow up on that with regard to the collection of
6 the information. There are -- we do have staff
7 contacts that can help you in that regard, probably
8 I'm thinking Merri Horn would probably be -- I don't
9 know if you know Merri Horn, but we can certainly get
10 you the contact. She works in my Rulemaking Branch.

11 DR. VETTER: Through an exchange of e-
12 mails I did hear from her.

13 MR. LIETO: Lots of times people get --
14 you get asked for the information and so forth and I
15 think there's some real underlying importance
16 attached, obviously.

17 DR. MILLER: Absolutely.

18 MR. LIETO: And if -- not to say whenever
19 you get asked by -- asked something from the NRC it's
20 not important, but informational items may not be a
21 high priority in relationship to other daily
22 activities.

23 DR. MILLER: Tom, you're trying to secure
24 copies of the letter, so at least all of the Committee
25 members have the letter.

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1 MR. ESSIG: There were a number of
2 attachments and copies are --

3 MR. LIETO: And we could maybe use --
4 sending something to the various -- professional
5 newsletters and ask them to print something to the
6 effect of this and if you got questions where to go,
7 just to kind of maybe get some of those blanks filled
8 in.

9 CHAIRMAN CERQUEIRA: I guess for the staff
10 we identified as a fact that even though you may have
11 put together a procedure in place, the end users have
12 not gotten in a very systematic way --

13 DR. MILLER: Well, I don't know if that's
14 true or not.

15 MR. ESSIG: Well, at least data points.

16 DR. MILLER: Yes, two data points that
17 said you two personally didn't see it and what I'd
18 have to go back and check is who was the addressee of
19 the letter to each of your licensees or was there an
20 oversight and you didn't get it.

21 CHAIRMAN CERQUEIRA: Dick?

22 DR. VETTER: I would not suggest it was
23 not systematic. I'm assuming that a lot of people got
24 this e-mail. But I don't know. Maybe there was a
25 letter of some sort as well. I don't know about that.

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1 I'm not suggesting it's not systematic. What I object
2 to was, what I objected to was the fact that I was
3 being asked to share my inventory with a contractor
4 who was working on behalf of the NRC.

5 That was all explained to me very, very
6 clearly and politely. But when I read down, okay, I
7 asked where was this going and they said it's strictly
8 voluntary and it's going to be shared with the
9 following and obviously the contractor, but when you
10 read down further, there are numerous federal agencies
11 who will have access to the data.

12 I am a little worried about the potential
13 openness of this. Here I am supposed to be taking
14 action to prevent someone from coming in and stealing
15 our radioactive inventory --

16 DR. MILLER: And now you're e-mailing it
17 out to everybody.

18 DR. VETTER: I'm e-mailing it out.

19 DR. MILLER: I was not aware that that was
20 going on. I had just assumed that the way the data
21 was being collected was people were --

22 DR. VETTER: And I'm certainly
23 exaggerating. I'm not saying it's e-mailed to
24 everybody. I'm just worried about the number of
25 agencies who will have access to it and the number of

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1 people within those agencies that have access to it.

2 I haven't been reassured about the
3 safeguarding of this data.

4 DR. MILLER: That's a fair comment.

5 CHAIRMAN CERQUEIRA: What's the wishes of
6 the Committee now? We've identified that there may be
7 some issues and I apologize for my broad statement.

8 MR. LIETO: I guess I'll just make a
9 recommendation and maybe we can go from there, would
10 be that ask NRC Staff to give us information on who
11 licensees can contact as a verifying source if they
12 have concerns about completing these inventories. And
13 secondly, to urge licensees to respond to this inquiry
14 if they have not already done so.

15 DR. MILLER: Merri Horn is the NRC project
16 manager for this effort.

17 MR. LIETO: I'm looking, like I said, just
18 sort of an informational broadcast versus some of the
19 listservers and physics listservers and Society
20 listservers and newsletters type of thing. Get the
21 word out.

22 CHAIRMAN CERQUEIRA: Dick?

23 DR. VETTER: Personally, Ralph, I'll
24 disagree with that. I would rather not go public, but
25 rather that I get another e-mail of some sort directed

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1 to me and to you and all those who are requested to do
2 the e-mail, reassuring us of some things, rather than
3 tell the whole world that we're supposed to do this.
4 Now the whole world knows we're doing it.

5 CHAIRMAN CERQUEIRA: Ruth?

1 MS. MCBURNEY: In Texas, we have --
2 there's been another follow-up from NRC with a list of
3 our licensees that have not responded and we took the
4 initiative to contact all of them and have reassured
5 them that this is information that is being collected
6 for this database and that's what the agreement states
7 are doing is sending out another contact to all those
8 licensees. Now whether NRC is going to do that, I
9 don't know.

10 CHAIRMAN CERQUEIRA: Does the Committee
11 want any further action on this or just sort of an
12 information item for staff?

13 DR. VETTER: I guess I think the Staff
14 just need to be aware of what our concerns are and to
15 perhaps act accordingly.

16 MR. LIETO: I have no problem with that.

17 CHAIRMAN CERQUEIRA: That's been
18 registered. All right. I think we should go back to
19 the agenda.

20 Several members have identified the fact

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1 that they have early flights and have to be out of
2 here by 3 o'clock so in order to -- and Dr. Nag,
3 unfortunately had to leave early already, so I think
4 it will be important to try to get through some of
5 these issues in a timely fashion.

6 The first item is proposed changes to
7 abnormal occurrence criteria and Angela Williamson
8 will be doing the presentation.

9 Angela, are you going to need the full
10 hour, do you think?

11 MS. WILLIAMSON: No. I shouldn't. It
12 depends on how many questions you have.

13 CHAIRMAN CERQUEIRA: Okay.

14 MS. WILLIAMSON: Okay, I'll make this very
15 quick --

16 CHAIRMAN CERQUEIRA: No, you don't have to
17 make it quick, but we should get to the points and
18 provide the information you need.

19 MS. WILLIAMSON: I want to start out by
20 saying that I probably should have named this, instead
21 of proposed changes to abnormal occurrence criteria
22 which sort of suggests that this is a definite thing
23 that we're looking to do, I should have probably made
24 it more clear that this is not -- changes to the AO
25 criteria is not within the realm or the authority of

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1 my particular office, Nuclear Materials Safety and
2 Safeguards. It's actually within the realm of the
3 Office of Research.

4 So what I'm about to discuss with you
5 today I should probably call it preliminary proposed
6 changes because actually the Office of Research, they
7 own the AO criteria and it's possible that there will
8 be no changes. So I just want to make that very clear
9 to everyone that we want your input, but for reasons
10 that may not be clear to me or anyone in NMSS, it just
11 may not go forward.

12 DR. MILLER: I guess if I could just
13 augment what Angela is saying. I think what would be
14 valuable to us and NMSS is these are some views that
15 developed at NMSS, so it would be helpful if we could
16 get the Committee through dialogue to either support
17 it, recommend modification to it, including don't go
18 forward with it or whatever, so that we can continue
19 to dialogue with the Office of Research with regard to
20 what the appropriate recommendation would be, if any,
21 for a change.

22 MS. WILLIAMSON: Okay, I want to very
23 quickly define abnormal occurrence. An abnormal
24 occurrence, as you can see on the screen is an
25 unscheduled incident or event which the NRC determines

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1 to be significant from the standpoint of public health
2 and safety.

3 And there are several different types of
4 AOs. The less common types, what I mean by that term
5 is that the types that we don't see occurring as often
6 amongst licensees are those involving releases to the
7 environment, involving theft or diversion, or
8 involving the design or construction of license
9 facilities. And as you might guess, the more common
10 types of AOs involve over-exposures and medical
11 events.

12 Now if this transpires, this proposed
13 change goes forward, what I have here in the red text
14 shows you what we plan to add to the medical event AO
15 criteria. What we're saying here is that we want the
16 consideration that a dose to those organs, those
17 organs, the lens of the eyes, the gonads, so on and so
18 forth, but we want to add or to tissue which results
19 in permanent functional damage. The reason why we're
20 considering adding that language to the medical event
21 AO criteria is that it would be a way for us to
22 definitively capture events involving intravascular
23 brachytherapy.

24 However, we don't want to catch every
25 event involving intravascular brachytherapy so by

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1 adding the language or to tissue which results in
2 permanent functional damage, that would exclude those
3 IVB events in which the tissue just got a little --
4 just got over-exposed, but there was no permanent
5 damage done to the tissue.

6 DR. WILLIAMSON: Can you go back to that
7 slide? Two comments. One, I think it would be
8 helpful if you outlined for the group what the purpose
9 of AO is and how it is used in your congressional
10 reporting. I'm not sure that everybody here has been
11 involved in the discussion of the AO provision before.

12 Secondly, go ahead, I'm sorry.

13 MS. WILLIAMSON: Okay.

14 DR. WILLIAMSON: Then I'll ask my other
15 question.

16 MS. WILLIAMSON: Okay, we are required to
17 report certain events to Congress and these events are
18 defined as abnormal occurrence events and so what we
19 have to do is we have to -- every year we have to
20 capture those events that meet the abnormal occurrence
21 criteria definition and we assemble a report for
22 Congress and we forward it to them. The report I
23 believe is called NUREG-1100 if memory serves me
24 correctly. And as far as I know, it's for their
25 information. I don't know that they do anything more

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1 with it than just be informed by it.

2 Dr. Miller, you might want to correct me
3 if I have an incorrect understanding of that, but they
4 do want to know about these things.

5 I suppose it's always possible for them to
6 come back to us and ask us questions about those
7 things, but I cannot speak to what is routinely done
8 with this information.

9 DR. MILLER: Just so that we're all clear,
10 the abnormal occurrence report to Congress covers all
11 of NRC's regulated activities for reactors to
12 materials. So over the course of many years if we go
13 back to Three Mile Island and Chernobyl and things
14 like that, the Congress is always interested in the
15 state of affairs in what I'll call the nuclear arena.
16 So that abnormal occurrence report is something that
17 Congress has asked for over time.

18 Depending upon what happens in any given
19 year and what the nature of Congress is, sometimes we
20 get feedback, sometimes we don't.

21 DR. WILLIAMSON: Okay, now my technical
22 question. It is not clear from this what you want to
23 include and exclude. I think I hear you saying that
24 you want to exclude events which may give 10 gray to
25 some tissue in intravascular brachytherapy due to an

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1 equipment malfunction or something, as we discussed in
2 the last meeting, but not unless it results in
3 permanent functional damage to the tissue. Is that
4 correct? You want to not report 10 gray events unless
5 they have a functional damage to the tissue?

6 MS. WILLIAMSON: No. There's an "or"
7 there.

8 DR. WILLIAMSON: Yes, I see.

9 MS. WILLIAMSON: It's "or". So what we're
10 saying is the rest of it still applies, but in
11 addition, would be inclusion of any event in which
12 there's permanent functional damage to tissue because
13 you see there can be 10 gray to a person's finger, but
14 that's not going to result in permanent functional
15 damage, obviously.

16 But if there's 10 gray to tissue which
17 causes permanent functional damage, there really
18 narrows down that type of event, what kind of event
19 would that happen in which that might occur, an IVB.

20 DR. WILLIAMSON: I'm still confused. The
21 way it's written just in the black which I assume is
22 the current rule is that any event which gives a 10
23 gray to any tissue or organ is automatically going to
24 be reported as an AO, isn't it?

25 MS. WILLIAMSON: No.

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1 DR. WILLIAMSON: No? It says there "is
2 equal to or greater than 1 gray to a major portion of
3 the bone marrow, dah, dah, dah, or equal to or greater
4 than 10 gray to any other organ.

5 MS. WILLIAMSON: Organ.

6 DR. WILLIAMSON: Okay, so the distinction
7 rests in your mind on what is a tissue versus an
8 organ.

9 MS. WILLIAMSON: Exactly.

10 DR. WILLIAMSON: So you don't consider the
11 epithelium of a blood vessel to be an organ?

12 MS. WILLIAMSON: Exactly.

13 CHAIRMAN CERQUEIRA: Doug?

14 DR. EGGLI: So Angela, you're saying if
15 permanent injury results at a dose of less than the
16 1000 rad dose then that's reported in addition to any
17 dose over and above?

18 MS. WILLIAMSON: No, that's not what I'm
19 saying.

20 MS. MCBURNEY: The 10 gray still goes --

21 MS. WILLIAMSON: Exactly. The 10 gray,
22 the criteria above what you see in red has nothing to
23 do with permanent functional damage. That's just
24 strictly the reporting of that dose to that type of
25 organ.

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1 DR. EGGLI: But if any dose causes
2 permanent functional damage it's reportable?

3 MS. MCBURNEY: No. Above 10 gray.

4 DR. WILLIAMSON: It's got to be above 10
5 gray.

6 CHAIRMAN CERQUEIRA: Ralph?

7 MR. LIETO: I think the fix to this would
8 put in there after your first red or put a parentheses
9 3 and then just say equal to or greater than 10 gray
10 to tissue which results in blah, blah, blah which
11 sounds like what you want.

12 DR. WILLIAMSON: What's your definition of
13 organ?

14 MS. WILLIAMSON: Organ is not defined in
15 Part 20.

16 DR. EGGLI: I have another question on the
17 A part. Do you really mean there "unintended dose to
18 the bone marrow"? What about an intended or planned
19 dose to the bone marrow?

20 MS. WILLIAMSON: Well, if it's planned, if
21 it's therapeutic, that's different. We're talking
22 about doses that people receive that they shouldn't
23 have received. When those doses are at those limits
24 are greater, then they would meet the AO criteria.

25 DR. WILLIAMSON: See, it has to be a

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1 medical event or misadministration already, so that
2 means there has to be some component of rogue
3 delivery.

4 MS. WILLIAMSON: Exactly. Appendix A,
5 criterion 4 for medical licensees states that a
6 medical misadministration or a medical event that --
7 so this is merely beyond being just a medical event or
8 a misadministration. If you're in an agreement state,
9 it's a little bit more than that. It's a dose
10 threshold that includes a medical event or
11 misadministration.

12 DR. WILLIAMSON: So a treatment with a
13 leaking source that gave a correct dose of 10 gray to
14 the tumor would be an AO, even though the dose is
15 correctly --

16 MS. WILLIAMSON: No, no, no. If you
17 prescribe a dose, that's different.

18 DR. WILLIAMSON: Well, I'm just reading
19 your definition. See, a correct treatment given with
20 a leaking source as I understand a medical event
21 because it was given with a leaking source, it's a
22 medical event independent of whether there was any
23 dose delivery error or not. So as I would read this
24 a correctly given treatment, given with an incidently
25 leaking source would both be a medical event and also

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1 an abnormal occurrence just because both paragraph A
2 -- so, I think Dr. Eggli's point has some merit still.

3 There are classes of misadministration or
4 medical event that you might not want to report here
5 that seem to satisfy this definition. I guess I
6 consider that an incidental comment.

7 CHAIRMAN CERQUEIRA: Leon?

8 DR. MALMUD: Jeff, are you recommending
9 some changes in the words as they are on this graph,
10 on this --

11 DR. WILLIAMSON: Well, that sort of
12 depends on the way this is interpreted and handled at
13 the level of guidance and implementation.

14 I'm just pointing out that the way AO is
15 now defined it actually could include a large class of
16 events that weren't intended. Like if you treated a
17 prostate brachytherapy patient with 75 seeds, one of
18 them happened to crack open in the procedure and leak,
19 that would be a medical event if you detected that
20 because you treat the patient at the leaking source
21 and because you gave 140 gray correctly or incorrectly
22 it doesn't matter to the prostate which is some organ.
23 This would satisfy that definition. That's all I'm
24 saying, an observation I'm making.

25 CHAIRMAN CERQUEIRA: Dick, help us out

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1 here.

2 DR. VETTER: Just to clarify, first of
3 all, the only thing new is what's in red. Is that
4 correct?

5 MS. WILLIAMSON: That's correct.

6 DR. VETTER: And is the intention for the
7 10 gray to apply to that tissue?

8 MS. WILLIAMSON: Yes.

9 DR. VETTER: Then how about if you remove
10 the comma and the word "to", "to any other organ or
11 tissue which results in permanent functional damage",
12 is that your intention?

13 MS. MCBURNEY: Then the permanent
14 functional damage would also apply to organ, as well,
15 if you did that.

16 CHAIRMAN CERQUEIRA: So Ruth, how would
17 you change it to make it --

18 DR. VETTER: Then the first suggestion
19 where we --

20 MS. MCBURNEY: I like the suggestion of as
21 a 3, to make it clearer, equal to or greater than 10
22 gray to tissue which results in permanent functional
23 damage.

24 CHAIRMAN CERQUEIRA: Ralph, would that fix
25 it?

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1 MR. LIETO: It was my suggestion, of
2 course.

3 (Laughter.)

4 MS. SCHWARZ: I have a question. Is that
5 unintended dose?

6 CHAIRMAN CERQUEIRA: That's unintended.

7 DR. WILLIAMSON: Not necessarily, if it's
8 a leaking source, it could be the intended dose.
9 That's my point.

10 DR. SULEIMAN: I'd like to clarify
11 something.

12 CHAIRMAN CERQUEIRA: Sure.

13 DR. SULEIMAN: The term "organ" and
14 "tissue", I was waiting for it to reappear, but the
15 terms are used synonymously. I mean you have dose
16 models and I think the way it's worded here it sounds
17 like it's an either or and I think maybe to any other
18 organ or tissue would probably be -- if you just put
19 organ or organ and tissue would probably be more
20 meaningful.

21 DR. WILLIAMSON: I think it would be good
22 if our medical experts here could define for us what
23 tissue and organ means because it does seem an
24 inconsistency. I would think that all organs are
25 tissues, but perhaps not all tissues are organs.

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1 DR. MALMUD: The largest organ in the body
2 is the skin. And the expression of the term "tissue"
3 seems to be applying to a region of that organ, rather
4 than the organ in toto. And it is quite possible to
5 give quite a significant dose to a portion of that
6 organ which is quite damaging, yet the majority of the
7 organ is not affected.

8 So tissue from my understanding of it and
9 we can pull out a copy of Dorland's if we wish to
10 confirm it, but can be any collection of cells from
11 any organ. But an organ has a definite definition and
12 the largest organ in the body is the skin.

13 So I think that it is the skin, in
14 particular, which is generating this issue for us
15 because clearly it seems that the intent was to deal
16 with a portion of that organ rather than the organ in
17 toto. Am I correct?

18 MS. WILLIAMSON: Yes, exactly. We have
19 the dose limits for organs which is in black. So what
20 we're trying to do is narrow down the tissue issue.

21 DR. WILLIAMSON: Would it be more helpful
22 if you said "part of an organ receiving at least 10
23 gray which results in permanent functional damage"?

24 MS. WILLIAMSON: What we're trying to do
25 is capture IBV events in which there's permanent

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1 functional damage.

2 DR. WILLIAMSON: And you don't think
3 they're captured now because when a 10 gray medical
4 event occurs it only occurs to a fraction of the
5 epithelial lining of the blood vessels so therefore
6 you view it as not an AO?

7 MS. WILLIAMSON: It can be argued either
8 way. If in an IVB event 10 gray or a 1000 rads occurs
9 or greater occurs outside of the intended treatment
10 site, it can be argued that that's an AO.

11 What we're trying to do is not forward 12
12 AOs to Congress in a year.

13 DR. WILLIAMSON: I understand.

14 MS. WILLIAMSON: But what we want to do is
15 narrow that definition so that just certain IVB events
16 are captured and what makes the most sense to us at
17 this point is just to only forward those in which
18 there's permanent damage inadvertently done to the
19 patient.

20 DR. WILLIAMSON: What is confusing me, I
21 guess, is in your minds, the minds of the staff, what
22 is the difference between tissue and organ and I've
23 heard two possible things. I mean one might consider
24 organs as discrete anatomic structures that are
25 covered with epithelial linings or something and

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1 tissue is like connective tissue that's not itself an
2 organ. That's one possible interpretation. The other
3 interpretation has been raised by maybe our Vice Chair
4 and he suggested maybe your concern is partial versus
5 whole organ irradiation.

6 So I'm uncomfortable because the
7 terminology and intent isn't very clear.

8 MS. WILLIAMSON: The short answer to that
9 is that they can, to some extent, can be a bit
10 interchangeable because organ is not formally defined
11 in Part 20.

12 DR. WILLIAMSON: But organ, I'm sure your
13 OJC would say then that the definition of the word
14 would revert to ordinary anatomic or medical uses. So
15 just because it's not defined in Part 20 doesn't mean
16 you have license to use the words anyway you want.

17 MS. WILLIAMSON: Well, we do have the
18 option to consider IVB events in which an unintended
19 portion of the vessel was irradiated at 1000 rads or
20 greater. We have the option right now to consider
21 those AOs.

22 So what we're trying to do is find a way
23 to not consider those AOs in the short term. Now we
24 can always go back -- I can't say we can always go
25 back. We can consider formally defining organ in Part

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1 20 which --

2 DR. WILLIAMSON: That's a lot of work.

3 MS. WILLIAMSON: But in the meantime, just
4 for the purpose of taking care of this AO criteria, we
5 can --

6 DR. WILLIAMSON: I know. I'm not trying
7 to be -- attack your intention. I'm just saying what
8 I hear isn't making sense and holding up to critical
9 inspection and it seems to me it leaves a big
10 ambiguity what phrases conditions 2 and 3 mean unless
11 it's spelled out a little more. And so that's why I'm
12 asking you what exactly do you mean by organ versus
13 tissue and do you -- if you mean partial irradiation
14 of an organ, then you should say partial irradiation
15 of an organ or portion of an organ that results in
16 permanent functional damage, if that's the issue.

17 CHAIRMAN CERQUEIRA: Sally?

18 MS. SCHWARZ: That's what I was going to
19 say, why not say or to a portion of an organ or part
20 of an organ which results in permanent functional
21 damage to the tissue, just change that.

22 CHAIRMAN CERQUEIRA: Dr. Malmud likes
23 that.

24 DR. MALMUD: I like that because it still
25 uses the word organ, appropriately and refers to the

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1 portion of the organ as tissue which is also correct.
2 Does that capture the spirit of what was intended
3 though, Angela?

4 MS. WILLIAMSON: It's a slightly different
5 answer than I expected, but --

6 (Laughter.)

7 If you have a formal recommendation, then
8 I would --

9 DR. WILLIAMSON: Can I ask a question to
10 Dr. Malmud first?

11 CHAIRMAN CERQUEIRA: Go ahead.

12 DR. WILLIAMSON: Does every collection of
13 cells in the body belongs to an organ or are there
14 collections of cells in the body that do not belong to
15 organs?

16 DR. MALMUD: Well, the circulating blood
17 cells are generally not referred to as an organ,
18 meaning the contents of our blood vessels. So I guess
19 in that instance the answer is no. Every collection
20 of cells is not necessarily --

21 DR. WILLIAMSON: But all other ones
22 besides the circulating blood cells --

23 MR. LIETO: Let me clarify. I actually
24 published some stuff that refers to tissue and/or
25 organs and I'm going to quote from the ICRP

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1 Publication 8. I just happen to have it with me,
2 okay?

3 (Laughter.)

4 I'm just going to quote one sentence. I
5 don't think we need to get into it. I think organ
6 doses are defined historically for nuclear medicine
7 dosimetry calculation and I think hear we're talking
8 about dose to a certain part of normal tissue. I
9 didn't want to use the word tissue but it may
10 transcend several organs. I mean it's not limited.
11 But to avoid confusion the expression "other organs
12 and tissues has been used in the Tables of Biokinetic
13 Data." Because the term is used inconsistently,
14 tissue, doses. I think it may have entered the
15 literature when we were talking about mammography
16 doses where the breast consists of adipose and
17 glandular tissues and it's the glandular tissue that's
18 at risk. So the real academic said it's really
19 critical tissue within that organ.

20 But I think for this discussion, I think
21 -- you don't want to average the dose to part of the
22 blood vessel when it in fact, if you were to define
23 the blood vessels as an organ or tissue, you'd have to
24 average all of the tissue in the entire body. So I
25 think you're really talking about a high dose to a

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1 very small geometric area of the body.

2 MS. WILLIAMSON: That's correct. That's
3 correct.

4 CHAIRMAN CERQUEIRA: Lynne, do you have a
5 comment in the back?

6 MS. FAIROBENT: Lynne Fairobent with ACR.
7 I actually had two questions. One may be for Jeff
8 Williamson since Dr. Nag had to leave.

9 Jeff, in adding this sort of additional
10 language will we be capturing AOs perhaps unintendedly
11 from permanent seed implants where seeds may migrant
12 to the lung that we may not have captured before or to
13 other tissue?

14 And then secondly, the way this is
15 structured, in order for A to be valid, there's an
16 "and" that follows the end of A and we have not seen
17 what follows this. So I don't know what the other
18 conditions are for meeting this in order to be an AO.

19 I don't know Angela, if you have that
20 additional text with you or not.

21 MS. WILLIAMSON: I don't.

22 MS. FAIROBENT: Obviously, A is tied to
23 something else in order to be a valid criterion and
24 without seeing that I'm actually at a loss for what is
25 the "and" criteria that needs to also be met in this.

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1 DR. WILLIAMSON: I think to try to answer
2 the first part of the question which was directed to
3 me, I think migration of a seed into the lung would
4 not be because Angela's trying to tie this to a
5 permanent functional injury. So I guess if seed
6 drifted into the lung and caused some terrible medical
7 complication, then yes, but obviously the vast
8 majority, if not all of these seeds that migrate may
9 cause a large focal dose in the lung, but they don't
10 cause a permanent functional injury. So they would
11 not be reported.

12 I don't know. You know, please don't
13 misunderstand the reason for my concern, but you've
14 now put in this rule language two different concepts,
15 tissue and organ and people can have a lot of
16 arguments about what that means, so if there would be
17 some way of saying what you need to say without having
18 to wrestle with this. Maybe you could say and modify
19 number two so it says "glandular organ" and then
20 number 3 could be "or any other tissue" and that would
21 make it clear. Perhaps that would be one way. I just
22 don't know.

23 MS. WILLIAMSON: Well, maybe adding
24 glandular organ would make it a little more clear.

25 DR. SULEIMAN: No. Glandular implies a

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1 secretory or excretory function that not all organs
2 may have.

3 MS. WILLIAMSON: Okay.

4 DR. MALMUD: I think if I may try to quote
5 that which Sally said earlier and if we go back to
6 that Appendix A, we read through sub A as it is. Then
7 it says "or the gonads" on line 4 "comma, or equal to
8 greater than 10 Gy to any other organ, or insert
9 number 3 equal to or greater than 10 to any portion of
10 an organ which results".

11 I'll say that again. It's as you have it
12 up there with 2 saying "equal to or greater than 10 to
13 any other organ, or (3) equal to or greater than 10 Gy
14 to any portion of an organ which results in permanent
15 functional damage."

16 MS. WILLIAMSON: Is that the
17 recommendation of the Committee then?

18 DR. MALMUD: I present it as a question.
19 Is that wording acceptable to the Committee?

20 CHAIRMAN CERQUEIRA: Dr. Vetter says yes.
21 Sally agrees?

22 MS. SCHWARZ: Yes.

23 CHAIRMAN CERQUEIRA: Agreement on this
24 side? What about over here, Ralph, you object?

25 MR. LIETO: So the vessel would be

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1 considered part of an organ.

2 DR. MALMUD: The blood vessel would be
3 part of the organ in which it's located.

4 MR. LIETO: So for the heart I could see
5 that. What happens when we start looking at larger
6 veins and arteries for these types of intervascular
7 brachytherapy? This treatment is coming down the pike
8 or like we're doing now in research in terms of
9 dialysis patients. Then a definition -- I wouldn't
10 think it would fit.

11 CHAIRMAN CERQUEIRA: I feel a little
12 uncomfortable not having any of the radiation
13 oncologists here, Dr. Nag and Dr. Diamond. But it
14 seems like everybody else is pretty much in agreement.

15 We have Dr. White in the back who is a
16 radiation oncologist.

17 MR. WHITE: Actually, I'm a medical
18 physicians, Gerry White from AAPM.

19 I hesitate to engage in a technical
20 disagreement with the Committee, but just back to the
21 prostate seed embolized in the lung. It's not
22 immediately -- and Jeff has a lot more dosimetry
23 calculation experience than almost anybody in the
24 world, but it's not immediately clear to me that an
25 iodine seed embolized in a vessel in the lung,

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1 necessarily gives a lower total dose than a thousand,
2 than an intravascular event that you want to capture.

3 The red language does not talk about
4 permanent functional damage to an organ. You don't
5 have to have failure of the lung function in order to
6 be captured.

7 DR. WILLIAMSON: But there's one thing
8 you're forgetting. There are really three conditions
9 that have to be met for the red text. First, it's got
10 to be a misadministration. In the case of a seed
11 embolizing in a natural way to the lung is
12 specifically exempt. Seed migration is specifically
13 exempted as grounds for a medical event. It wouldn't
14 even come that far.

15 So it has to have first be a medical event
16 on some grounds or another. Secondly, it has to give
17 this dose, more than 10 gray, to the structure,
18 whatever it is, that's what we're debating and then
19 for the red text, not only does it have to meet those
20 first two conditions, but there has to be a third
21 condition of permanent functional damage. And this is
22 the difficulty we're wrestling with.

23 The only disadvantage I can think of Dr.
24 Malmud's suggestion is that possibly it now makes 2
25 sound like it has to be a whole organ dose. So whole

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1 organ doses don't have to have permanent functional
2 damages, but partial organ irradiations do to be
3 counted in this and I'm not sure -- somebody
4 interpreting number two number is being so limited so
5 that if half the kidney is irradiated, but there's no
6 permanent functional damage, that's not going to be an
7 AO any more, whereas you had the discretion to
8 consider it an AO the way this was written. So it's
9 kind of a complicated issue.

10 MS. WILLIAMSON: Okay. I want to make it
11 clear. Maybe I didn't hear you right. I want to make
12 it clear that in the other cases, when you see number
13 one equal to or greater than 1 gray or 100 rads to a
14 major portion of the bone marrow, to the lens of the
15 eyes or the gonads, or equal to or greater than 10
16 gray or a 1000 rads to any other organ, permanent
17 functional damage does not apply to 1 or 2.

18 DR. WILLIAMSON: I realize that.

19 MS. WILLIAMSON: Okay, okay.

20 DR. WILLIAMSON: What I'm saying is you're
21 adding a condition number 3.

22 MS. WILLIAMSON: Right.

23 DR. WILLIAMSON: Which is very similar to
24 2, except now the criteria are partial organ
25 irradiation and functional damage. So it makes it

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1 seem by implication that number 2 is limited to whole
2 organ irradiation and I'm not sure that's the
3 consequence you intend. Because now someone can come
4 and argue, you know, okay, I made a big boo boo with
5 cobalt-60 teletherapy, put the field in the wrong
6 place and I zapped half the kidney to a dose of more
7 than 10 gray. Well, the patient's kidney function is
8 still okay, no permanent function, no damage and I've
9 only irradiated half the organ, therefore it shouldn't
10 be an AO because your condition number 3 implies that
11 condition number 2 applies only to whole organ
12 irradiation.

13 MS. WILLIAMSON: We don't want the
14 definition of irradiation to an organ to change in any
15 way. All we really want to do is capture.

16 DR. WILLIAMSON: I know you don't want to
17 --

18 MS. WILLIAMSON: Is capture the IVB events
19 in which permanent functional damage occurs. That's
20 all we want to do. We just want to limit it to that,
21 so we capture just those and not regular IVB -- this
22 was, we thought, our way of addressing certain IVB
23 events. What we're looking for language that will
24 help us to capture just those IVB events and not
25 affect the organ limits that are up there on the

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1 screen.

2 DR. MALMUD: May I suggest once again that
3 we use the wording that was suggested by Dr. Schwarz
4 and beginning with line 4, (2) equal to or greater
5 than 10 gray to any other organ, or (3) equal to or
6 greater than 10 gray to any portion of an organ which
7 results in permanent functional damage.

8 Now may I suggest that we tentatively
9 agree on that, but get the opinion of the two
10 radiation oncologists who are members of this
11 Committee, but are absent from the Committee at the
12 moment and then give a conditional approval if they
13 agree. If they disagree, then we'll have to deal with
14 it once again.

15 Is that reasonable?

16 MS. WILLIAMSON: It sounds like you want
17 us to bring this back before the Committee?

18 DR. MALMUD: No, I don't want to bring it
19 back if the two radiation oncologists agree, then it's
20 done. Can we do that?

21 MS. WILLIAMSON: If you're recommending
22 something, we need a motion.

23 DR. MALMUD: I'll make that a motion that
24 we adopt the wording introduced by Dr. Schwarz, the
25 wording I just read and that we approve -- I make a

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1 motion that we approve the wording I just read,
2 conditional upon the agreement of the two radiation
3 oncologists, members of this Committee who are absent
4 right now. And that would complete it, if they agree.

5 CHAIRMAN CERQUEIRA: Is there a second on
6 that?

7 DR. VETTER: Second.

8 CHAIRMAN CERQUEIRA: Any further
9 discussion? Dr. Miller?

10 DR. MILLER: This has been a great
11 intellectual discussion. It's probably over my
12 engineer's head, but what I just heard Dr. Malmud
13 propose causes me to be concerned about the issue that
14 Jeff brought up with regard to No. 2. What is the
15 intent of No. 2? Is it intended that you would get 10
16 gray or more to the whole organ or if you got it to a
17 portion of the organ, could that still be considered
18 an AO? If the intent is that it could still be a
19 portion of the organ, and be an AO, is No. 3 undoing
20 part of the intent of No. 2, if anybody follows what
21 I said.

22 DR. WILLIAMSON: I do. And it's up --

23 DR. MILLER: It's caused me to have to go
24 back and think okay, what do we really mean by No. 2.

25 MS. MCBURNEY: That was my concern too as

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1 to how that might impact then what No. 2 means.

2 DR. WILLIAMSON: But I actually like the
3 new interpretation of No. 2 so I will vote for it as
4 it stands.

5 DR. MILLER: What it would mean in my
6 understanding of it would mean that No. 2 would then
7 become attached to a meaning of a dose to a whole
8 organ and No. 3 would only become an AO if a portion
9 of that organ was actually damaged.

10 DR. WILLIAMSON: Actually damaged.

11 DR. MILLER: Which I think is a reasonable
12 definition.

13 DR. WILLIAMSON: Except that -- I do think
14 it's reasonable, but it's different than what you have
15 now. That's all I've been trying to point out to you.

16 CHAIRMAN CERQUEIRA: Dr. Malmud and then
17 Dr. Eggli.

18 DR. MALMUD: It's that which I intended
19 for the outcome to be, but I remain concerned that the
20 two radiation oncologists who have not had a chance to
21 review this agree.

22 One of them may say wait a minute, this is
23 not sufficient. We really need to be concerned about
24 10 gray to a part of an organ which doesn't appear to
25 give permanent damage, but which we know may cause

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1 permanent damage.

2 If they say that, then we're back to
3 relooking at this, but I would value their opinion
4 very much.

5 CHAIRMAN CERQUEIRA: Doug and then Sally?

6 DR. EGGLI: First of all, I don't think
7 you've put a time limit on the development of the
8 permanent damage which may be made having expressed
9 that here, but I think that the concept of it being an
10 event if there's a consequence fits the whole concept
11 of risk-informed policy which is to say even if the
12 partial organ got a 1000 gray, if there are no
13 functional impairments that result from that, should
14 it philosophically be an unusual occurrence that needs
15 to be reported?

16 And again, to go back to the new
17 philosophy that that we're not just reporting for the
18 sake of reporting, but we're reporting because it
19 means something. This new definition, I think fits
20 the concept of a meaningful abnormal occurrence.

21 CHAIRMAN CERQUEIRA: So risk-informed,
22 performance-based.

23 Sally?

24 MS. SCHWARZ: And what I was just going to
25 suggest is that if the decision of the whole Committee

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1 is required, can the medical oncologists, radiation
2 oncologists be e-mailed for an answer as far as their
3 vote?

4 CHAIRMAN CERQUEIRA: Well, I don't know so
5 much a vote -- I guess if both of them approve it,
6 then basically we would have the approval of the
7 Committee. If they don't, then it would really need
8 to come back for further discussion between the
9 radiation oncologists who are more intimately involved
10 in doing this and may have other awarenesses than what
11 we're having.

12 DR. WILLIAMSON: I think for Dr. Diamond
13 and Dr. Nag to give an informed judgment, I think to
14 vote on this fresh without any background or any
15 explanation or hearing any of the -- at least a
16 summary of this debate, it's probably not realistic.
17 Unless there's a real urgency associated with this, I
18 would suggest we bring it up at our mid-meeting
19 conference call and get their opinion after explaining
20 the debate.

21 CHAIRMAN CERQUEIRA: Ralph?

22 MR. LIETO: When will the transcript of
23 this be available because I would say just say hey
24 guys, go read these pages on the transcript. This is
25 what everybody said back and forth and we need a

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1 decision on the motion and give them maybe a couple of
2 weeks after the transcript is available to them and go
3 from there.

4 CHAIRMAN CERQUEIRA: I see general nods of
5 approval.

6 Leon?

7 DR. MALMUD: I would like to ask Angela
8 Williamson if there is a sense of urgency about this?

9 MS. WILLIAMSON: No, there's not. Like I
10 said before, this product is really owned by the
11 Office of Research and for other reasons that we're
12 not clear on, they may decide that this is not even a
13 smart thing to do at this time.

14 So we were just trying to get some very
15 preliminary opinions about what you think of this.

16 CHAIRMAN CERQUEIRA: We have a call on the
17 question.

18 All in favor?

19 (Ayes.)

20 Opposed?

21 So the motion was carried and basically if
22 -- Angela, when you get the transcripts, if you could
23 identify this particular discussion item and make sure
24 that Dr. Nag and Dr. Diamond receive it and ask them
25 specifically to comment on the motion and any

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1 additional information that they feel is relevant
2 which may change the wording that was suggested. If
3 they approve, then I think you have your answer. If
4 they don't approve and you need more information, it
5 really does need to come back to the Committee.

6 Jeff?

7 DR. WILLIAMSON: I'm sorry --

8 CHAIRMAN CERQUEIRA: We already voted on
9 it.

10 DR. WILLIAMSON: I know, but could we have
11 at least a brief answer to the question that was
12 raised by Lynne Fairbent? What follows -- I'm sorry,
13 could we have a brief answer to Lynne Fairbent's
14 question? What is the other condition.

15 CHAIRMAN CERQUEIRA: Could you repeat the
16 question, Jeff? None of us can recall.

17 DR. WILLIAMSON: The question is what is
18 the qualification following the "and", the final "and"
19 in that paragraph?

20 MS. WILLIAMSON: Unfortunately, I don't
21 have that with me.

22 CHAIRMAN CERQUEIRA: So we can't answer
23 that question.

24 MS. WILLIAMSON: No, we can't answer that.

25 DR. MILLER: Angela, is that something

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1 that as we move on to the next topic that you could go
2 up and get?

3 MS. WILLIAMSON: Yes.

4 DR. MILLER: At least the Committee would
5 have that available before we adjourn today.

6 CHAIRMAN CERQUEIRA: It would put closure
7 on this particular item.

8 DR. MILLER: Because it's right in the AO
9 report.

10 MS. WILLIAMSON: Yes.

11 CHAIRMAN CERQUEIRA: Great. All right,
12 thank you very much, Angela.

13 The next item on the agenda then is the
14 transition issues in Part 35 implementation. And our
15 own Ralph is going to --

16 MR. LIETO: Well, you have -- I think it
17 was distributed yesterday or this morning, basically
18 it's the printout of the slide from the presentation
19 this morning on transition issues.

20 There were really three specific issues
21 that were addressed. One has to do with individuals
22 currently in training programs. And the
23 implementation of the training and experience rule
24 which I know that it's supposed to become effective
25 next fall, actually this fall.

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1 CHAIRMAN CERQUEIRA: October 24, 2005, it
2 will be three years since the rule was enacted and
3 then it does become the official standard.

4 MR. LIETO: So that individuals,
5 physicians, medical physicists, whoever, who are --
6 pharmacists who are in training now, that if they need
7 to document their training and experience to meet the
8 preceptor requirement, that the implementation of this
9 would occur for those -- the requirement for the
10 preceptor would apply to those who are entering
11 programs this year.

12 One suggestion was June of 2004, but
13 whatever. I'm not married to a specific date of the
14 year, but I think it shouldn't apply retrospectively
15 to individuals who are completing their training in
16 the next year or so.

17 CHAIRMAN CERQUEIRA: Or who started their
18 training.

19 MR. LIETO: That's right.

20 CHAIRMAN CERQUEIRA: Doug?

21 DR. EGGLI: I need to agree with that. As
22 a person who writes a dozen preceptor statements a
23 year and I've never had to for the people with deemed
24 status, it would be very hard for us to go back and
25 reconstruct the experience of our senior residents in

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1 order to write a legitimate preceptor statement for
2 them.

3 So I agree with Ralph that some kind of a
4 transition time is necessary for us to start to
5 collect the data that we need to write a valid,
6 verifiable and documentable preceptor statement.

7 CHAIRMAN CERQUEIRA: Jeff?

8 DR. WILLIAMSON: What is the Staff's
9 expectation for the amount of data that must be
10 collected and recorded to verify for a preceptor
11 statement?

12 CHAIRMAN CERQUEIRA: Do you have any
13 expectations on this?

14 You're willing to just take the letter.

15 MR. ESSIG: I'd have to defer to one of
16 the --

17 CHAIRMAN CERQUEIRA: Roger is making his
18 way to the microphone.

19 DR. BROSEUS: We shared with the Advisory
20 Committee a direct revision of Form 3313A. And it's
21 based on the current form. There's discussion in our
22 guidance in Volume 9 of NUREG-1556 and so we're just
23 going one step beyond that and the only changes there
24 are where there are changes in the rule that would
25 result in a need for change. For example, the

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1 decoupling of the preceptor statement from the
2 requirement for board certification, results in a need
3 for an individual or licensee actually, to submit a
4 preceptor statement up to this point, if a board was
5 recognized by the NRC. That was sufficient.

6 There are a couple of other changes, for
7 example, based on the recommendations of the
8 Committee, they asked to have recommended and we
9 incorporate it into the proposed rule requirement for
10 T&E training and experience that is specific to the
11 types of use a person is applying for as an RSO, AMP,
12 ANP, etcetera. Okay?

13 The third significant change comes in for
14 collecting data to enable a medical physicist to be an
15 RSO since we're accommodating a new class. Not
16 withstanding the comments that we've heard from Dr.
17 Leito today, we have accommodate in our draft form
18 changes to accommodate that new class.

19 And so I personally don't see big changes
20 in this and I don't personally see a big issue here.

21 CHAIRMAN CERQUEIRA: Doug?

22 DR. EGGLI: Right now, for our residents
23 who are diplomats of the American Board of Radiology,
24 most of them don't require a preceptor statement to
25 get a license. Board certification is adequate proof.

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1 For the alternate pathway people which has
2 been all of our cardiology fellows who come through,
3 I document their experience on every procedure, the
4 number of procedures they perform, what they've done
5 in the hot lab, what kind of regulatory activity
6 they've engaged in, how many times they've milked a
7 generator, how many times they've compounded a
8 radiopharmaceutical, how many times they've injected
9 a patient, how many times they've done a contamination
10 survey, how many times they dealt with the equipment
11 in setting up the examinations.

12 All of these are required of the nuclear
13 cardiology certifying exam and nuclear cardiology
14 certifying exam requires these items, in fact, as part
15 of the preceptor statement for a preparation for the
16 preceptor statement for licensure. I cannot go back
17 and reconstruct that information for other 200 series
18 radiology residents and we have not kept track of that
19 information as we know.

20 CHAIRMAN CERQUEIRA: So you're saying that
21 basically what you're doing in a sense that right now,
22 even the radiologists and the nuclear medicine
23 physicians would require that sort of receptor letter.

24 DR. EGGLI: They require that kind of
25 documentation on a preceptor statement on which we

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1 have had for American Board of Radiology and for
2 American Board of Nuclear Medicine. We have not
3 collected that because they had beam status. We've
4 collected it for the cardiology fellows because
5 previously they were alternate pathway and we wanted
6 a thorough and complete preceptor statement for the
7 individual.

8 DR. WILLIAMSON: So I'm going to ask Roger
9 again, if I may, Mr. Chair?

10 CHAIRMAN CERQUEIRA: Yes, please. Ask
11 Roger.

12 DR. WILLIAMSON: Does the preceptor
13 statement for the 3500 AUs require the level of detail
14 that Dr. Eggli has mentioned?

15 DR. EGGLI: If you look at the preceptor
16 statement it does.

17 CHAIRMAN CERQUEIRA: You'll need a
18 microphone.

19 DR. BROSEUS: I'll put on a mic so you can
20 be sure to hear me.

21 CHAIRMAN CERQUEIRA: Plan to stay awhile
22 perhaps.

23 DR. BROSEUS: As I understand the
24 question, what's the level of detail required for an
25 authorized user to have this documentational preceptor

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1 statement for use under the 200 --

2 DR. EGGLI: Right, the preceptor statement
3 --

4 DR. BROSEUS: Under the current rule,
5 under the current rule it is sufficient to be board
6 certified.

7 DR. EGGLI: Right.

8 DR. BROSEUS: Okay?

9 DR. EGGLI: So they don't have --

10 DR. BROSEUS: Under the coming rule, if a
11 board certified, if you're board certified by a board
12 recognized by the NRC, plus a preceptor statement and
13 the preceptor statement there's some discussion right
14 now about how that should be structured, not
15 structured, but what a test versus certifying. So the
16 wording -- basically, it's document board
17 certification and have a preceptor statement.

18 Now if somebody is coming in on the
19 alternate pathway, there shouldn't be really big
20 changes. There were some what I would call tweaks to
21 the requirements.

22 DR. EGGLI: The preceptor statement for
23 the board certification candidate looked like the
24 alternate pathway --

25 CHAIRMAN CERQUEIRA: I don't know how it

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1 could in the sense that if it can be -- we haven't
2 really decided whether you need to be an authorized
3 user or you know an authorized medical physicist to
4 sign it. Maybe if the program chair is going to sign
5 it, they're not going to have that kind of knowledge.

6 DR. EGGLI: Currently, there's only one
7 preceptor statement included for all comers that have
8 a preceptor statement and that has links on it for
9 delineating the experience with multiple categories of
10 200 use.

11 DR. BROSEUS: For the alternate pathway.

12 DR. EGGLI: Yes, that's because the board
13 certification pathway doesn't require a preceptor
14 statement at all currently.

15 DR. BROSEUS: Correct. And one would
16 still have to -- an individual who was an authorized
17 user, applying for authorized user status for example,
18 you still need to document what the training and
19 experience was to meet the alternate pathway and
20 there's quite a detailed --

21 DR. EGGLI: The question is does one have
22 to in the future for the board certification
23 candidates have to document experience in a similar
24 fashion to the alternate pathway as it currently
25 exists?

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1 DR. BROSEUS: Under our draft, the only
2 change was (1) document board certification; (2) have
3 a preceptor statement and (3) document that T&E that
4 is specific to the type of use. That's a new
5 requirement that you all recommended.

6 DR. EGGLI: That's the --

7 CHAIRMAN CERQUEIRA: Donna-Beth, do you
8 have a comment? Can you clarify it?

9 DR. HOWE: Yes. I think what we do is we
10 have a preceptor statement that meets the rule and
11 Roger is going a little bit beyond where you're
12 looking for the answer. The answer you're looking for
13 is what does the preceptor have to say when the
14 individual is board certified?

15 DR. EGGLI: Exactly.

16 DR. HOWE: And what the preceptor has to
17 say is they recognize the person is board certified
18 and then they have to make the statement that they
19 believe, according to the current rule, current and
20 proposed rule, that the individual is competent to
21 function independently as an authorized user, an
22 authorized medical physicist, an authorized nuclear
23 pharmacist.

24 So instead of documenting all of the hours
25 and things for the alternative pathway, they're just

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1 saying we recognize he's board certified and that he
2 can function independently.

3 It's a simpler, there's less information
4 on the form.

5 DR. WILLIAMSON: So I think the answer is
6 no, but it's not being given -- it's being given in a
7 very hedged way.

8 CHAIRMAN CERQUEIRA: I don't fully -- are
9 you happy?

10 DR. EGGLI: No.

11 CHAIRMAN CERQUEIRA: Do you understand it?

12 DR. HOWE: You do not have to quantify
13 their training and experience other than the fact they
14 have the board certification. But then you have to be
15 comfortable if you're the authorized user to state
16 that you think they can function independently.

17 DR. BROSEUS: Donna-Beth, correct me if --

18 DR. EGGLI: Which may be a function of
19 those items that I'm not quantitating?

20 CHAIRMAN CERQUEIRA: Exactly.

21 DR. BROSEUS: Let me take it one step
22 further and correct me if I'm wrong.

23 DR. HOWE: Then there's the other
24 modalities.

25 DR. BROSEUS: Our draft also includes a

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1 space to fill in by the authorized user those sections
2 that they're attesting to the ability of the person to
3 meet the requirements. And that's about it for the
4 information.

5 In other words, if it's 35.200, fill in
6 35.200, make a statement. It's not a lot of stuff and
7 I would suggest that you may find it useful to go back
8 and look at the draft that we sent out and I would
9 expect we could share that data with you.

10 DR. WILLIAMSON: I am looking at the
11 proposed form 313 and that's what it says here. It
12 says preceptor certification. There's a blank. Yes,
13 I certify that the individual in Item 1 has
14 satisfactorily completed the requirements in Part 35,
15 sections and paragraphs. Yes, I certify that the
16 individual has achieved a level of competency to
17 function independently as an authorized blank for
18 blank uses. And it's just this little tiny section.
19 So that's what's there.

20 DR. EGGLI: As a preceptor who does a lot
21 of these, how will I be taken to task for that
22 statement? I will have no supporting documentation
23 for that first attestation on the preceptor statement.

24 DR. WILLIAMSON: Well, I think this is --
25 I'm going to speculate now and say what I think is in

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1 the staff's minds. I could be wrong, but I think what
2 they have in mind is a process that's very similar
3 when you write a letter of recommendation for somebody
4 who is up for tenure or promotion and you give kind of
5 a general overview of their abilities or merit, given
6 their career for this position. And I think what they
7 have in mind is a similar kind of subjective, if you
8 want to put it that way, judgment.

9 CHAIRMAN CERQUEIRA: Roger and Donna-Beth,
10 is that your interpretation?

11 DR. HOWE: That's my interpretation
12 because when we did the OMB clearance for the current
13 313A, the documentation and record keeping was just to
14 fill the form out. There was no requirement in the
15 rule or anywhere else for NRC to collect any other
16 data or to have any other records. So it is the
17 Board's certification. It is the certification
18 statement.

19 CHAIRMAN CERQUEIRA: Now is it your intent
20 also for people who are applying via training and
21 experience or the alternative pathway that that same
22 form would be used?

23 DR. HOWE: Yes. If you look at the form
24 it takes you, Element 1 identifies the person that
25 wants to be an authorized user, ANPA. Item 2, I

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1 think, or Item 3 is the Board certification. It tells
2 you to go to certain parts of the form. And then the
3 rest of the people keep right on going down the form
4 and they have to provide the documentation to show
5 their -- for nuclear medicine, their hours added up to
6 700 for the didactic and the work experience.

7 CHAIRMAN CERQUEIRA: So basically, there's
8 documentation of 700 hours and now what -- so if Dr.
9 Eggli who is an authorized user signs the form, you're
10 going to be happy with it. There's still a lot of
11 discussion as to who can sign that form certainly for
12 the people that are applying via board certification.
13 It may not be an authorized user, an authorized
14 medical physicist, an RSO.

15 DR. HOWE: All I can comment to is the
16 proposed rule right now and the proposed rule would be
17 if the individual wanted to be an authorized user for
18 200, then the person signing the preceptor statement
19 that they thought they could function independently,
20 they have board certification --

21 CHAIRMAN CERQUEIRA: Right.

22 DR. HOWE: That they could function
23 independently as an authorized user for 200 uses,
24 would be an authorized user for 200 uses.

25 CHAIRMAN CERQUEIRA: That's still our

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1 understanding, but we've heard a lot of objections
2 from the boards themselves that they would not be able
3 to complete that.

4 Jeff?

5 DR. WILLIAMSON: I really think that we
6 have to look at this on the terms it's being handed to
7 us. This is, I think, viewed by the staff. I'm
8 summarizing what I think their intent is now. They
9 can correct me if I'm wrong. We have a certain
10 process we do now. In the Radiation Safety Committee
11 in the broad-scope licensing when we approve
12 authorized users, if they're fourth year residents who
13 have not yet passed the boards, we go through this
14 very long detailed chronology of how many cases
15 they've done, category by category, name them as
16 authorized users on the license if they meet the
17 alternative pathway requirements and we have to have
18 a lot of documentation for that.

19 If they have board certification, you
20 know, we make the presumption that they've met the
21 eligibility requirements for those boards. They have
22 the 700 hours or its equivalent. They have the
23 appropriate case experience required by the residency
24 and accreditation committees and so forth and we don't
25 have to do that.

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1 In the Radiation Safety Committee we look
2 to see that they really have that certificate. We
3 examine the years of experience they've had at other
4 institutions and we vote, yes, you may be an
5 authorized user and there's no presumption that in the
6 Radiation Safety Committee we have to collect this
7 huge ream of data on them like we do the uncertified
8 candidates. And I think that's the spirit of which
9 that's intended here, for all the categories is that
10 in addition they want some individual who is an AU or
11 ANP or whatever who has some knowledge of the
12 candidate's training and is in a position to attest to
13 the competence of the person to do this job. They
14 want a signature and that's basically all that's being
15 asked.

16 DR. EGGLI: And I guess the question comes
17 down to what's the liability on that signature because
18 in the board certification previously, I wasn't
19 required to make any kind of attestation for someone
20 who is board certified. Now I am being required to
21 and it is one issue again to provide a chronological
22 list of experiences. That's very objective and there
23 is no risk if you're signing that kind of attestation.

24 The more general attestation not backed up
25 by any kind of documentation is for the preceptor, a

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1 higher risk process, particularly if there are
2 consequences that fall back on that preceptor at some
3 point in the future if that individual doesn't perform
4 up to snuff.

5 CHAIRMAN CERQUEIRA: Yes, but I think the
6 argument has been that some of that is no different
7 than anything else that we do in medicine, that that's
8 kind of there are other safeguards in place and that
9 the NRC should only be involved in the issues of
10 radiation safety --

11 DR. WILLIAMSON: We all participate in
12 credentialling activities. We write letters of
13 recommendations. Hospital credentialling committees
14 make judgments based on looking at the person's CV
15 without examining this huge volume of data to really
16 show the person did these things, so I think we're
17 maybe making a little too much out of this?

18 DR. EGGLI: Actually, that may not be
19 quite true because to be credentialed for a finite
20 number of procedures in any hospital these days you
21 have to produce the documentation that you've had the
22 experience.

23 Credentialling, these days, is a function
24 of documentation of experience, but you cannot be
25 credentialed in many areas without documentation.

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1 DR. WILLIAMSON: Well, I think the NRC is
2 saying that's up to you then what standards of
3 evidence you require.

4 CHAIRMAN CERQUEIRA: That's been
5 basically, you know, and I think the SNM really argued
6 that they shouldn't be involved in this at all, that
7 basically it should be left up as a practice of
8 medicine issue beyond a certain hour of training and
9 experience.

10 Leon?

11 DR. MALMUD: Doug, you're correct. The
12 credentialling process is though independent of that
13 which we are being asked to do with regard to the NRC.

14 DR. EGGLI: I understand. And we're
15 credentialling them?

16 DR. MALMUD: Correct. So that I think a
17 university certifies an individual has completed his
18 or her requirements for a degree and it's signed by
19 the President of the University, the Chairman of the
20 Board, neither of whom has ever even met the
21 candidate. They have relied upon the processes within
22 the university to certify that these students have
23 finished the requisite number of credits and courses,
24 and hence they sign it. I think that we're in a
25 similar situation on a lower scale with regard to

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1 certifying that the resident has had adequate
2 training. We need not personally have been involved
3 in that training, although we understand from the NRC
4 that they want the person who assumes the
5 responsibility for it to be an AO himself or herself.

6 Is that a fair summary, Dr. Howe?

7 CHAIRMAN CERQUEIRA: Okay. Lynne, you've
8 been waiting patiently.

9 MS. FAIROBENT: Lynne Fairobent, ACR. A
10 couple of points. One, Dr. Eggli, I think that you've
11 hit the nail on the head. We have or share some of
12 your similar concerns from our members now with the
13 decoupling of the preceptor statement from the board
14 process.

15 It is unclear or not clarified yet and I'm
16 hopeful as Ralph has urged this morning that there be
17 a meeting with the boards and stakeholders to discuss
18 the implementation as we go forward on recognition of
19 the board process.

20 I think it's equally important that there
21 be discussions on what is an appropriate preceptor
22 statement. I think that with the decoupling of the
23 preceptor from those individuals who would have now
24 come in by virtue of board certification, these issues
25 are raised and I do think Dr. Eggli that at this point

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1 you are probably going to have to provide those
2 detailed documentations on your radiologists coming
3 through nuclear medicine departments because they may
4 or may not have completed their board certification
5 process at the time they're coming through under your
6 training program. They may not have sat for their
7 final orals or if they had, the results of the oral
8 exam may not yet be known to you as the preceptor
9 authorized user who needs to sign to give them that
10 documentation to then move on to be listed on their
11 first license.

12 I think there are a whole host of
13 implementation issues with the decoupling of the
14 preceptor statement from the board processes that had
15 not been recognized prior to when they were linked
16 together. I think that this is something in the
17 implementation phase that we all are going to have to
18 sit down and collectively look at appropriate guidance
19 and two-way discussion because it's now my members
20 that are going to have to be signing the preceptor
21 statements.

22 I think you very well articulated it, the
23 difference between what you do now for an individual
24 under the alternative pathway, versus someone who is
25 coming to you via board certification. I think has

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1 been minimized and no longer that distinction is
2 there.

3 DR. EGGLI: And finally, my only reason
4 for raising this issue was to make sure that there
5 isn't a group who gets caught in this transition.

6 MS. FAIROBENT: Yes, and I would agree
7 with Ralph's comment earlier. I think it's very
8 important that we look at the timeliness of when these
9 new regulations apply to those in-training programs
10 and I think it's also critical that the new
11 regulations and the timeliness of them are given
12 adequate transition time to be reflected by the
13 residency review committees who set the training
14 curriculums as well as the boards to reflect whatever
15 changes may necessarily be on their examination
16 process.

17 CHAIRMAN CERQUEIRA: But, Lynne, we've
18 gone over that before, and it doesn't -- none of the
19 changes that the NRC is going to require now are any
20 more than what they have required in the past. So the
21 Residency Review Committee should not have to
22 implement any changes in the hourly training
23 requirements for people who are applying.

24 MS. FAIROBENT: It may not be in the
25 number of hours. It may be in subject content area to

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1 ensure that --

2 CHAIRMAN CERQUEIRA: For diagnostics,
3 certainly no, and even for the radiation oncology.
4 The only areas where that may become an issue is in
5 specific devices, and we've come up with ways to deal
6 with that.

7 MS. FAIROBENT: We've talked in the
8 radiation -- with our radiation oncologist at ACR, and
9 there is a potential, and the potential is for ROs
10 under 390, in order to be able to do unsealed material
11 use, and whether or not they -- in their residency
12 programs that material is being sufficiently covered.
13 We believe it is, but they are going back and looking
14 at it.

15 CHAIRMAN CERQUEIRA: But if it isn't, then
16 all they have to do is document specific training in
17 that instrumentation, which is, I think, the point
18 that has been made a few times.

19 Ralph, and then Jeff.

20 MR. LIETO: Two things. I disagree with
21 the statement that was made before that whatever
22 training and experience criteria you want to
23 establish, or make an attestation, is up to you. I
24 think that sets a tremendous disquality across the
25 system.

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1 I think there should be minimum standards
2 established, and I think that goes into the -- you
3 know, what we were talking about or presented this
4 morning to the committee about what -- what is the --
5 what is the preceptor attesting to? And what
6 documentation do they need?

7 I think that we've already identified some
8 of the issues for people who are not board certified.
9 But, then again, I think there may be those people who
10 are seeking board certification and are in transition
11 that may need the specific documentation.

12 My second point is I'd like to get back to
13 the original transition issue, which is about those
14 individuals who are in training and when these
15 training and experience requirements should go into
16 effect for them. In other words, the suggestion was,
17 and I'll just make it as a recommendation, that
18 training and experience should not have to -- or
19 should apply to individuals entering training programs
20 after June of 2004.

21 CHAIRMAN CERQUEIRA: Well, actually, the
22 new -- the revised rules are in effect. I guess that
23 three-year period is really for the agreement states
24 to become compliant, right? So people who started who
25 are already in training can apply either under the new

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1 rule, which became law in October 24, 2002, or under
2 the existing rules, which we extended, because the old
3 rule, you know, became -- you know, was no longer
4 applicable, other than the fact that we did a two-year
5 extension.

6 So I agree with you, we need to set the
7 rules for grandfathering, but I think technically
8 people who -- you know, it applies to people who are
9 currently in training, and even people -- you know,
10 because the new rules did go into effect in 2002. And
11 I think the 2005 requirement is for compliance by the
12 agreement states. Am I correct on that? Yes, okay.

13 Now, Jeff, you had a comment, and then
14 we'll go to --

15 DR. WILLIAMSON: Yes, I have three
16 comments. One is a response to what Lynne said, and
17 I think the case she presents is of a radiology
18 resident who has completed the training program but
19 not yet completed board certification either for fact
20 that the results are not known or maybe has failed or
21 conditioned the exam.

22 Well, that's no different than it is now.
23 And so I don't see how that supports -- has anything
24 to do with the issue of what level of documentation
25 you have to keep for board certified candidates.

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1 The second point is is it has taken us 30
2 minutes to get out of the NRC staff the answer about
3 what is the level of documentation required on the
4 part of a preceptor for an individual that is board
5 certified. And I had to actually read their mind, so
6 to speak, or interpolate.

7 So, clearly, you know, I think NRC has to
8 come up with a -- I appreciate why they're being so
9 cautious and wanting to cite just what the rule
10 language is. But to state clearly, unambiguously, in
11 ordinary language what is expected or not expected,
12 and where the burden of -- and indicating to what
13 extent the burden of deciding the level of
14 documentation depends on the individual preceptors or
15 the community as a whole.

16 You know, you really need to communicate
17 this clearly, and we shouldn't have to be guessing
18 what you all mean, like I did.

19 And then, finally, they said yes or no,
20 after I had repeated it, you know, in a couple of
21 different ways in simple, ordinary language. Now, you
22 know, the other half of the committee doesn't like it,
23 but I think maybe that's the way it is. That's really
24 -- okay, I'll stop there.

25 CHAIRMAN CERQUEIRA: Ron?

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1 DR. ZELAC: Ron Zelac, NRC. I think it
2 might be somewhat instructive on the question that
3 Jeffrey was just mentioning to keep in mind the
4 current rule, the rule that we're operating under now,
5 the requirements that exist now.

6 The proposed rule changes to training and
7 experience are not becoming more prescriptive by any
8 means. If anything, they're moving in the other
9 direction. So where we are now can be looked at as a
10 baseline for where we are going.

11 And the current requirements, as most of
12 you know, are -- and particularly I'll choose an
13 example of 200 usage -- we are talking about a total
14 -- and the alternative pathway. We're talking -- and
15 the preceptor requirements, in terms of what the
16 preceptor has to attest to or certify.

17 The current rule simply states a total
18 number of hours of training and experience. Yes,
19 indeed, there are particular topics that are covered
20 that are supposed to be included in the training and
21 experience. But the attestation at the bottom by the
22 preceptor is simply referring to the totality of that
23 -- the 700 hours, and what has been covered in that
24 700 hours, and the ability of the individual to serve
25 independently.

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1 In fact, it says the individual -- this is
2 the -- what the preceptor is attesting to. "The
3 individual has satisfactorily completed the
4 requirements in paragraph C(1), which is the
5 alternative pathway" -- and this is common for the
6 other as well -- "of this section, and has achieved a
7 level of competency sufficient to function
8 independently as an authorized user for the medical
9 uses authorized under," and so forth.

10 That's all that's being asked for, and no
11 detailed records are required, as Donna-Beth had
12 mentioned, on the part of the preceptor in order to
13 make this attestation and provide the required
14 certification.

15 DR. WILLIAMSON: Thank you for that
16 clarity.

17 CHAIRMAN CERQUEIRA: Yes. And, Doug,
18 getting back to some of your points, I mean, initially
19 when this was being drafted, we had put in specific
20 hours in terms of didactic-type material. And it was
21 actually the SNM that did not want any of that in
22 there, and it was really at their request that that
23 was taken out for the 200 users, and it was just left
24 to 700 hours total, without any documentation, you
25 know, of specific areas covered.

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1 DR. EGGLI: Now, the only thing that's
2 unresolved is essentially, since the NRC wants an AU
3 to sign off, there's a reason for that. The question
4 is: what is the liability effectively of the
5 preceptor in this process? The only -- and I
6 understand the Society's goal in eliminating lists.

7 But yet for the person who actually
8 functions as the preceptor, the list serves as a
9 backup reference if the credentials of the individual,
10 from the radiation safety point of view -- not from
11 the point of view of medical practice but from the
12 radiation safety point of view, are ever questioned.

13 It would strike me that the -- that NRC
14 wants an AU's signature because they want somebody
15 that they can hold responsible.

16 CHAIRMAN CERQUEIRA: Well, I think it's a
17 simplification that, you know, getting back to Leon's
18 point, that the president of the university signs off
19 without having -- you know, and he certainly is not
20 attesting that this person has mastered all of the
21 material.

22 DR. EGGLI: But the president of the
23 university doesn't have the NRC breathing down his
24 neck.

25 CHAIRMAN CERQUEIRA: No, that's true. And

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1 I -- there may be some implications that have to be
2 addressed. But certainly, at this point, I think as
3 that individual is signing -- and we still have a lot
4 of debate, but they have, you know, covered the
5 material, and they can do it competently.

6 DR. EGGLI: And the RRCs historically have
7 not looked at the -- the RRCs have historically not
8 looked at the content vis-a-vis the NRC requirements
9 in great detail, as they -- as they evaluate the
10 program.

11 CHAIRMAN CERQUEIRA: I think that's valid,
12 yes.

13 Ron?

14 DR. ZELAC: The purpose, as I understand
15 it -- and if there's someone else that has a different
16 point of view, please correct me -- the purpose, as I
17 understand it, of having an authorized individual sign
18 the preceptor statement is primarily because the
19 authorized individual knows what the duties are, knows
20 what the concerns are, knows what it should -- what
21 information and knowledge is required in order for
22 this individual for whom he or she is signing to
23 function independently as the authorized whatever.

24 That's the purpose, not to have some way
25 to go back to then chastise a preceptor whose

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1 signatory didn't perform as expected. That's the
2 contrast with the alternative, which has been put
3 forth several times, to have something akin to a
4 program director for a training program sign.

5 The program director may or may not be an
6 authorized individual. The program director who is an
7 authorized individual will clearly, and should
8 clearly, know what the requirements are for a person
9 to function independently. Whereas the program
10 director might be well removed from the specific needs
11 if he is not, or she is not, actually a user.

12 CHAIRMAN CERQUEIRA: That certainly was
13 the intent all along, but I think what you're seeing
14 now is the reality of people getting cold feet and
15 having to sign that statement. That's --

16 DR. WILLIAMSON: Well --

17 CHAIRMAN CERQUEIRA: That's the bottom
18 line.

19 Yes.

20 DR. WILLIAMSON: Well, I think that, you
21 know, this is sort of a new performance-based, risk-
22 based -- no, risk-informed, performance-based
23 environment. We asked for flexibility; we got it.
24 So, you know, I actually think the burden --

25 (Laughter.)

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1 -- the burden is on us and our societies
2 to kind of come up with reasonable criteria how we're
3 going to do this. And I think we should do it
4 ourselves rather than ask them to do it, if you want
5 my opinion on the matter.

6 I don't think this is an issue that we
7 should ask for laws and more regulations that --
8 prescriptive regulations that we have to write. I
9 think we should, you know, take the challenge of
10 keeping our own house in order and solve the problems
11 ourselves.

12 I think a second point I want to make is
13 -- respond to Dr. Cerqueira's suggestion that we have
14 an opportunity to change this from an authorized
15 person preceptor to some program director or something
16 else. I think that was recommended and has been long
17 the position of this -- of the ACMUI.

18 I think we can talk about it as much as we
19 want. The staff has in their hands an SRM from the
20 Commissioners which said, "No, you're not doing it
21 that way. The preceptor is going to be the way it is,
22 and it's going to be an authorized person." So, you
23 know, I think there's not much they can do except
24 advise us how we might approach the Commission again
25 if we wish to try to at this, you know, late moment

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1 try to get that overturned.

2 I just want to point that out as an
3 element of process. The staff, at this point, has no
4 ability to reverse that decision.

5 CHAIRMAN CERQUEIRA: Yes. So, you know,
6 it must be the role of the Chairman's last meeting,
7 because I can remember when Barry Siegel had his last
8 meeting going into a tirade that sometimes you get
9 what you ask for.

10 (Laughter.)

11 And we've been asking the NRC to get off
12 our backs for the longest time. Well, now they've
13 done it, and we're going to have to assume, you know,
14 some -- we're going to have to be very careful of the
15 people we sign off on. That's part of the
16 responsibility that we're assuming.

17 But I think all of us on the committee
18 five years ago, and on the committee now, would rather
19 have policing from within than having the NRC
20 necessarily, you know, impose some of these rules and
21 regulations.

22 All right. Ralph, what's the next item?

23 (Laughter.)

24 That's point one of slide 1.

25 MR. LIETO: Do I really need to go on?

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1 (Laughter.)

2 Well, you know, I'll be honest with you.
3 I'm still -- what is the resolution regarding
4 individuals and training? Basically, SOL? I mean,
5 they're stuff out of luck?

6 CHAIRMAN CERQUEIRA: No, I don't think
7 there's a problem.

8 MR. LIETO: Sadly out of luck?

9 CHAIRMAN CERQUEIRA: No. I think, you
10 know, basically, they can still apply under the old
11 rules pre-October 24, 2002, which was, you know, the
12 alternate pathway, or by board certification without
13 any other documentation. So that is in effect until
14 October 24, 2005.

15 Part of the reason we're trying to do this
16 revision is to have something else in place when that
17 temporary extension goes away to fix some of the other
18 problems that we identified with the revision which
19 was implemented on October 24, 2002.

20 So, technically, people who started their
21 training up until that point can apply either under
22 the old or the new rules. And so I guess if you
23 started your --

24 MR. LIETO: Well, I'm trying to think,
25 okay, let's say someone comes out of a program in

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1 December 2005. All right? They have to have a
2 preceptor statement. Okay? And --

3 MS. McBURNEY: Have they passed their
4 boards?

5 MR. LIETO: -- and/or have passed the
6 boards.

7 DR. WILLIAMSON: No, they have to pass --

8 MR. LIETO: Not and/or, but or have passed
9 the boards.

10 DR. WILLIAMSON: No.

11 CHAIRMAN CERQUEIRA: Well, since they
12 started their -- well, I mean, if they started their
13 training at a point where the old rule was still in
14 effect, which will be until October 2005, all they've
15 got to do is present their board certification without
16 anything else, and that should automatically qualify
17 them.

18 MR. LIETO: No, because the new rules will
19 be in effect after that point.

20 CHAIRMAN CERQUEIRA: Right.

21 MR. LIETO: The old ones go away.

22 CHAIRMAN CERQUEIRA: Right.

23 MR. LIETO: So even though their training
24 would occur under -- when you had the two method --
25 the two -- should I say criteria -- now you only have

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1 the one.

2 CHAIRMAN CERQUEIRA: Yes. But they
3 started their training when the old one was in effect,
4 so they apply under either one.

5 DR. WILLIAMSON: Can I comment on this?
6 I think that you're wrong. I think once the rule
7 changes, the rule changes.

8 CHAIRMAN CERQUEIRA: But what do you --

9 DR. WILLIAMSON: And it doesn't matter
10 when your training starts, you have to follow the new
11 rule. There is no discussion.

12 CHAIRMAN CERQUEIRA: Well, I would
13 disagree with that, because you can't --

14 DR. WILLIAMSON: Well, that's the way it
15 is.

16 MR. LIETO: That's my point.

17 DR. WILLIAMSON: Can I try to answer
18 Ralph's question? I think --

19 CHAIRMAN CERQUEIRA: Well, no, no, wait a
20 minute, because I -- I'm not sure I'm totally wrong.
21 Leon, I mean, what's your feeling as an educator who
22 -- when people come into a training program, are they
23 held to the rules that are --

24 VICE CHAIRMAN MALMUD: If you want my
25 candid opinion as an educator, I don't know what all

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1 the excitement is about, because it's the simplest
2 thing in the world. I don't know what all of the
3 concern is about, because it's the simplest thing in
4 the world for the training program director, or his
5 authorized user designate, to fill out this form with
6 the resident.

7 It can be done today. There is no
8 deficiency that I'm aware of in any training program.
9 In fact, the training program's requirements for
10 education far exceed the minimum requirements of the
11 NRC. So I think we are worried about something that's
12 not an issue, and I would have no difficulty at all in
13 dealing with the issue today.

14 We have a tradition of filling out these
15 forms. I don't see where the enormous workload is.

16 DR. WILLIAMSON: I guess I'm saying -- I
17 would agree completely with Dr. Malmud. I don't think
18 there's a problem. I think that, you know, now we
19 have a board certification pathway without a preceptor
20 statement required for a little while longer, and we
21 have an alternative pathway.

22 When the new rule takes effect, we'll have
23 an alternative pathway that's essentially just a minor
24 modification of the one we have today. It's very,
25 very similar. It's not going to require very

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1 different reporting or documentation requirements. We
2 will now have a board certification pathway that is
3 the same except for one more requirement, and that is
4 the preceptor statement.

5 But we've just heard there are no new
6 reporting or documentation requirements for either
7 pathway. So I don't understand what is the concern
8 about retrofitting, you know, existing -- students who
9 are just about to go in the training pipeline. To me
10 this seems like there's not a problem.

11 MR. LIETO: You know, I -- then, why, on
12 God's green earth, did you guys have me sit before the
13 Commission and present this? We went through it in
14 the morning, and no one -- no one challenged that that
15 was not needed to be presented.

16 DR. WILLIAMSON: Well --

17 MR. LIETO: There's no way -- hold on.

18 DR. WILLIAMSON: All right.

19 MR. LIETO: If this was not -- I mean, you
20 know, I'm really upset about the fact that I sit
21 before this Commission and present this as a
22 transitional issue when really it's not an issue. If
23 it's not an issue, it should have never even been put
24 on their plate.

25 Secondly, if none of these transition

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1 issues are going to be addressed -- in other words,
2 these are things that we're going to just say, "The
3 rule comes into effect. You have to deal with it.
4 That's the way life is." I mean, that makes it very
5 simple. It makes it simple for everybody.

6 Some people are going to be
7 disenfranchised; others aren't. But I think, you
8 know, if that's the attitude that we're going to
9 take --

10 DR. WILLIAMSON: No, no.

11 MR. LIETO: -- I -- well --

12 DR. WILLIAMSON: Let me defend myself.

13 MR. LIETO: Well, let me finish.

14 DR. WILLIAMSON: Okay.

15 MR. LIETO: Then I think that -- that one
16 of the things that needs to be understood is what this
17 committee is going to ask the staff for and what
18 they're not. If these are not transitional issues,
19 then let's not discuss them. Okay? We've got other
20 things on the agenda to address.

21 DR. WILLIAMSON: I think that in terms of
22 my answer to you it is not clear to me until this
23 moment -- until we had this long discussion and got
24 the appropriate feedback from the staff that it wasn't
25 a valid issue.

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1 You know, it is only through this
2 conversation it has sort of -- and detailed review of
3 this Form 313A, which I should have admittedly maybe
4 reviewed before, that it has sort of become clear how
5 this particular transition issue does not seem to be
6 a problem for NRC. It may be a problem for our
7 community how to absorb it.

8 But the other point is the other
9 transition issues I think are very important. I
10 think, you know, just because, you know, it -- it
11 turns out upon detailed review and debate that maybe
12 there wasn't so much of a problem with the training
13 program retrofitting does not mean that the other
14 issues are not perfectly valid.

15 I happen to think the grandfathering, the
16 issue of AUs not being mentioned on agreement state
17 licenses, the problem of multiple AUs, the problem of
18 what do you do when you get a new unit and there isn't
19 an AU in your institution who can sign the precept,
20 all of these are I think really important problems.

21 VICE CHAIRMAN MALMUD: Ralph, it is a
22 transition issue, and it's correctly brought before
23 the committee.

24 My point was that what's being asked of us
25 is not an enormous burden. It's an additional form,

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1 which we already have a staff to deal with. So we
2 could actually just say, "Beginning July 1st, for
3 everyone who hasn't completed training by July 1,
4 2004, this form is a requirement." And that would be
5 -- that would serve everybody well.

6 I have a question about your point, Ralph.
7 Who are you concerned would be disenfranchised?
8 That's what I didn't quite grasp. Who is going to be
9 disenfranchised? Who are you concerned about?

10 MR. LIETO: Well, regarding these
11 transition issues, I think there are issues regarding
12 medical physicists, and there is also the issues
13 regarding authorized users who provide diagnostic
14 studies with the I-131 imaging and localization
15 procedures. These are issues that came up not only
16 here, they've come up I think -- I'm pretty sure
17 they're on the comment page -- regarding the proposed
18 rule, and they are issues that have been brought up to
19 me personally by individuals.

20 VICE CHAIRMAN MALMUD: But that is the
21 issue that we were just discussing with regard to the
22 authorized user certification.

23 MR. LIETO: No. My point was about all of
24 the transition issues.

25 VICE CHAIRMAN MALMUD: Oh.

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1 MR. LIETO: I mean, if we're going to --
2 I mean, basically, the -- you know, the sense that I'm
3 getting is that the rules, when they come into effect,
4 okay, that -- that's the way we're going to have to
5 deal with them. It just gives me the sense that, why
6 -- why are we discussing transitional issues? Okay?

7 If the tact is going to be that we're
8 going to just say, "You've got to comply with the
9 rules. When they come into effect, the new rules come
10 into effect, you have to accommodate them." We've
11 gotten what we want.

12 DR. WILLIAMSON: I --

13 CHAIRMAN CERQUEIRA: Go ahead.

14 DR. WILLIAMSON: Okay. I think it's not
15 sort of zero or one, black and white. I think that
16 one transition issue seems to have turned out maybe to
17 not be as serious an issue as we thought. So that
18 doesn't mean the others aren't.

19 I really think that our charge here is to
20 look at the transition issues, and within the confines
21 of the SRM that kind of is right now I think a
22 realistic political barrier that we can't transgress,
23 we need to figure out and help the staff figure out
24 how we can tinker with the rule language to make sure
25 that we have, you know, enough flexibility in the rule

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1 language to accommodate the transition issues.

2 So it's -- okay. So it's half and 9.5.
3 So one issue -- one transition may not be a real
4 transition issue, or at least one that concerns the
5 NRC anymore. It concerns us as a community.

6 But the other 9.5 I think are really valid
7 issues, and I think what we need to do is one by one
8 assess the staff's views on them, look at the rule
9 language, and see if we can tinker with it to make it
10 have the requisite level of flexibility to accommodate
11 these in a satisfactory way. That's an important duty
12 in the next 30 days that we have to do.

13 CHAIRMAN CERQUEIRA: Yes. I agree with
14 that. And then, again, you know, we've got this
15 revision which your committee has worked on, which has
16 gone to the -- to the main NRC that still is going to
17 need changes to try to give us a fix that's going to
18 occur when the old rule goes away.

19 DR. WILLIAMSON: Yes. I think they can
20 accommodate words like "attest" and --

21 CHAIRMAN CERQUEIRA: Right.

22 DR. WILLIAMSON: -- instead of "certify."
23 And I think we can probably, you know, modify the
24 language. Where I think we will get in trouble is if
25 we try to, you know, run broadside against what the

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1 SRM said and decouple AU or authorized personage from
2 being a preceptor. I think that, you know, that will
3 require another ruling by the Commission to an
4 alternative SRM.

5 And we didn't really make the case I think
6 clearly enough to them that we wanted another
7 decision. If we really thought we needed to do that,
8 we should have done that in a more clear form. But
9 that would have required a great deal -- you know,
10 several hours of analysis and debate to figure out
11 that problem.

12 I think we've got a lot of work ahead of
13 ourselves to go through each one of these transition
14 issues in detail.

15 CHAIRMAN CERQUEIRA: Yes, I think we do,
16 and we're also going to -- two of our committee
17 members are going to be leaving in about half an hour
18 So I think we probably should move on with some of
19 these issues.

20 DR. MILLER: Dr. Cerqueira?

21 CHAIRMAN CERQUEIRA: Yes?

22 DR. MILLER: I just wanted to make a point
23 of clarification on something that was said earlier.
24 The expiration date for the old rule is not 2005, it's
25 2004.

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1 CHAIRMAN CERQUEIRA: Okay. You're right.
2 Okay. So that's sooner.

3 DR. MILLER: So that's part of the reason
4 for the urgency of trying to get the revised rule
5 promulgated prior to that happening.

6 CHAIRMAN CERQUEIRA: Yes. Okay, you're
7 right. I misspoke, you're right.

8 All right. So, Ralph, do you want to go
9 on with some of the other issues? What are we getting
10 here?

11 MR. LIETO: The one maybe that might be
12 the most straightforward would have to do with the
13 authorized users of I-131 for diagnostic purposes
14 meeting the training and experience for written
15 directive use. There are those individuals out there
16 that have -- that do not do therapeutic applications,
17 just do the imaging and localization procedures.

18 With the transition of the Part 35
19 revision that is based on activity, the imaging and
20 localization procedures for I-131 move into a written
21 directive category. And so you now have to have --
22 well, there is a concern that those individuals are
23 now going to have to apply as authorized users under
24 a category that they do not have the training and
25 experience --

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1 CHAIRMAN CERQUEIRA: We're talking about
2 the endocrinologists, is that -- no?

3 MR. LIETO: Not just endocrinologists, but
4 it could also be radiologists who are doing just
5 imaging and localization procedures under the old
6 Part 200 --

7 CHAIRMAN CERQUEIRA: Right.

8 MR. LIETO: -- which the I-131 was. It's
9 not that they aren't familiar with the documentation
10 aspects for above the 30 microcuries, but now they
11 have to meet the therapy application criteria, which
12 they -- therapeutic application criteria, which they
13 did not have to do and have not done before, and may
14 not have the training and experience for documenting
15 it.

16 VICE CHAIRMAN MALMUD: Ralph, these are
17 people who are currently doing it, currently using
18 I-131 for --

19 MR. LIETO: That's correct.

20 VICE CHAIRMAN MALMUD: -- diagnostic
21 purposes, let's say in doses up to three millicuries
22 for whole body scanning, for post-operative evaluation
23 of thyroid metastases.

24 MR. LIETO: Correct.

25 VICE CHAIRMAN MALMUD: Okay. And is that

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1 privilege going to be taken away from them? Won't
2 they be grandfathered? Question. Actually, Dr. Gray,
3 do you want to address it? Excuse me.

4 DR. HOWE: Can I address the issue?

5 VICE CHAIRMAN MALMUD: Dr. Howe.

6 DR. HOWE: Yes. We're currently dealing
7 with that issue right now on licensing as we're
8 bringing old licenses into the new Part 35. And what
9 we've recognized -- it's even a little more complex
10 than we thought -- is that we do have nuclear medicine
11 physicians that are used to using diagnostic I-131 for
12 whole body scans.

13 And we're making sure that those
14 individuals are granted the authorization under 300 to
15 continue to do those procedures. So they are
16 grandfathered into what they could do before. We are
17 bringing it up. They are going to be identified as a
18 limited use under 300 for the less than 30 millicurie
19 criteria.

20 Another element that we're finding that
21 you haven't addressed is that we have a number of
22 I-131 300 users that in the past we have authorized
23 for hyperthyroidism, thinking that they were under 30
24 millicuries, and, in fact, they are over. And so
25 we're having to recognize them as -- as also meeting

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1 the criterion over 30, and giving them the
2 authorization on the license that they can use that
3 material.

4 Your other issue is that current nuclear
5 medicine people in training will have to meet
6 additional criteria, and they will have to meet the --
7 I think it's 80 hours of therapy training and
8 experience that's for the 30 -- for the 392 or the
9 393, depending on how much activity they'll be using
10 later. They will need to meet that criteria, but they
11 won't have to meet the full 300 -- the 390 criteria.

12 MR. LIETO: Well, is there a concern that
13 you're going to have on their -- on the license they
14 will be listed as being qualified or authorized for
15 under 33 millicuries for therapy application when
16 really they don't have the training and experience for
17 it? Or is it going to be specific -- more specific
18 than that?

19 DR. HOWE: They are not going to be
20 authorized for full 300 use, because their training
21 and experience is under the 392/394. So they will be
22 authorized to use under whatever the activity --
23 maximum activity is for 392, or the maximum activity
24 for -- the minimum activity for 394.

25 So that authorization will be in the

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1 license, so that those physicians can continue to do
2 what they had historically been doing.

3 DR. WILLIAMSON: What about new
4 physicians? What about -- you know, it seems to me
5 that the nuclear medicine imaging people are the most
6 qualified people to read these I-131 uptake exams. So
7 how could -- I think the question before us is: how
8 can we modify the rule in a perspective way to make
9 sure that this group of people in the future doesn't
10 get disenfranchised?

11 VICE CHAIRMAN MALMUD: If I may, I believe
12 that Dr. Howe has just explained to us that the
13 current users will be grandfathered for I-131 for
14 diagnostic purposes and I-131 for therapeutic purposes
15 in excess of the assumption of 30 millicuries, which
16 had been the limit, but which will be raised to some
17 higher number. Did I understand you correctly?

18 DR. HOWE: We don't distinguish between
19 diagnostic and therapy anymore. It's --

20 VICE CHAIRMAN MALMUD: All right.

21 DR. HOWE: -- a written directive or not
22 a written directive. So they will be authorized for
23 -- so if you were a diagnostic nuclear medicine
24 physician that was doing three to five millicurie
25 whole body scans, then you'll be authorized for 200

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1 use, and you'll be authorized for 300 for use for
2 which a written directive is required for materials
3 under so many millicuries, which is the 392 criteria.

4 VICE CHAIRMAN MALMUD: How many
5 millicuries is that in the 392 criteria? The reason
6 I'm asking the question is it's relevant clinically,
7 you know, that if the patient is being treated for
8 Grave's Disease, in general the dose would be less
9 than 30 millicuries, but not always. But if they're
10 being treated for Plummer's Disease, the dose might be
11 higher, up to 50 millicuries, roughly speaking.

12 DR. HOWE: Yes. The numbers in here are
13 33 millicuries. And what we found out is what we
14 thought was an even split earlier at 33 millicuries to
15 the hyperthyroid versus the cancer patients isn't
16 there.

17 There are some -- some procedures that are
18 over 33 that are not for cancer treatment, and so
19 we're having to -- to make sure that those physicians
20 are still authorized to do -- use that amount of
21 activity that they need to use.

22 VICE CHAIRMAN MALMUD: You are, of course,
23 correct. And those patients who are not cancer
24 patients, but who require a higher dose of I-131, are
25 generally patients who have Plummer's Disease, which

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1 is nodular toxic hyperthyroidism -- nodular toxic
2 goiter.

3 So, once again, I think what you're
4 communicating to us is that those who are currently
5 providing those services will not be disenfranchised.

6 DR. HOWE: That's correct.

7 VICE CHAIRMAN MALMUD: Okay.

8 DR. HOWE: And --

9 VICE CHAIRMAN MALMUD: That gives to Dr.
10 Lieto the assurance that I believe he was seeking in
11 making this an item on the agenda.

12 Is that correct, Ralph?

13 MR. LIETO: Yes.

14 DR. HOWE: But one of his issues was that
15 now an up and coming 200 physician will have to meet
16 the criteria, not just of 200 but also some of the
17 criteria in 300, and that is true also.

18 VICE CHAIRMAN MALMUD: Yes, that's for an
19 up and coming nuclear physician.

20 DR. HOWE: That's correct.

21 VICE CHAIRMAN MALMUD: Yes. I think --

22 DR. EGGLI: Or diagnostically valid as --

23 VICE CHAIRMAN MALMUD: I beg your pardon?

24 DR. EGGLI: Or for a diagnostically
25 valid --

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1 VICE CHAIRMAN MALMUD: Well, I think there
2 the question is a little -- is not being addressed
3 directly, because Dr. Howe indicates this was for an
4 up and coming nuclear physician, but not necessarily
5 for a radiologist who does nuclear medicine. Is that
6 correct, Dr. Howe?

7 DR. HOWE: It would be anyone that would
8 be coming in for 200 uses. I was just using nuclear
9 physician to kind of distinguish between our --

10 VICE CHAIRMAN MALMUD: Okay.

11 DR. HOWE: -- 400, 500, 600 category.

12 VICE CHAIRMAN MALMUD: Now, if I may, it
13 would then -- what would then happen is that the
14 credentialing process for the radiologist who wants to
15 do I-131 therapy for thyroid cancer --

16 DR. WILLIAMSON: Yes. Just imaging.

17 VICE CHAIRMAN MALMUD: You -- no, I don't
18 believe -- were you discussing imaging with more than
19 30 millicuries?

20 DR. EGGLI: No. Imaging with more than 30
21 microcuries.

22 DR. WILLIAMSON: Yes, that's what we're
23 discussing.

24 DR. HOWE: Yes. And if you're over 30
25 microcuries, which means you need a written directive,

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1 then you'll come under 35.392, which is less than or
2 equal to 33 millicuries.

3 DR. EGGLI: At a diagnostic level that
4 will not be --

5 VICE CHAIRMAN MALMUD: No, you didn't --
6 would you please repeat what you just said, Dr. Howe?

7 DR. HOWE: Okay. If you are a diagnostic
8 physician --

9 VICE CHAIRMAN MALMUD: Radiologist.

10 DR. HOWE: -- using nuclear medicine
11 procedures, and you're using over 33 microcuries --
12 33 microcuries is the point -- 30 microcuries is the
13 point at which you need a written directive. Okay?

14 So you will then have to meet not only
15 criterion 200, but the criteria in 392, for those uses
16 that you have. If you are currently doing those
17 things, we will give you the authorization in your
18 license to continue to receive that material.

19 VICE CHAIRMAN MALMUD: Thank you. Now,
20 what about the issue that I believe Dr. Eggli is
21 addressing, and I think Dr. Williamson indirectly
22 addressed, and that is a radiology resident who will,
23 I believe under the new ABR rules, only require four
24 months of nuclear medicine training in his or her
25 residency, who finishes the residency, has had a four-

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1 month rotation in nuclear medicine, and is at a remote
2 hospital and wants to use I-131 in a therapeutic
3 modality for either Grave's Disease, Plummer's
4 Disease, or thyroid cancer, in doses of 10, 20, 50,
5 100 millicuries -- millicuries.

6 There it would require not an NRC
7 recognition, but would that require just the
8 credentialing of the hospital? Or would the NRC have
9 an interest in that as well?

10 DR. HOWE: We have an interest in
11 authorization if you go over 30 microcuries, because
12 you go from 200 to 300. We don't distinguish whether
13 you're diagnostic or you're therapeutic in 300. We
14 just distinguish that you now need a written
15 directive.

16 But if your practice is limited to I-131,
17 then you have these alternative requirements in 300
18 for 392 or 394, which are dependent upon your having
19 training and experience using the amount of material
20 that's in 392 or 394. Those are not the full
21 requirements for 390. So you will need to meet the
22 requirements in 290 and 392 or 394.

23 VICE CHAIRMAN MALMUD: So that if the
24 training supervisor or the authorized user for that
25 resident, when he or she completed this training

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1 program, indicated that that individual had had
2 experience in the use of I-131 for the treatment of
3 hyperthyroidism and thyroid cancer, and attested to
4 that, that individual would qualify for use of I-131
5 for -- in doses in excess of 33 microcuries?

6 DR. HOWE: That individual would
7 essentially I think be attesting that they've
8 successfully completed 80 hours of classroom
9 laboratory training applicable to the medical use of
10 sodium iodide 131. For procedures requiring a written
11 directive, the training must include those items.
12 They could be done concurrently with the 200, but it
13 would be that 80 hours, and the authorized user could
14 certify that.

15 VICE CHAIRMAN MALMUD: So the director of
16 the Residency Training Program, or the authorized
17 user, would have to have certified that the radiology
18 resident, in completing his or her four years of
19 radiology residency, had included within that training
20 80 hours with respect to the use of unsealed
21 radioisotopes for therapy.

22 DR. HOWE: Well, it doesn't have to be for
23 therapy, just requiring a written directive.

24 VICE CHAIRMAN MALMUD: Okay. Thank you.

25 DR. EGGLI: The issue here is, though, the

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1 diagnostic imaging, not the therapeutic. This person
2 will have to have 300-level qualifications to
3 administer 500 microcuries of iodine MIBG for a
4 standard diagnostic study.

5 DR. HOWE: And that's correct, but it will
6 be -- ah, that would be 390, because it's not --

7 DR. EGGLI: That would be 390.

8 DR. HOWE: -- sodium iodide 131.

9 DR. EGGLI: That would be 390. So to do
10 diagnostic nuclear medicine, the complete spectrum,
11 the candidate will now have to qualify under 290 and
12 under 390.

13 CHAIRMAN CERQUEIRA: Right.

14 DR. HOWE: That's correct.

15 DR. EGGLI: And that's a dramatic increase
16 in the requirement for diagnostic, not therapeutic,
17 nuclear medicine.

18 CHAIRMAN CERQUEIRA: Right. Neki, you
19 wanted to make a comment?

20 MS. HOBSON: Well, I'm, you know,
21 listening to all of this discussion, and it seems to
22 me the discussion is coming from the point of how
23 these regs are going to affect the physicians, the
24 health care deliverers.

25 And I'm just wondering, how is it going to

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1 affect patients? Are there going to be enough people
2 out there qualified and licensed or empowered to
3 perform the kind of procedures that are needed? Or
4 will patients either have to go without those
5 procedures or travel four hours away to find a
6 practitioner who is qualified?

7 So, you know, from a patient's
8 perspective, how is this going to --

9 CHAIRMAN CERQUEIRA: I think the rules are
10 less restrictive, so in a sense it should make it --
11 there should be more people out there available to do
12 it. What we're doing now is identifying certain
13 little unanticipated results, which may prevent some
14 physicians from not performing some of these
15 procedures.

16 But that really wasn't the intent, and
17 we're trying to find ways of revising the rule which
18 will allow that, so that, you know, nuclear medicine
19 physicians or radiologists who can, you know, do
20 diagnostic and therapeutic treatment with I-131, how
21 can we make it available to them without adding any
22 more restrictions? So I --

23 MS. HOBSON: Wouldn't, you know, a person
24 who is now qualified and authorized to do X
25 procedure --

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1 CHAIRMAN CERQUEIRA: Right.

2 MS. HOBSON: -- if under the new regs, as
3 they are, you know, applied, understands and sees, oh,
4 in order to continue doing this, I'm going to have to
5 go and have this additional training.

6 CHAIRMAN CERQUEIRA: Well, they would --

7 MS. HOBSON: Wouldn't that discourage
8 them?

9 CHAIRMAN CERQUEIRA: That would be
10 grandfathered in, but -- for the people that are
11 currently doing it. But for the new people, it would
12 be a problem, and that's what we're trying to resolve.
13 And Dr. Howe is going to tell us how we can do it.

14 Or, Jeff, do you know how we can --

15 DR. WILLIAMSON: Well, I think these
16 transition issues really do bear on Neki's question.
17 So a key one is to make sure, you know, in general
18 terms that there are enough grandfathered AMPs and AUs
19 of various flavors that there doesn't become a crisis
20 in getting new people through the pipeline, and to
21 also make sure the grandfathering is done. That's the
22 ultimate goal.

23 I do think, though, this actually connects
24 with the first issue that Ralph raised, because, you
25 know, although I'm not a diagnostic practitioner, I am

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1 now understanding that nuclear medicine practitioners
2 -- up and coming ones now, not old one but new ones,
3 who get trained in diagnostic radiology with their
4 four- or seven-month training period -- four months,
5 okay -- four months -- will have board certification
6 pathway open to them for 200 uses not requiring a
7 written directive.

8 And they're going to have to go through
9 the alternative pathway of 35.392, in which case, you
10 know, that's a change, and there will have to be some
11 documentation kept.

12 DR. EGGLI: I just have to go through
13 the --

14 DR. WILLIAMSON: No.

15 DR. EGGLI: -- not sodium iodide. We're
16 talking about iodide-labeled --

17 DR. WILLIAMSON: Oh, I see.

18 DR. EGGLI: -- radiopharmaceuticals, which
19 will put them --

20 DR. WILLIAMSON: Oh.

21 DR. EGGLI: -- into --

22 DR. WILLIAMSON: Within this --

23 DR. EGGLI: -- 390 for diagnostic imaging.

24 DR. WILLIAMSON: This is an important
25 point that I think needs to be addressed maybe in

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1 this.

2 DR. EGGLI: We have taken a portion of
3 diagnostic imaging and taken it out of 290 and put it
4 into 390, and they are low-dose diagnostic studies.

5 DR. WILLIAMSON: So the 35 -- the limited
6 indication categories, the less than 33 millicuries
7 and greater than 33 millicuries, specifically are
8 limited to sodium iodide and not other compounds of
9 iodine.

10 DR. EGGLI: 392 and 394 are specifically
11 limited to sodium iodide.

12 DR. WILLIAMSON: Well, I think the staff
13 better consider revising 392 and 394 to allow a
14 broader spectrum of radionuclides to be used in these
15 categories, so that there isn't this problem. It's
16 quite unreasonable now to, you know, add this huge
17 requirement on imaging physicists.

18 I think this is maybe a place where a
19 motion is needed to advise the staff to seek a fix to
20 the rule language.

21 CHAIRMAN CERQUEIRA: So what motion are
22 you making, Jeff?

23 DR. WILLIAMSON: Well, I think the --

24 CHAIRMAN CERQUEIRA: Or Doug.

25 DR. WILLIAMSON: I'm not an expert in

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1 this. I'm going to suggest one --

2 CHAIRMAN CERQUEIRA: John Graham used to
3 be. He's no longer here.

4 DR. WILLIAMSON: -- of the nuclear
5 medicine people make a motion to --

6 DR. HOWE: Can I make a quick point?

7 DR. WILLIAMSON: Yes.

8 CHAIRMAN CERQUEIRA: Yes.

9 DR. HOWE: If you read 35.40, which is
10 written directives, a written directive must be dated
11 and signed by an authorized user before the
12 administration of I-131, sodium iodide, greater than
13 sodium iodide, 30 microcuries -- any therapeutic
14 dosage of unsealed byproduct material, or any
15 therapeutic dose of radiation from a byproduct
16 material.

17 So I think in the MIBG you may have
18 greater than 30 microcuries, but it's not 30
19 microcuries of sodium iodide. And so I think if it is
20 not considered a therapeutic dosage, then that
21 particular use will still come under 200. But what we
22 have to deal with that used to be under 200 that goes
23 to 300 is the sodium iodide that goes over 30
24 microcuries.

25 DR. WILLIAMSON: So now what I'm hearing

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1 -- I just want to -- is that other chemical forms of
2 radioactive iodine, organically bound, whatever they
3 are, that are more than 30 microcuries can still be
4 administered by new 35.200 diplomates, so to speak,
5 without a written directive, even though it exceeds 30
6 microcuries. It could be 10 millicuries, for example.

7 But if it's sodium iodide, 10 millicuries,
8 that's needed for imaging or diagnostic purposes, that
9 would have to be done through 390 -- 35.392, which
10 means there is an extra documentation pathway that is
11 not -- or a requirement that is not currently present
12 that board-eligible candidates or board-certified
13 candidates will have to keep.

14 CHAIRMAN CERQUEIRA: Okay.

15 DR. WILLIAMSON: Does everyone agree with
16 that?

17 CHAIRMAN CERQUEIRA: Yes. Yes. All
18 right. Now, we have someone in the back who has been
19 standing there quite a long time, and I -- I didn't
20 mean to overlook you.

21 I'm sorry. You've been standing there for
22 a while to make comments, and I didn't recognize you.
23 Please --

24 MR. MOORE: Thanks. I'm Scott Moore. I'm
25 the Chief of the Rulemaking and Guidance Branch, and

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1 I'm Dr. Miller's division.

2 CHAIRMAN CERQUEIRA: An important person.

3 MR. MOORE: Thanks. Our staff briefed you
4 yesterday on the proposed rule comments and on the
5 next steps in the rule.

6 And I guess I just want to mention to you
7 all that I'm concerned about these transitional issues
8 that you all are talking about now following the
9 Commission briefing, and some of the comments that
10 were mentioned this morning in the Commission briefing
11 about the proposed rule and the tradition. And since
12 that falls into my branch's domain, I need to bring
13 them to your attention.

14 Dr. Lieto made comments during the
15 proposed rules/public comment period, but I think it's
16 important that the committee under that the committee
17 as a whole did not officially comment during the
18 proposed rule stage. Dr. Lieto did as an individual,
19 but the committee did not.

20 And you all are talking about how you can
21 best help us -- the staff -- out on the proposed rule,
22 and how you can help us out over the next 30 days.
23 And, you know, Dr. Williamson has said that the staff
24 better consider revising the rule, and you'd advise
25 the staff to seek a fix in the rule.

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1 But the way you can best do that is to
2 submit comments to us as a committee, and the comment
3 period closed on Monday, February 23rd. We are just
4 beginning to analyze those comments. Although we cut
5 off the comment period on the 23rd, we are authorized
6 to seek -- to accept comments after the end of the
7 comment period if we're able to do so and it doesn't
8 negatively impact our rulemaking process -- namely, it
9 doesn't impact the schedule process for the rule.

10 So if we have comments trickle in after
11 the comment period has closed, and we can take them,
12 and it doesn't impact our rulemaking, then generally
13 we'll consider them. So if the committee itself can
14 get comments, and get combined comments from the
15 committee to us as a committee set of comments, then
16 we could consider them in the rule.

17 They would get docketed, and we would
18 consider them as ACMUI comments with respect to the
19 rule, and we would be able to consider them in
20 preparation of the final rule as an ACMUI position
21 with respect to the proposed rule. And that would
22 carry a lot of weight, and it would allow us to
23 consider where the ACMUI is.

24 But we could only do that if you got us
25 something quick. And when I say "quick," I would be

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1 thinking in terms of a few weeks. Anything beyond a
2 few weeks, if it trickled out into the five-, six-week
3 timeframe, it becomes less and less likely, and then
4 beyond about six weeks I'd say we probably wouldn't be
5 able to consider that.

6 I just want to let you all know how you
7 can be most effective in interacting with us in the
8 rulemaking process.

9 Now, if you remember our presentation
10 yesterday, I mentioned to you the next step that we
11 come back to you formally as a committee is, when
12 we're in the draft final rule stage, we will come to
13 you at the same point that we go to the agreement
14 states with a draft final rule and seek your comments
15 at that point.

16 But at that point, we'll have some
17 prepared text, and you'll be less able to influence
18 the process. I mean, we will have drafted words based
19 on feedback that we will have gotten from Dr. Lieto
20 and everybody else that commented on the proposed
21 rule, and we'll have something crafted.

22 If you really want to influence us on the
23 process, the way to do so is to get something on the
24 record as soon as possible.

25 CHAIRMAN CERQUEIRA: Well, thank you for

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1 those comments. And it's really -- yes, go ahead.

2 MR. ESSIG: I've been dying to hand out
3 some material. I'm afraid we're going to lose a
4 couple of people here, but I didn't want to interrupt.

5 CHAIRMAN CERQUEIRA: All right. Okay, if
6 you can just -- yes.

7 MR. ESSIG: The material that we had
8 talked about earlier -- and I just want to make sure
9 -- I mean, I can always mail it to them, but as long
10 as they're here, this --

11 CHAIRMAN CERQUEIRA: Well --

12 MR. ESSIG: Particularly to answer Rich
13 Vetter's concern earlier, here is the letter that went
14 to licensees on the interim source inventory I'll
15 pass, and then the source inventory itself. I'll pass
16 going in two directions.

17 Here -- because Commissioner McGaffigan
18 mentioned that this morning in his presentation -- is
19 the IAEA Code of Conduct for safety and security of
20 radioactive sources. That I will pass in both
21 directions.

22 And then, lastly, for information is the
23 response letter signed by the Chairman that tasks the
24 ACMUI with doing a review of the -- of the input from
25 Marcus and Siegel. I don't know that you've seen

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1 that, but it's the last sentence in the letter.

2 DR. HOLAHAN: And I'd like to clarify for
3 the record, you were right when you said you got an
4 e-mail. The letter was attached to the e-mail. It
5 was a PDF file that was sent out by our contractor.
6 So you didn't actually receive a letter from us. It
7 was a letter signed by Marty Virgilio, but it was part
8 of the e-mail.

9 MR. ESSIG: Okay. Sorry for the
10 interruption.

11 DR. MILLER: Is that what you received,
12 Ralph, or --

13 MR. LIETO: I got an e-mail, but I --
14 there was -- I am almost -- almost absolutely certain
15 -- I don't remember a PDF attachment. I don't know if
16 maybe --

17 DR. HOLAHAN: I have the actual file that
18 was sent out in the inventory, and I can give you a
19 copy of that. You've responded. Your institution has
20 responded.

21 (Laughter.)

22 MR. LIETO: Oh, God. I can just imagine
23 who did.

24 (Laughter.)

25 CHAIRMAN CERQUEIRA: Well, which really

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1 brings up another point is --

2 DR. MILLER: That was my concern earlier.

3 CHAIRMAN CERQUEIRA: Who got the letter?
4 There should be somebody --

5 DR. HOLAHAN: I asked Merri Horn to check,
6 and she has indicated that she has received responses
7 from all licensees and the ACMUI, except one.

8 CHAIRMAN CERQUEIRA: Yet some of the
9 members were not aware of it. Okay.

10 DR. HOLAHAN: Well, it was sent to your
11 RSO.

12 CHAIRMAN CERQUEIRA: Okay.

13 DR. HOLAHAN: So the RSO should have
14 responded.

15 CHAIRMAN CERQUEIRA: Yes. A quick
16 comment? Yes.

17 DR. WILLIAMSON: Well, I don't have a
18 comment on these issues. I have a comment on the
19 transition issues.

20 CHAIRMAN CERQUEIRA: All right. So --

21 DR. WILLIAMSON: We're going to go back to
22 that.

23 CHAIRMAN CERQUEIRA: So we'll say good-bye
24 to Dr. Vetter and Dr. Schwarz. Yes. We need to go
25 back to the transition issues, because, you know, they

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1 need our input. And a lot of these issues are very
2 important, and we're certainly not going to be able to
3 get it done by the end of this meeting, but we need to
4 have some orderly format and assign individuals to get
5 this back to them to get the committee's input.

6 Go ahead.

7 DR. WILLIAMSON: Yes. That is basically
8 -- you've stated my point very eloquently. I am
9 concerned that if we don't work through this list of
10 issues today and figure out which ones really are
11 issues that need to have group comment on, you know,
12 we're going to be not in a position to make -- create
13 an informed letter expressing our concerns.

14 So, you know, is this issue of the I-131
15 or I-125 imaging a real one or not? I --

16 DR. EGGLI: I think the issue there is
17 there has been non-uniform requests on inspections,
18 because the inspectors in Region I have required us to
19 do a written directive for all radiopharmaceuticals
20 that are iodine-labeled greater than 30 microcuries.

21 So if it's only sodium iodide, we have
22 less of a concern. But as we did our quality
23 management program under the old rule, we were
24 required to do a written directive for every iodinated
25 radiopharmaceutical over 30 microcuries.

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1 DR. WILLIAMSON: Well, I would say that,
2 you know, given there's this doubt, I think our -- I,
3 first of all, think we should rise to the occasion and
4 write a letter as a group, and make sure that within
5 two weeks we're prepared to, you know, meet by
6 federally noticed teleconference, or whatever, to
7 finalize it.

8 So this should probably be one of the
9 issues that's mentioned where we're getting ambiguous
10 or ambivalent sorts of responses from various sectors
11 of the Commission, and that this is a major concern
12 that -- how are 200-level practitioners going to
13 continue to do various forms of I-131 imaging that
14 they have done in the past? As a profession -- new
15 ones, I mean.

16 CHAIRMAN CERQUEIRA: Neki?

17 MS. HOBSON: Yes. I just have one quick
18 comment. I'm still concerned about continued
19 availability of these procedures to patients. And
20 when I see that, you know, the experts on this panel
21 -- and I'm very, very respectful of the qualifications
22 of all the people, besides myself -- if they don't
23 even understand what the regulations are really
24 saying, how are licensees and the inspectors out in
25 the field going to understand it?

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1 How can -- like this clarification about
2 the sodium iodide. Would the average licensee ever
3 pick up on that, or just, you know, how are you going
4 to deal with educating people and not have them just
5 say, "Oh, well, never mind. We're just not going to
6 do that anymore."

7 CHAIRMAN CERQUEIRA: That's a very
8 important issue, and, you know, I -- I think it
9 definitely needs to be addressed. The idea of
10 workshops and sort of when people do site visits, it's
11 an issue. And certainly the agreement states, which
12 are the bulk of the sites out there, hasn't even been
13 addressed.

14 So I think those are very valid points
15 that we need to get addressed in really a timely
16 fashion.

17 Ralph?

18 MR. LIETO: The point you made about
19 agreement states -- Donna-Beth, when you -- in terms
20 of the tact that's being taken right now, will that
21 become the precedent for the agreement states to
22 follow? Or will they be -- will they be allowed to --

23 CHAIRMAN CERQUEIRA: Transition.

24 MR. LIETO: -- develop their own?

25 MS. MCBURNEY: Just speaking for one

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1 agreement state, we would be looking at it from the
2 standpoint of like for the -- for example, the iodine-
3 131 issue. If it says sodium iodide above a certain
4 amount, those -- those isotopes that are tagged with
5 other material than for imaging would still be under
6 our equivalent of 35.200.

7 We would probably do the grandfathering of
8 those current authorized users in the same way that
9 NRC is doing that. What other -- let's see. That's
10 all, yes. And I would assume that the other agreement
11 states would do likewise.

12 We're kind of paying attention to what
13 goes up on the web on the Q&A to keep up to date on --
14 on how -- how these rules are being implemented in
15 order to get an orderly transition into our rulings.

16 CHAIRMAN CERQUEIRA: Ralph?

17 MR. LIETO: Will it be up to the licensee
18 -- I guess, you know, I don't necessarily need an
19 answer right now, but will it be left up to the
20 licensee to make that initial -- that initial request
21 for change for the implementation of this new Part 35?
22 Or will it be done as maybe their license is amended?
23 Or is there going to be some other trigger for this
24 license, only when it's renewed or --

25 DR. HOWE: I think you heard today that

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1 Region I, which is our largest region right now, is
2 revising the old licenses to the new Part 35 format as
3 amendment requests are coming in.

4 And then, clearly, when we get a question
5 from a licensee, because of the issue of being able to
6 receive material when they're only authorized for 200
7 under their old license, and they are using I-131 over
8 30 microcuries, those come to the front pretty fast,
9 and we -- we issue new licenses for those.

10 So I think it's -- it's happening on a
11 day-to-day basis. We're not waiting for renewals. I
12 think Pam was pretty clear on that. We're not waiting
13 10 years to bring the licenses into conformance with
14 new 35. We're doing them as they need to be brought
15 in. It goes without saying that we do it upon
16 licensee request, too.

17 CHAIRMAN CERQUEIRA: All right. Well,
18 now, Ralph, this is a very important issue, and I
19 think certainly for the diagnostic community. And I
20 -- does the NRC staff feel that they've got adequate
21 input? And I guess in terms of your needs for the
22 rulemaking, it has to be in writing, doesn't it? I
23 mean, just -- this discussion doesn't really suffice.

24 MR. MOORE: Yes, sir, that's correct. We
25 need it in writing. We need it on the docket. The

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1 ACMUI discussion, although it's helpful to hear your
2 thinking and it gives us background on where you're
3 coming out, and it's helpful to hear various sides of
4 the discussion. It's not the same, because it's not
5 up on the record for other members of the public to
6 hear.

7 It needs to be docketed, and it needs to
8 be docketed through SECY, the same as all other
9 comments. For instance, Dr. Lieto commented much the
10 same as the comments that were presented to the
11 Commission this morning, and that needs to be up on
12 the docket and docketed through SECY. So we do need
13 formal comments, yes, sir.

14 CHAIRMAN CERQUEIRA: Yes. And I guess all
15 of the committee members got the material for comment,
16 but that's really not a comment from the full
17 committee, which really this meeting should have been
18 sort of scheduled around trying to get that -- to get
19 that done.

20 And I'd sort of like the committee and
21 staff to give me some advice -- actually, give Dr.
22 Malmud some advice on how to move forward with getting
23 these comments to -- to them.

24 VICE CHAIRMAN MALMUD: Well, let's take a
25 look at the bullet points on Ralph's page. The first

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1 one is individuals currently in training programs.
2 Now, the question that you raised, Ralph, was, do
3 these individual -- if I understood you correctly, is,
4 do these individuals require some form of attestation
5 statement for the NRC? Is that correct?

6 MR. LIETO: I think more the -- related to
7 the documentation of training and experience for the
8 preceptor to make the attestation I think is -- it
9 would be more the issue.

10 VICE CHAIRMAN MALMUD: And since the new
11 rule goes into effect in October '04, is that correct?

12 DR. WILLIAMSON: It's October.

13 VICE CHAIRMAN MALMUD: October '04.

14 DR. WILLIAMSON: Yes.

15 VICE CHAIRMAN MALMUD: Would it seem
16 reasonable that we recommend that those entering
17 programs after June 30, '04, as you had suggested,
18 Ralph, be furnished with these statements at the time
19 of completion of their training?

20 That those entering the program after July
21 -- after June 30th, meaning those that enter July 1st
22 or after -- it's an approximately date, some residents
23 start a week before June 30th, but those entering for
24 the academic year, want to put it that way, beginning
25 June -- beginning July '04, would require these

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1 statements? Does that create a burden for anyone?
2 Would that satisfy the NRC requirements?

3 DR. WILLIAMSON: I thought we had
4 concluded with this long discussion previously that
5 there -- other than this concern identified
6 specifically about 392-type uses that there weren't
7 any additional documentation requirements from the
8 point of view of NRC for applicants coming via board-
9 certified pathways, that it was the responsibility of
10 the community or the individual preceptors to
11 determine what level of documentation they were
12 satisfied with, and that there is not a need for
13 fixing the rule language at this time. I thought that
14 was our consensus.

15 VICE CHAIRMAN MALMUD: Is that correct,
16 Ralph?

17 MR. LIETO: Yes. I think the committee
18 had decided that the individuals in training was no
19 longer an issue.

20 VICE CHAIRMAN MALMUD: Does the NRC staff
21 require that be in writing from this committee?

22 MR. MOORE: I'm sorry. I didn't hear the
23 background to the question.

24 VICE CHAIRMAN MALMUD: I'm trying to
25 resolve these issues that Ralph has brought up on the

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1 transition issue page. The first one is individuals
2 currently in training programs. This is an issue
3 which we think really is not one of great substance.

4 It's simply a matter of documentation --
5 that those who enter training programs beginning July
6 1st of 2004 would require such statements to satisfy
7 the NRC requirement from the authorized user at the
8 time of completion of their training. Do you want a
9 statement from us to that effect?

10 CHAIRMAN CERQUEIRA: Well, he needs
11 something in writing, I think.

12 VICE CHAIRMAN MALMUD: That's what I mean.

13 CHAIRMAN CERQUEIRA: So I'm --

14 DR. MILLER: Scott, maybe you could go
15 through what we just talked about with regard to what
16 would be the easiest and fastest legal path --

17 MR. MOORE: Sure --

18 DR. MILLER: -- for the committee to get
19 us their comments with the least impact on the
20 committee.

21 MR. MOORE: We're looking for ways to
22 simplify the process. What we need is a clear
23 statement of what the position is, and if we look at
24 the transcript there's going to be various comments
25 about what the position should be.

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1 If you can clearly articulate what the
2 position is as a committee, it doesn't have to be
3 signed by everybody. If somebody could clarify what
4 the position is, it can be even -- we can even
5 receive, I believe by e-mail, can't we -- we can
6 receive a position by e-mail, and that can be e-mailed
7 in by the chair of ACMUI or by an ACMUI member
8 speaking for ACMUI to the SECY.

9 So as far as the individual positions, if
10 you could just clarify what they are and send them in
11 to SECY --

12 VICE CHAIRMAN MALMUD: I would like to do
13 that while the committee is still here, and that's why
14 I'm asking --

15 MR. MOORE: Yes.

16 VICE CHAIRMAN MALMUD: -- that question of
17 you. So my question is, regarding the first item on
18 the agenda -- individuals currently in training
19 programs -- we have been told that we have no
20 flexibility on the issue of the person signing off
21 being the authorized user. So we're working from that
22 as an axiom. Though we may not be happy with it,
23 we're working with that as an axiomatic basis.

24 So do you want a statement from us which
25 says that that authorized user documentation will be

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1 provided to all those who enter training programs
2 after July 1st?

3 MR. MOORE: Yes. We think you can pass a
4 motion here as a committee, and then we could take the
5 transcripts back and docket that and pull that as a
6 comment from the transcripts.

7 VICE CHAIRMAN MALMUD: Yes. I understand
8 that. And what I'm trying to ask you is, is the
9 statement that would satisfy your needs, and our needs
10 at the same time, one which states that this committee
11 will take the vote, this committee wishes to authorize
12 -- wishes to require, with you, that individuals who
13 enter training programs July 1, 2004, or thereafter,
14 will require statements by the authorized user
15 certifying that they have had the requisite training.

16 DR. WILLIAMSON: I don't understand the
17 substance of the motion. I mean, it doesn't matter
18 whether they entered before or after. The way the
19 rule is written now, come October 2004, everybody who
20 is not grandfathered and who wants to be an authorized
21 personage is going to require a preceptor statement.

22 So I think maybe if we disagree with that
23 then we need to vote -- someone needs to make a motion
24 saying that graduates who enter a training program on
25 or before X date should be exempted from this

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1 requirement. And we should just say it flat out, and
2 then we vote on it, and it's in the record. And I
3 think that will satisfy their needs if it's an
4 official motion of this committee.

5 VICE CHAIRMAN MALMUD: Do you wish to make
6 that motion?

7 DR. WILLIAMSON: Okay. I think somebody
8 who is -- I -- all right. I'll make it, so that we
9 can get going. Okay. So the ACMUI proposes that the
10 staff add to the current regulation an exemption which
11 allows matriculants into post-graduate training
12 programs who enter on or before June 30, 2004, will
13 not require a preceptor statement to become an
14 authorized person through the board certification
15 route.

16 VICE CHAIRMAN MALMUD: Is there a second
17 to that motion?

18 MR. LIETO: Second.

19 VICE CHAIRMAN MALMUD: Ralph. Any
20 discussion? Mr. Chairman?

21 CHAIRMAN CERQUEIRA: Yes, go ahead.

22 DR. WILLIAMSON: I don't think there's a
23 need for this motion.

24 VICE CHAIRMAN MALMUD: There is a need.
25 It has to go -- it has to be made public, and we --

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1 DR. WILLIAMSON: Mr. Vice Chair, we have
2 I think determined through conversation with the NRC
3 staff that there isn't a problem to be solved, and
4 there is really no need to modify the rule language.

5 DR. EGGLI: The original concern was the
6 need for documentation that we would have to produce
7 retrospectively. The NRC staff has now said that
8 there is no specific required documentation, which I
9 think resolves the issue of the people in that
10 transitional status.

11 DR. WILLIAMSON: So I would recommend we
12 not approve this motion.

13 VICE CHAIRMAN MALMUD: You can withdraw
14 it.

15 DR. WILLIAMSON: I could withdraw the
16 motion, but I've done it -- for the sake of
17 discussion, I've put it out there.

18 CHAIRMAN CERQUEIRA: Ruth?

19 MS. MCBURNEY: Okay. I agree, I don't
20 think there is an issue to be commented on, and this
21 is pertaining to the current rule. It's not
22 pertaining to the proposed rule. So, also, there is
23 not an issue in that with this reduced requirement for
24 what goes into the preceptor statement. There
25 shouldn't be a problem.

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1 MR. MOORE: If I may? This is Scott Moore
2 again. It is up to you as a committee to choose what
3 to comment on in the proposed rule. One method would
4 be to make motions and have them entered into the
5 record in the minutes, and then we would get that
6 docketed. Another manner would be to send us an
7 e-mail. Another manner would be to send us a letter.
8 That -- the mechanism is up to you.

9 VICE CHAIRMAN MALMUD: Those are the three
10 mechanisms.

11 MR. MOORE: And they're --

12 VICE CHAIRMAN MALMUD: Are you proposing
13 that since this committee is together now, and since
14 we've had a discussion, and since we regard the first
15 issue essentially as a non-issue, that we formalize
16 our statement and get it into the minutes and give it
17 to you now, rather than in an e-mail or by some other
18 means of communication at a later date?

19 That's what -- that was the purpose of my
20 motion, and you made that motion. Have you withdrawn
21 the motion?

22 DR. WILLIAMSON: I will be happy to
23 withdraw the motion. And if the chair wishes, I will
24 try to make it in a more negative way, so that you can
25 have something to enter into the record if that is

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1 your desire.

2 VICE CHAIRMAN MALMUD: Ralph is very
3 concerned about people -- about the transitional
4 issues, and I'm trying to address the concerns of --

5 DR. WILLIAMSON: I think not every --

6 VICE CHAIRMAN MALMUD: We have to
7 communicate this to the appropriate party. Here is a
8 means of communicating it. We are sitting here.
9 Would you rather send an e-mail than just make a
10 statement right now?

11 DR. WILLIAMSON: No. I would rather we
12 drop this issue and move on to the more important
13 ones, because we've determined this one is not really
14 a problem. That would be my suggestion.

15 VICE CHAIRMAN MALMUD: Does the NRC staff
16 person here feel that there has been adequate
17 communication from this committee to him with regard
18 to the committee's desires, without the motion, and
19 without the e-mail?

20 DR. WILLIAMSON: Just this transition
21 issue. I do not mean to include the other --

22 VICE CHAIRMAN MALMUD: I'm referring to
23 the first bullet point.

24 DR. MILLER: From the NRC staff
25 perspective, what I'm hearing is you're not going to

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1 comment on this issue.

2 DR. WILLIAMSON: Yes.

3 DR. MILLER: And if that's the committee's
4 view, and that's what you decide --

5 DR. WILLIAMSON: I will retract the
6 motion. I withdraw the motion, and I'll make a new
7 one. The --

8 VICE CHAIRMAN MALMUD: No, you don't need
9 to. So the -- go ahead. The absence of a comment
10 means that we agree with whatever comes down with
11 regard to the first issue.

12 DR. WILLIAMSON: Yes.

13 VICE CHAIRMAN MALMUD: Is that the
14 agreement of the committee? Ralph, does that satisfy
15 you? You presented this.

16 MR. LIETO: Yes, I presented this on
17 behalf of the committee, but I -- I would agree that
18 we should leave it as a non-issue and move on.

19 VICE CHAIRMAN MALMUD: Thank you.

20 Next item, AMP grandfathering. Do we
21 agree to the issue as it is currently being dealt
22 with? Or does the committee wish to make a comment
23 for the record?

24 Dr. Williamson?

25 DR. WILLIAMSON: Well, I would like to

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1 defer.

2 MR. LIETO: I'll just restate what my --

3 VICE CHAIRMAN MALMUD: Yes.

4 MR. LIETO: -- what the concern is.

5 VICE CHAIRMAN MALMUD: Yes, why don't you
6 restate it.

7 MR. LIETO: The concern is is that in many
8 states authorized medical physicists -- or that this
9 is a new designation. So there is not a history to
10 reference regarding individuals in this category.

11 In many state -- I don't know if I should
12 say in many, but in several agreement states
13 physicists -- authorized medical physicists --
14 individuals who are practicing and meeting the
15 authorized medical physicist definition are not listed
16 on the license. So there is not that designation that
17 they can use as a grand -- to grandfather them.

18 So those are a couple of the major
19 concerns. And I don't know -- Jeff, is there any
20 other that you can think of?

21 DR. WILLIAMSON: Well, let's maybe do that
22 one. I think that's -- that's an important one.

23 VICE CHAIRMAN MALMUD: So you've expressed
24 the concern.

25 DR. WILLIAMSON: Yes.

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1 VICE CHAIRMAN MALMUD: Do you have a
2 motion to express beyond the concern?

3 DR. WILLIAMSON: Well --

4 VICE CHAIRMAN MALMUD: We have two
5 physicists discussing this at the moment. Dr.
6 Williamson?

7 DR. WILLIAMSON: I defer to Ms. McBurney.

8 MS. MCBURNEY: I don't -- I don't think
9 that a comment on the NRC rule would help this
10 situation. It's more of a transition issue in those
11 agreement states in which authorized medical physicist
12 was not a -- a defined item, and those people were not
13 already listed on the license.

14 VICE CHAIRMAN MALMUD: So if the NRC is
15 looking for guidance, we have no -- no guidance to
16 give except for a statement. And the statement is?

17 DR. WILLIAMSON: No. I think we do need
18 to come up with something, so --

19 MS. MCBURNEY: I mean, you could comment
20 on -- on the concern, but how that would affect the
21 final rules in this area I don't know.

22 DR. WILLIAMSON: Well, I think we need to
23 say something. This is really an important issue. We
24 need -- it's critical for the conduct of health care
25 that there be a, you know, population of grandfathered

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1 AMPs or, you know, the system is going to be in great
2 difficulty.

3 So I think we need to make a motion to the
4 effect that, you know, NRC needs to consider
5 alternative language and/or guidance procedures to
6 ensure that physicists currently practicing or playing
7 the role of HDR physicists, gamma knife physicists, or
8 cobalt-60 teletherapy physicists, or intravascular
9 brachytherapy physicists, in agreement states are
10 appropriately grandfathered, regardless of whether
11 they are mentioned by name on agreement state or NRC
12 licenses.

13 VICE CHAIRMAN MALMUD: That's a motion.
14 Is there a second to that motion?

15 DR. EGGLI: Second.

16 VICE CHAIRMAN MALMUD: It's been seconded.
17 Is there any further discussion of that motion? All
18 in favor of that motion.

19 DR. MILLER: Can I ask a question?

20 VICE CHAIRMAN MALMUD: Please do.

21 DR. MILLER: Why is it only an agreement
22 state issue?

23 MR. LIETO: It's not. It would be an NRC
24 -- for example, if they're not listed in an agreement
25 state, and they go into an NRC state to be added to a

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1 license, there is nothing to reference that they've
2 been doing this for -- you know, for X number of
3 years, or whatever. So how would the NRC grandfather
4 them if they've never been listed on a license?

5 MS. McBURNEY: It's a transboundary issue.

6 MR. LIETO: So there is --

7 DR. WILLIAMSON: And I consider it to be
8 an important agreement state issue, too, because the
9 compatibility level requires NRC -- the agreement
10 states to adopt this language, which would
11 disenfranchise their own physicists if they followed
12 it literally.

13 VICE CHAIRMAN MALMUD: Was the suggestion,
14 therefore, that this be augmented to be an NRC and
15 agreement state issue?

16 DR. WILLIAMSON: Well, I think that -- I
17 believe it's -- if it's addressed in the 3500
18 language, which is compatibility level B, the
19 agreement states will be forced to follow suit.

20 So my -- the essence of my point was that
21 the rule language and/or statements of consideration
22 or guidance, whatever the mechanism is, because we
23 don't know what that is right now, needs to somehow
24 ensure that physicists who are playing the functional
25 role in licensed activities for these authorized AMPs

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1 of different flavors are grandfathered, regardless of
2 whether they are mentioned specifically in the license
3 or not.

4 So, and a mechanism needs to be found to
5 identify and grandfather these individuals who are
6 playing that legitimate role. That's the motion.

7 VICE CHAIRMAN MALMUD: Is there comment?

8 DR. HOLAHAN: Yes. Guidance is not a
9 matter of compatibility. So only the rules are
10 compatible.

11 MR. LIETO: So, Trish, then there would
12 need to be something in the final rulemaking process
13 that addresses that, is that correct?

14 DR. HOLAHAN: Yes, that's true, if you
15 wanted to apply to agreement states as well.

16 DR. WILLIAMSON: So I think, then, it can
17 be amended to say, then, I guess rule language or
18 statements of consideration that may clear the intent,
19 if you think the statements of consideration would
20 give you enough of a lever to have transitional
21 procedures that would conflict with the, you know,
22 literal word of the rule. That's up to you guys.
23 You're the regulators.

24 We have identified the problem and I think
25 insist that it be fixed, and I think everyone agrees

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1 around this table it's an important issue.

2 VICE CHAIRMAN MALMUD: So that the motion
3 might sound like this. That the committee expresses
4 its concern that current physicists in a variety of
5 roles in the provision of medical physics be
6 recognized for their current effort and grandfathered
7 accordingly under the new regulations.

8 DR. WILLIAMSON: I preferred my statement,
9 which was far more precise.

10 VICE CHAIRMAN MALMUD: Do you wish to
11 repeat your statement?

12 DR. WILLIAMSON: Yes, I will repeat my
13 statement.

14 VICE CHAIRMAN MALMUD: I was trying to get
15 the motion.

16 DR. WILLIAMSON: Okay. All right. The
17 ACMUI recommends that the NRC modify the language of
18 the new training and experience rule and/or associated
19 statements of consideration to ensure that medical
20 physicists playing the functional role of authorized
21 medical physicist for intravascular brachytherapy,
22 high-dose rate brachytherapy, cobalt-60 teletherapy,
23 and cobalt-60 gamma knife therapy, be grandfathered as
24 AMPs in these respective categories regardless of
25 whether they are currently mentioned explicitly in

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1 agreement statement or NRC licenses at the time of the
2 implementation of the new rule.

3 VICE CHAIRMAN MALMUD: Thank you. That's
4 a motion. Is there a second to that motion?

5 PARTICIPANT: I second it.

6 VICE CHAIRMAN MALMUD: Is there discussion
7 of the motion? All in favor of the motion? Any
8 opposed to the motion?

9 MS. MCBURNEY: Abstain.

10 VICE CHAIRMAN MALMUD: There's one
11 abstention. The rest are affirmatives.

12 The next item is the authorized users of
13 I-131 for diagnostic purposes meeting T&E for written
14 directive use. Who wishes to address that concern for
15 this committee to the NRC, so that it will be a matter
16 of record? Ralph, do you want to tackle that one,
17 or --

18 MR. LIETO: I'll give it a try.

19 CHAIRMAN CERQUEIRA: Or Doug.

20 MR. LIETO: I would move that licenses be
21 amended to provide that current authorized users of
22 sodium iodine-131 for imaging and localization greater
23 than 30 microcuries be allowed -- or continue to be
24 authorized for those purposes.

25 VICE CHAIRMAN MALMUD: That is a motion.

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1 Is there a second to the motion?

2 DR. EGGLI: Second.

3 VICE CHAIRMAN MALMUD: Dr. Eggli. Is
4 there any discussion of the motion? All in favor?
5 Any opposed? Any abstentions? That carries
6 unanimously.

7 All right. And the fourth item is --

8 DR. WILLIAMSON: I'm sorry, Mr. Chair. We
9 -- we have a related issue on this point to consider.
10 We have dealt only with the grandfathering of current
11 practitioners of 35.200. I think we need to ensure
12 that future practitioners in localization and imaging
13 who current -- are able, through the normal training
14 pathway of 35.200, be allowed to practice I-131
15 imaging when it's a non-iodated, non-sodium iodide
16 radiopharmaceutical in excess of 30 microcuries. I
17 don't know if I got it out right.

18 VICE CHAIRMAN MALMUD: Yes, you did.

19 DR. WILLIAMSON: Okay.

20 VICE CHAIRMAN MALMUD: So the committee --

21 DR. WILLIAMSON: The regulations, if
22 necessary, need to be amended before being
23 implemented, to ensure that that activity can be
24 carried out under 35.200.

25 DR. EGGLI: Can I ask a question of staff

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1 in that regard? The hours of requirement for 392, can
2 they be done currently with the 700 hours in 290? Or
3 do they have to be done in addition to the 700 hours
4 in 290?

5 DR. HOWE: You have to look carefully at
6 what the topics are and whether the topics should be
7 addressing therapeutic or otherwise. And you have to
8 make sure you meet your total number of hours for
9 whichever category.

10 DR. EGGLI: You're saying your -- you say
11 you're no longer distinguishing between therapy and
12 diagnosis in -- and in 392, which is the less than 33
13 millicuries. We do not have a problem for future
14 trainees for diagnostic purposes if the 700 hours in
15 290 can be done concurrently with the 80 hours in 392.
16 However, if they have to be done sequentially, then we
17 have a problem. So the question is: can these hours
18 be done concurrently?

19 DR. HOWE: The requirements in 392 are
20 that the -- they have to have training applicable to
21 the medical use of sodium iodide for the procedures
22 requiring a written directive. And they must include
23 these topics, and they have to have 80 hours of
24 classroom and laboratory training specific to that for
25 sodium iodide use.

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1 DR. EGGLI: Right. But could those 80
2 hours count as part of 290?

3 VICE CHAIRMAN MALMUD: Doug? Excuse me.
4 The answer to your question is: by tradition, yes.

5 DR. EGGLI: I know by tradition, but --

6 DR. HOWE: But, by tradition, you're way
7 over the 700 hours. It's minor.

8 DR. EGGLI: Except that the radiology
9 residency is decreasing its required time to be more
10 compatible with the new regulation.

11 DR. HOWE: Okay. Well, it says for
12 medical use for unsealed byproduct material for
13 imaging and localization studies -- their imaging and
14 localization studies. And then you have to meet the
15 criteria, so --

16 DR. EGGLI: Right.

17 DR. HOWE: -- I think as long as the
18 objective is both imaging and localization, and I-131,
19 then you're okay. But if there's one that's not in
20 both of them, then you're going to have to add that
21 little --

22 DR. EGGLI: And I do understand that. But
23 we're looking at the overlap only. I'm looking, in my
24 mind, at the overlap right now, not -- not -- nothing
25 other than the overlap.

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1 DR. HOWE: I think if you -- if it could
2 be imaging localization, and it's also I-131 --

3 DR. EGGLI: Right.

4 DR. HOWE: -- and you're doing I-131, then
5 it can cover into the imaging and localization.

6 DR. EGGLI: Okay. As long as the specific
7 criteria from 392 are included.

8 DR. HOWE: Yes.

9 DR. EGGLI: Okay. Thank you.

10 DR. WILLIAMSON: I've just heard enough
11 contradiction from the various headquarters and
12 regional staff that I'm concerned about non-sodium
13 iodide imaging when it involves doses in excess of
14 30 microcuries of I-131, that I thought maybe we
15 should go on record, you know, recommending that staff
16 comb through this new regulation with a fine-tooth
17 comb and fix it if necessary to allow 35.200
18 practitioners in future to do whatever form of I-131
19 imaging they want to do, excepting sodium iodide
20 imaging in excess of 30 microcuries, without
21 additional training and experience. That would be my
22 motion.

23 VICE CHAIRMAN MALMUD: That motion -- is
24 there a second to the motion? I don't think we
25 have --

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1 MR. ESSIG: If I could bring up a
2 procedural issue.

3 VICE CHAIRMAN MALMUD: We don't have a --

4 MR. ESSIG: You don't have a quorum.

5 VICE CHAIRMAN MALMUD: We don't have a
6 quorum.

7 MR. ESSIG: You just lost -- Ruth McBurney
8 left. You need seven.

9 VICE CHAIRMAN MALMUD: So we cannot
10 present that as a motion, though it is meritorious.
11 We could e-mail you on that issue, and Dr. Howe and
12 staff are -- would happily accept an e-mail to that
13 point.

14 DR. WILLIAMSON: I don't think we can act
15 as a group without a noticed meeting. I don't think
16 we can --

17 VICE CHAIRMAN MALMUD: At our next
18 telephone conference call, we can deal with the issue.

19 DR. WILLIAMSON: Well, that will be too
20 late.

21 VICE CHAIRMAN MALMUD: That's too late.
22 All right.

23 DR. WILLIAMSON: I think we --

24 DR. HOLAHAN: You can send it
25 electronically to -- and then send it in to us as --

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1 when you get --

2 DR. WILLIAMSON: Without review --

3 DR. HOLAHAN: Yes, without a notice.

4 DR. WILLIAMSON: -- by the public? We can
5 come up with a joint --

6 DR. HOLAHAN: Yes.

7 DR. WILLIAMSON: -- ACMUI position?

8 DR. HOLAHAN: Because it goes on the
9 public document.

10 DR. WILLIAMSON: But we can't have a
11 telephone conference about it.

12 MS. WILLIAMSON: Excuse me. It looks like
13 you have a quorum now.

14 VICE CHAIRMAN MALMUD: How many constitute
15 a quorum? We have seven. We now have a quorum.
16 Okay.

17 MEMBER WILLIAMSON: Let's vote on this
18 issue.

19 VICE CHAIRMAN MALMUD: Would you just
20 quickly before we leave the quorum again make the
21 motion? The ACMUI recommends that the staff carefully
22 review the revised part 35 training and experience
23 rule to ensure that future 35.200 practitioners will
24 be allowed to provide I-131 imaging and localization,
25 excluding sodium iodine, radiopharmaceuticals in any

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1 dose needed without further training and experience.

2 MEMBER EGGLI: Second.

3 VICE CHAIRMAN MALMUD: I have a question.

4 Do you mean any dose?

5 MEMBER WILLIAMSON: Any dose in excess of

6 30 microcuries.

7 VICE CHAIRMAN MALMUD: What about five

8 millicuries?

9 MEMBER WILLIAMSON: If five millicuries
10 are needed, then so be it. Five millicuries.

11 VICE CHAIRMAN MALMUD: That clarifies.

12 Did you second the motion?

13 MEMBER EGGLI: I did.

14 VICE CHAIRMAN MALMUD: I will call the
15 vote. Any further discussion of the motion?

16 (No response.)

17 VICE CHAIRMAN MALMUD: All in favor?

18 (Whereupon, there was a show of hands.)

19 VICE CHAIRMAN MALMUD: It is unanimous.

20 We have dealt with all of the issues, Ralph, that you
21 brought before us.

22 MEMBER EGGLI: Actually, I would like to
23 codify in a motion a question for Donna-Beth.

24 VICE CHAIRMAN MALMUD: I just wanted to
25 ask Ralph a question before we left this page.

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1 MEMBER EGGLI: This is still on this issue
2 of I-131 for diagnosis.

3 VICE CHAIRMAN MALMUD: All right.

4 MEMBER EGGLI: I would like to make a
5 motion that the sense of the Committee be relayed to
6 staff that diagnostic use of sodium iodide, which
7 falls under 392 for diagnostic use only, that the
8 ACMUI recommends that there be a clarification that
9 that can be included in the 700 hours of training for
10 200 use as long as it is limited to diagnostic imaging
11 and localization only and they meet the specific
12 experience requirements listed in 392.

13 MEMBER WILLIAMSON: Second.

14 VICE CHAIRMAN MALMUD: Is there any
15 discussion of that?

16 (No response.)

17 VICE CHAIRMAN MALMUD: All in favor?

18 (Whereupon, there was a show of hands.)

19 VICE CHAIRMAN MALMUD: So you have the
20 spirit of the Committee. I think you already told us
21 that it was okay, but it is now formalized, Dr. Howe.

22 MEMBER HOBSON: Dr. Malmud? These motions
23 are going into the minutes. We don't get the minutes
24 like for a couple of months. Now, will the NRC staff
25 get the minutes in a timely fashion so that they can

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1 be docketed and put into the record?

2 VICE CHAIRMAN MALMUD: The NRC staff?
3 Three members of the staff have shaken their heads
4 affirmatively.

5 CHAIRMAN CERQUEIRA: Yes.

6 VICE CHAIRMAN MALMUD: Let the record show
7 that three members of the NRC staff have shaken their
8 heads affirmatively that they will have received it.
9 Dr. Williamson?

10 MEMBER WILLIAMSON: Well, I think there
11 are numerous more issues we might need to comment on.
12 I think that I am not personally satisfied that the
13 rule language defining preceptor allows the level of
14 flexibility needed to accommodate the many scenarios
15 that Ralph outlined in his presentation this morning.

16 Example, right now preceptor is defined as
17 the individual who supervises and directs and provides
18 the training of the authorized person applicant. I
19 think I am concerned how that is going to fit with,
20 just to give an example, for example, the practice
21 which acquires a gamma knife and there is no
22 authorized user on site.

23 So now I am worried that the restrictive
24 way in which the preceptor requirement is written may
25 prevent or preclude, for example, the medical director

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1 of the one-week course in gamma knife from signing a
2 preceptor statement on behalf of that person.

3 I am worried about a situation if a
4 practice acquires an HDR device, in which case most of
5 the training is provided, actually, by non-licensed
6 personnel from the vendor, who are not necessarily
7 even physicians. Who is going to sign the preceptor
8 statement for both physicists and --

9 VICE CHAIRMAN MALMUD: Dr. Williamson, how
10 is that being handled currently? Would you educate
11 the Committee as to how it is occurring currently?

12 MEMBER WILLIAMSON: Currently, one way it
13 is being handled is that now board certification
14 provides the credentials. So there is no need for a
15 preceptor statement at all. And basically the
16 community goes and the practice goes and does these
17 courses and begins the practice.

18 VICE CHAIRMAN MALMUD: Yes.

19 MEMBER WILLIAMSON: So there isn't a
20 requirement. So I am worried more about the odd
21 scenarios when a qualified practitioner in the sense
22 that the community uses the word a "qualified" medical
23 physicist, a qualified radiation oncologist, comes to
24 acquire a new modality. Their training is many years,
25 decades behind them. They have to acquire a new

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1 modality. How is this to be handled?

2 I am not convinced at this point that the
3 rule language is sufficiently flexible to basically
4 systematize the processes that are in effect in the
5 community now by which we get this done because new
6 users, people, physicians, and physicists, move from
7 practice to practice. And they have to acquire
8 knowledge to competently perform new modalities. This
9 happens all of the time.

10 VICE CHAIRMAN MALMUD: Ralph?

11 MEMBER LIETO: I would probably add that
12 almost any use in section 1000 would apply because --

13 VICE CHAIRMAN MALMUD: It's new
14 technology.

15 MEMBER LIETO: It's new technology, and
16 your listing of authorized users and so forth on the
17 license specifically lists those modalities in 1000 by
18 application. So if you get a new modality in, whether
19 it is a GliaSite or TheraSpheres or any of those
20 modalities in pharmaceuticals as well as the machines
21 that Jeff mentioned, I would see that licensee would
22 be under that same situation.

23 MEMBER WILLIAMSON: So one thing I could
24 propose maybe as a specific is to modify the
25 definition of preceptor to include not only those who

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1 direct and provide the training but have knowledge of
2 the applicant's capability to successfully perform the
3 safety duties associated with the modality.

4 VICE CHAIRMAN MALMUD: How could we have
5 knowledge of the applicant's ability with the modality
6 when the modality is new? Why don't we leave the
7 definition as it is since the practice as it is has
8 been unchallenged thus far?

9 MEMBER WILLIAMSON: Honestly, I am not
10 sure how to handle this. I do think you may be right
11 that it may not be a problem, but it might. I am
12 concerned that perhaps without another 45-minute
13 conversation or dialogue with the staff, we will never
14 figure that out.

15 We have to go through these scenarios,
16 painful as it is, one by one and determine whether
17 there is a significant issue or not and then advise
18 the staff how the rule might or might not need to be
19 change.

20 VICE CHAIRMAN MALMUD: Dr. Eggli?

21 MEMBER EGGLI: I know in a new technology
22 issue for PET CT, most of the vendors are offering
23 training opportunities at a site where there is
24 someone who can preceptor your experience. Does that
25 not occur while in radiation oncology?

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1 MEMBER WILLIAMSON: I believe it is
2 customary with the gamma knife but not for HDR. Would
3 you agree with that?

4 MEMBER LIETO: I would agree with that,
5 yes.

6 MEMBER WILLIAMSON: For intravascular
7 brachytherapy, it is almost exclusively the vendor
8 that performs the training. And they don't send a
9 physician out there to do that. They send usually a
10 customer support person who has been well-trained in
11 the details of the protocol and the technical
12 operation of the device.

13 VICE CHAIRMAN MALMUD: Dr. Williamson,
14 isn't that issue generally dealt with at the level of
15 credentialing within the hospital or the institution
16 itself?

17 MEMBER LIETO: Well, you have to submit
18 the preceptor.

19 MEMBER WILLIAMSON: The preceptor is
20 required to be an authorized person practicing the
21 same modality.

22 VICE CHAIRMAN MALMUD: Dr. Zelac may have
23 some wisdom for us on the issue. Dr. Zelac?

24 DR. ZELAC: I will try to make a
25 worthwhile contribution. What I am looking at is the

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1 statements of consideration for the existing rule.
2 This question of where training could be received and
3 who could sign off on its being successfully completed
4 was raised at that time.

5 I am going to read from the statements of
6 consideration. It was the response of the NRC through
7 the comment on this issue. "We," meaning the NRC, "do
8 not believe that the rules should prohibit an
9 individual from obtaining training at locations whose
10 activities are supported by commercial manufacturers,
11 suppliers, or the owners' investigators."

12 Here is the critical part, "We will rely
13 on the preceptor's written certification for final
14 assurance that an individual has completed the
15 required training and experience and is competent to
16 function independently as an AU."

17 What these words say to me is that the
18 preceptor does not personally have to direct or
19 provide the training, but he has to essentially be
20 aware that appropriate training and experience has
21 been received and is willing to attest to that in the
22 preceptor statement.

23 VICE CHAIRMAN MALMUD: Thank you for that
24 information, Dr. Zelac.

25 MEMBER WILLIAMSON: That is why I propose

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1 the definition of preceptor be changed. So to follow,
2 this has been great that Dr. Zelac brought this up.

3 So if I go to Nucletron and I have the
4 training and treatment planning and I get all of the
5 training in operating the device and then I go and
6 talk to my colleague on the other side of town who has
7 not personally been involved in the provision of this
8 training to me and review my procedures and review the
9 training I have gotten with the vendor and presumably
10 by the relationship, this person already knows my
11 background and experience in general, I think it would
12 be reasonable that this person could attest to my
13 competence to perform these duties.

14 So this is a person who has not directly
15 provided the training but who has knowledge of my
16 clinical capabilities and training and attests that I
17 will do a good job.

18 So that is why I would propose inserting
19 those words into the rule to really make sure that the
20 rule has the flexibility to accommodate all of these
21 bizarre situations.

22 CHAIRMAN CERQUEIRA: My only concern about
23 that, maybe medical physicists work well together. I
24 think for physicians, sometimes to find a colleague
25 across town who is willing to assume any kind of

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1 liability when he is going to be competing against you
2 is going to be difficult.

3 So, even though that person may have
4 gotten all of the adequate training, to find somebody
5 who is willing to sign that preceptor statement may
6 not be as easy.

7 MEMBER WILLIAMSON: But it might be easier
8 if we make the rule more flexible. It could be
9 somebody across the state line in another city.

10 MEMBER EGGLI: In the case of this 1000
11 new technology, the person who signs the preceptor
12 statement has to be an authorized user or can it be
13 some other authorized person? For instance, could it
14 be the RSO of an institution that vouches for the fact
15 that the medical physicist or the physician has gone
16 and taken the training or does the authorized person
17 have to be in the same category? You are shaking your
18 head yes on "same category."

19 VICE CHAIRMAN MALMUD: I didn't understand
20 the last thing you said. Who is shaking?

21 MEMBER EGGLI: Dr. Zelac is shaking his
22 head yes that it has to be the same category.

23 VICE CHAIRMAN MALMUD: Same category.

24 DR. HOLAHAN: It has to be the same
25 category.

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1 MEMBER WILLIAMSON: So I really think does
2 the staff find it objectionable or does it think it
3 would help ease this transition if we substituted
4 those words into the rule language?

5 VICE CHAIRMAN MALMUD: Substituted which
6 words for which words?

7 MEMBER WILLIAMSON: Okay. Currently the
8 definition reads, "The preceptor's person who provides
9 or directs the training." I would say, "provides,
10 directs, or has knowledge of."

11 VICE CHAIRMAN MALMUD: We have a comment
12 from NRC.

13 MR. MOORE: At the risk of wading into
14 this, I can imagine some potential implementation
15 errors with people shopping for preceptors, especially
16 if you get trans-boundary issues going out of state.
17 I guess I can see, Dr. Williamson, out of state. You
18 can imagine things going way, way out of state, across
19 the country, people willing to sign off things far out
20 of country and other states entirely.

21 I guess we would need to find a way in
22 either implementation guidance or something to guard
23 against that.

24 MEMBER WILLIAMSON: Well, is the
25 alternative to do nothing and restrict the practice of

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1 medicine? Nobody has made an argument that the way
2 things work now is broken.

3 MR. MOORE: No. I am not --

4 MEMBER WILLIAMSON: You know, there is a
5 shortage of radiation oncologists and physicists. So
6 is my fix helpful or not?

7 VICE CHAIRMAN MALMUD: We have a comment
8 from the American College of Radiology.

9 MS. FAIROBENT: I just wanted to point out
10 an example of what we currently do through our
11 accreditation programs. And I hate to bring this one
12 in because currently it is not a modality that NRC
13 regulates, but for PET, for example, positron emission
14 tomography, in order for our physicians to become
15 recognized for our accreditation program, they have to
16 have 24 hours of training in PET.

17 Now, granted, a piece of that, they can
18 get through the training programs, the didactic
19 courses, but there is also an element that they have
20 to go and do some clinical applications. They go to
21 another facility. For example, one of our physicians
22 in Texas went to a colleague's facility who was
23 already accredited for PET in New Mexico.

24 It is not uncommon, at least for the ACR
25 positions, to go to other facilities, which may even,

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1 in fact, be across country. I don't see any
2 prohibition in concept that that other authorized user
3 should not be able to sign as a preceptor for the
4 second physician.

5 There is a problem in the definition of
6 preceptor as it is worded. And in our comments, we
7 have recommended a simplistic fix. We talked and
8 debated, Jeff, a lot about the type of language you
9 are suggesting, but I think that the removal of the
10 word "the" before "training and experience" in the
11 definition broadens it so that it is not unique to a
12 specific application and does allow the flexibility.

13 So I just point that out that it is not
14 uncommon for physicians to go either across town to
15 another colleague's facility across state in order to
16 get that initial training in order to be able to do a
17 new modality.

18 DR. HOLAHAN: But I would ask Lynne to
19 comment. Is it the authorized user in the same field?

20 MS. FAIROBENT: Yes. For example, it
21 would be --

22 DR. HOLAHAN: It is not like an RSO
23 signing off?

24 MS. FAIROBENT: Yes. For example, it is
25 physician to physician, who could then certify that

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1 they did the clinical. It is not that dissimilar for
2 what we do for a new physician who wants to do the
3 three iodine cases.

4 If their facility is not currently doing
5 the iodine therapies, they have to go somewhere to get
6 their initial three cases. So they would have to go
7 to a facility and work under an authorized user to do
8 those types of therapies to get those three cases that
9 are required under 394.

10 MR. MOORE: This is Scott Moore again.

11 I think what Lynne is describing makes a
12 lot of sense. My comments had to do with the
13 terminology "has knowledge of." I think you would
14 probably want to be very careful about loosening the
15 standards over broadly and being careful about what
16 "has knowledge of" means. Is there a level of what
17 "has knowledge of" means? I mean, if one doctor goes
18 to another doctor and just describes what they did
19 sufficient, is that "has knowledge of"?

20 VICE CHAIRMAN MALMUD: Thank you.

21 Yes?

22 MEMBER SULEIMAN: I hope this contributes.
23 FDA's experience, will approve the device, will
24 approve the drug, we really defer to the local
25 institution for the credentialing in whatever the

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1 local state.

2 But with any new technology, any emerging
3 technology, the vendor really invests quite a bit in
4 the training to get this thing off and running. So
5 who is going to teach the very, very first person?

6 So I think in an emerging technology, new
7 procedure and new protocol, you really have to defer
8 to the expertise of the local facility and the
9 manufacturer. Where that transforms into a more
10 established new procedure and, all of a sudden, then
11 you have enough bodies around to precept the others,
12 that is the critical thing, but I think you have to
13 cut a lot of slack early on.

14 I think people are excited about the
15 technology. And nobody wants it to fail. So I think
16 earlier on, there is probably a lot of attention. It
17 is a case of getting it rolling out.

18 But where you make that transition, maybe
19 when you decide to take it out of 1000, I don't know.
20 Clearly you have got to rethink the concept of
21 preceptor at that phase versus later on.

22 MEMBER WILLIAMSON: I think that is a good
23 point. It certainly adds a big burden to the
24 manufacturers to have to fly unnecessarily physicians
25 from one part of the country to another just to have

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1 a preceptor statement.

2 I guess I would question whether that is
3 a good use of resources to significantly modify the
4 pattern that is now existent within the regulated
5 community unless you think it is a clear and present
6 danger to public safety.

7 I have not heard anybody make that case.
8 So that is why I am trying. I am arguing that I think
9 these rules should be liberalized to accommodate the
10 current practice as much as possible.

11 Yes, I suppose people could cheat and so
12 forth. And maybe guidance could be an indication of
13 consequences if people didn't take these duties
14 seriously, but I think to add significant expense to
15 becoming an authorized user for HDR or intravascular
16 brachytherapy, which is not at this point found
17 necessary by the community, why impose more costs and
18 requirements to do this unless you really think there
19 is a risk to public safety? And, as I say, I don't
20 think anybody has made that case.

21 VICE CHAIRMAN MALMUD: Having said what
22 you said, do you still feel that your motion is
23 needed?

24 MEMBER WILLIAMSON: Well, I think it is a
25 useful motion, yes. I would amend it to remove the

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1 definite article "the," which would eliminate another
2 concern with the preceptor definition, which is that
3 the rule is not flexible enough to accommodate sort of
4 multiple persons signing off on different modalities.

5 If you read it literally now, it sounds
6 like for radiation oncologists and physicists, there
7 has to be a single sort of training person who oversaw
8 the training in all of these three or four different
9 modalities, which the way medicine is changing so
10 rapidly and dynamically, that is unreasonable.

11 So I think to eliminate the definite
12 article "the" to allow explicitly for the possibility
13 of multiple preceptors in different areas or even
14 different maybe one for the didactic part and one for
15 the practical part would be an appropriate thing to
16 do.

17 VICE CHAIRMAN MALMUD: I am not familiar
18 with the sentence or phrase in which it is suggested
19 that the article "the" be deleted. Does anyone have
20 that text that they could read to the Committee so
21 that we might hear it? And would you share that with
22 us? Which slide?

23 MEMBER LIETO: Actually, it was in the
24 slides from this morning. If you look at slide number
25 4, it has the current definition in section 35.2. It

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1 states, "The current definition of a preceptor is an
2 individual who provides or directs the training and
3 experience required for an individual to become" blah
4 blah blah.

5 VICE CHAIRMAN MALMUD: And it's the "the
6 training"?

7 MEMBER LIETO: And the suggestion was to
8 change that to "an individual who provides or directs
9 training and experience."

10 VICE CHAIRMAN MALMUD: That is a motion to
11 change the --

12 MEMBER WILLIAMSON: I am looking for the
13 text here so I can make it specific and focused for
14 you. 35.2, isn't it?

15 VICE CHAIRMAN MALMUD: 35.2, "Definition.
16 An individual who provides or directs the training and
17 experience required for an individual to become an AU,
18 an AMP, an ANP, or an RSO." And the word that we want
19 to delete is the third word on the second line? Is
20 that where the "the" appears?

21 MEMBER LIETO: Yes.

22 VICE CHAIRMAN MALMUD: And the preferred
23 wording would be "An individual who provides or
24 directs training and experience required for an
25 individual to become an AU, an AMP, an ANP, or an

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1 RSO."

2 Dr. Williamson has made the suggestion
3 that the word "the" be dropped between the two words
4 "directs" and "training." Is there a second for that
5 motion?

6 MEMBER EGGLI: I'll give it a second.

7 VICE CHAIRMAN MALMUD: It is seconded by
8 Dr. Eggli. Is there any further discussion of that
9 phrase?

10 MEMBER LIETO: I guess I would ask NRC
11 staff for an opinion. Another suggestion that we had
12 made this morning was to use the words "an individual
13 who provides, directs, or can verify the training and
14 experience."

15 MEMBER WILLIAMSON: Which is very similar
16 to my suggestion, "has knowledge of."

17 MEMBER LIETO: You think those are just
18 equivalent statements of the same with different
19 wording?

20 MEMBER WILLIAMSON: I think so. My
21 initial motion was actually a little different.
22 "Preceptor means an individual who provides, directs,
23 or has knowledge of training and experience required
24 for an individual to become" a dot dot dot dot.

25 DR. HOLAHAN: I, frankly, liked your

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1 wording better.

2 MEMBER LIETO: Of the second on?

3 DR. HOLAHAN: Yes, "verify."

4 MEMBER WILLIAMSON: I accept that.

5 VICE CHAIRMAN MALMUD: Therefore, the
6 preferred wording is "An individual who provides,
7 directs, or verifies training and experience required
8 for an individual to become," et cetera. Is that?

9 MEMBER LIETO: Yes

10 VICE CHAIRMAN MALMUD: That is a motion
11 from Dr. Lieto. Is it seconded by Dr. Williamson?

12 MEMBER WILLIAMSON: Yes.

13 VICE CHAIRMAN MALMUD: Any discussion?

14 (No response.)

15 VICE CHAIRMAN MALMUD: All in favor?

16 (Whereupon, there was a show of hands.)

17 VICE CHAIRMAN MALMUD: It carries
18 unanimously. Therefore, that is the last bit of
19 material which I believe we want to convey to NRC
20 staff with regard to communication by e-mail, other
21 means, or this Committee.

22 MEMBER WILLIAMSON: I don't think so.

23 VICE CHAIRMAN MALMUD: Dr. Williamson
24 would like to go on.

25 MEMBER WILLIAMSON: Unfortunately, our two

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1 radiation oncologists aren't here, but if they were
2 here, I would ask them if they were satisfied with the
3 wording for the training and experience requirements
4 for 35.300, which now read in sort of an ambiguous way
5 but appear if you read it literally to allow radiation
6 oncologists to continue being authorized users for
7 35.300 radiopharmaceuticals with board certification
8 as it is currently administered. That is my
9 understanding.

10 VICE CHAIRMAN MALMUD: May I suggest that
11 in the absence of the two radiation oncologists that
12 we not pursue this element of discussion but somehow
13 communicate with them and get back to the Committee at
14 the next meeting? Is that acceptable?

15 MEMBER WILLIAMSON: It will have to be.
16 It will be useful to get the staff's perspective on
17 the issue at this time so that we are prepared to do
18 this by e-mail in a timely fashion.

19 VICE CHAIRMAN MALMUD: We have a full
20 agenda for e-mail among us, you and I in particular.
21 But in the absence of the radiation oncologists, I
22 don't think we can really discuss it on their behalf.
23 Do you?

24 MEMBER WILLIAMSON: I think we could find
25 some useful information out from the staff that would

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1 be material to the discussions.

2 VICE CHAIRMAN MALMUD: Do we want to ask
3 a question of the NRC staff?

4 MEMBER WILLIAMSON: Yes, I do.

5 VICE CHAIRMAN MALMUD: May we limit that
6 inquiry to no more than five minutes since we are now
7 ten minutes beyond our agenda?

8 MEMBER WILLIAMSON: All right. Let me
9 find the appropriate section. 35.390 currently reads
10 that "An authorized user is certified by a medical
11 specialty board whose certification process has been"
12 blah blah blah blah. "To be recognized a specialty
13 board shall require all candidates for certification
14 to successfully complete the minimum of three years'
15 residency training in irradiation therapy or a nuclear
16 medicine training program or a program in a related
17 medical specialty that includes 700 hours of training
18 and experience as described in paragraph B.1."

19 That is what the words say. They could be
20 read as saying that if you have a residency under your
21 belt in either nuclear medicine or in radiation
22 oncology, that you need not satisfy to the letter all
23 of the requirements in paragraph B.1.

24 I will mention the information to the
25 Committee that paragraph B.1 includes the 700 hours of

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1 training and experience and lists many varied and
2 technical duties that you have to have experience
3 with, including 12 cases of experience.

4 So my question is, is it the intent of the
5 staff that the radiation oncology residency to be
6 recognized by the Commission not be held to all of
7 these detailed requirements in paragraph B.1?

8 VICE CHAIRMAN MALMUD: Dr. Howe?

9 DR. HOWE: I have to admit I had several
10 conversations going in each ear at the same time. So
11 I may not be able to answer exactly.

12 I think if we took a strict
13 interpretation, we would say that the residency had to
14 include 700 hours of training and experience in basic
15 radionuclide-handling techniques applicable to
16 unsealed byproduct material, which may not be in the
17 residency program.

18 Now, the alternative -- and I am not as
19 familiar with what the board certification criteria
20 are going to be for 390. In the past, the board
21 certification criteria for 930 I believe also included
22 certifications that the radiation oncologists had.
23 Therefore, they met the 300 criteria by the board
24 certification route.

25 But the way the new board certification

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1 criteria are written, I don't know if those same
2 boards would meet the criteria that are going to be
3 exclusively put into 390.

4 MEMBER WILLIAMSON: Well, I think this is
5 a really important issue because it is not every
6 radiation oncologist who practices radiopharmaceutical
7 therapy, but certainly a significant minority has, I
8 think. Unfortunately, my colleagues aren't here to
9 represent the issue, but I think this is a messy and
10 difficult problem.

11 DR. HOWE: And what happened under the old
12 rule was that the requirements to meet training and
13 experience requirements for 300 were 80 hours. We
14 applied the I-131 model to other isotopes because 300
15 said 80 hours of radiopharmaceutical therapy and they
16 had 3 cases of I-131 in either hypothyroidism and 3
17 cases in thyroid cancer.

18 We used the same model for going into
19 strontium and zevlin or other isotopes. So there was
20 an 80-hour criteria, where now 390 is a 700-hour.

21 So unless we had an equivalent to 392 or
22 394 for other isotopes, I believe you are right.

23 MEMBER WILLIAMSON: There is the problem.
24 I do not think this can be resolved by e-mail. I
25 think it is a sufficiently important issue that I

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1 believe we may have to have within the time frame
2 during which comments would be useful a teleconference
3 that includes the radiation oncologists where we can
4 attempt to come to a resolution and vote a motion on
5 this issue because I think it is a key one that I
6 think would dramatically change the practice of
7 radiation oncology and basically close, make it much
8 more difficult for radiation oncologists who are not
9 grandfathered to be able to combine
10 radiopharmaceutical therapy with the other therapies
11 that they use.

12 VICE CHAIRMAN MALMUD: Dr. Eggli?

13 MEMBER EGGLI: From a 390 practitioner's
14 point of view, I think whatever the reasonable
15 requirement is for training and experience to handle
16 390 should be applied uniformly to anyone who wants to
17 practice under the 390 rule. I don't think that a
18 practitioner who practices in the 400 or 600 series
19 should have a different requirement for handling 390
20 materials than anyone else who practices 390.

21 So what needs to be, there need to be
22 appropriate training requirements. And then everybody
23 needs to jump over that particular bar because the
24 fact that you can do brachytherapy or external beam
25 therapy doesn't mean that you have the experience to

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1 do unsealed source therapy.

2 I think there should be one set of
3 criteria for everybody. Whatever the right criteria
4 are, they should apply across the board to all
5 practitioners.

6 VICE CHAIRMAN MALMUD: Dr. Zelac?

7 DR. ZELAC: I am not sure this is going to
8 add very much except to raise the level of discussion
9 a bit. The proposed rule, which, of course, the
10 comment period on which has now expired, reflected the
11 recommendations that staff received from the Advisory
12 Committee. They are almost identical to the
13 recommendations that were received from the Advisory
14 Committee with respect to what the qualifications
15 should be for a particular board to become recognized.

16 So I ask the question of Dr. Williamson,
17 is this now second thought as to what the previous
18 recommendations were or am I misunderstanding
19 something?

20 MEMBER WILLIAMSON: I think there was a
21 mistake in the way the recommendations were
22 communicated to you because the initial result of the
23 subcommittee's deliberation was to have a sort of a
24 much more general description and less prescriptive
25 description of the technical training

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1 requirements/content requirements in the 700 hours and
2 put the 12 cases of experience as a requirement that
3 would be imposed upon all 35,300 practitioners,
4 regardless of whether they came through the board
5 certification pathway or the alternate pathway.
6 Somehow that got twisted around and converted back.
7 I think in the staff rewrite of our position, it was
8 not noticed.

9 So no, I think you will find if you
10 examine the record closely, the last time I believe we
11 even made a motion on this point that you might
12 consider going back to the November meeting and look
13 at the positions that we took, but I think that we had
14 a discussion about that and again recommended that
15 basically the core set of requirements that are not
16 common to radiation oncology training are the 12
17 cases.

18 And so it was recommended by the ACMUI
19 subcommittee that those be placed outside of the board
20 certification pathway as common requirements for both
21 alternate and board certification pathways so that at
22 least the radiation oncology certification covered the
23 didactic component.

24 VICE CHAIRMAN MALMUD: Dr. Eggli?

25 MEMBER EGGLI: I believe that the 12 cases

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1 is a common component, but I also believe that the
2 safe handling of unsealed sources is an uncommon
3 component and is not included in most therapy
4 residencies.

5 VICE CHAIRMAN MALMUD: I don't know what
6 the content of therapy residencies is. I can't
7 address the issue. Once again, I believe that we
8 should have this discussion with the two radiation
9 oncologists who are members of this Committee
10 available for their input.

11 MEMBER WILLIAMSON: I think that would be
12 wise. At least we have found out the staff's
13 perspective that basically if a motion is not made
14 that is more favorable to the radiation oncologist's
15 current status, they are basically going to be left
16 out in the cold on this issue.

17 And that group of practitioners, which is
18 able to provide the continuum of cancer care, is no
19 longer going to be able to prescribe that modality.
20 That would be a great loss to patients.

21 VICE CHAIRMAN MALMUD: You were addressing
22 a subcommittee. Who did that subcommittee consist of?

23 MEMBER WILLIAMSON: The subcommittee was
24 chaired by Dr. Vetter. It included myself, Ruth, Dr.
25 Diamond. Were you in it, Ralph? I can't recall.

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1 MEMBER LIETO: No.

2 VICE CHAIRMAN MALMUD: And Dr. Nag?

3 MEMBER WILLIAMSON: I am not sure if Dr.
4 Nag was.

5 VICE CHAIRMAN MALMUD: So you may wish to
6 --

7 MEMBER WILLIAMSON: Were you in it, Manny?

8 CHAIRMAN CERQUEIRA: No.

9 VICE CHAIRMAN MALMUD: You may wish to
10 have just a telephone conversation with that
11 subcommittee and get the consensus of that committee
12 transmitted to the ACMUI Committee. All right?

13 MEMBER WILLIAMSON: Will do.

14 VICE CHAIRMAN MALMUD: Thank you for
15 bringing it to the attention of the ACMUI, the entire
16 Committee.

17 I will turn the microphone back to Dr.
18 Cerqueira and to Angela Williamson.

19 CHAIRMAN CERQUEIRA: Actually, is
20 Donna-Beth Howe going to be doing proposed changes to
21 10 CFR Part 35? I guess we still have that up.

22 MR. ESSIG: May I offer while Donna-Beth
23 is setting up, if there are any matters of business
24 that the Committee wishes to pursue in the near term,
25 such as the one that involves the views of our two

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1 radiation oncologists, we want to pursue it as a
2 Committee, we have a 15-day lead time for noticing in
3 the Federal Register, 15 calendar days.

4 So that if we wanted to schedule something
5 now, we should be looking at a conference call about
6 three weeks hence to give us time to notice it
7 internally. That means go through the Office of the
8 Secretary, get it over to the Office of the Federal
9 Register, and allow for the 15-day time frame to be
10 met. So what is one thing that you may wish to think
11 about before we adjourn today? If we want to agree on
12 a date for a conference call, it is about three weeks
13 out.

14 CHAIRMAN CERQUEIRA: Now, Jeff, do you
15 know if Dr. Nag or Dr. Diamond were aware of this?

16 MEMBER WILLIAMSON: I think they were
17 aware. Yes, they definitely were aware.

18 CHAIRMAN CERQUEIRA: And the ACR is
19 obviously aware.

20 MEMBER WILLIAMSON: And the ACR is aware,
21 despite the fact they have said nothing.

22 MS. FAIROBENT: Dr. Cerqueira, there were
23 discussions throughout ASTRO with the oncologists.
24 Dr. Diamond and Dr. Nag are both aware of the issue.
25 This was also reflected in our comment letter that was

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1 signed by ACR, ASTRO, and others that was submitted to
2 NRC on the proposed rule.

3 CHAIRMAN CERQUEIRA: So I think the
4 appropriate course of action would be, Jeff, I think
5 if you could speak to the other two radiation
6 oncologists. And if they feel that it is a
7 sufficiently important issue, then we should try to
8 schedule a conference call.

9 MEMBER WILLIAMSON: I think one reason it
10 hasn't come up maybe as much as it should have is if
11 you read the current rule text, literally it looks
12 like it would allow radiation oncologists to continue
13 practicing just basically by board certification
14 alone, which was the situation, is the situation at
15 the present time and has been for many years now.

16 And there was a debate within the
17 community about how much this needed to be commented
18 on. I always felt it was a very high-risk situation
19 to let it hang on the interpretation of grammar and a
20 comma.

21 CHAIRMAN CERQUEIRA: I think Dr. Eggli's
22 point is that basically dealing with unsealed sources
23 is a unique experience which is not available to all
24 radiation oncologists. And the addition of the cases
25 would certainly strengthen up those requirements.

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1 Your subcommittee had that in some form.

2 MEMBER WILLIAMSON: We had that. And that
3 was recommended. And the rewrite, I believe, got
4 lost. Unfortunately, our subcommittee didn't review
5 the final draft closely enough.

6 CHAIRMAN CERQUEIRA: I think it will be
7 important to find it. And then certainly the
8 conference call after the input from the two radiation
9 oncologists and the minutes would be --

10 MEMBER WILLIAMSON: I believe if the
11 record is examined closely, the staff will find this
12 has been brought up at least at the last two or three
13 meetings by both Dr. Diamond and myself that we were
14 concerned that the subcommittee recommendations were
15 misrepresented.

16 CHAIRMAN CERQUEIRA: So, Tom, maybe if
17 somebody from staff could try to dig up that
18 information from the subcommittee, that would help
19 speed up the process.

20 Last comment?

21 MEMBER EGGLI: I think, as a very minimum,
22 it should be clear that current practitioners are not
23 excluded.

24 CHAIRMAN CERQUEIRA: Right.

25 MEMBER EGGLI: So that if there has to be

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1 a mechanism of accounting for people who are in
2 practice, they currently have the appropriate
3 experience at a very minimum.

4 CHAIRMAN CERQUEIRA: Good. I think that
5 is a good point.

6 Dr. Howe?

7 DR. HOWE: Yes. If you will remember back
8 to November's meeting, I brought ten issues that our
9 working group had identified as we were working on the
10 implementation of part 35 that I believe needed
11 rulemaking.

12 Since that time, we have identified some
13 additional issues. Some of them are relatively minor
14 changes to the rules. Others may be more involved.

15 The first part of the rule that I am going
16 to be addressing is 32.74, which is the part of the
17 rule that authorizes distribution of sealed sources
18 and devices by specific licensees to manufacture and
19 distribute these items to persons licensed pursuant to
20 part 35.

21 If you look at 32.74(a), you will find
22 that this is limited to use as a calibration or
23 reference source. That is going to be one issue. And
24 if you look after the ore, you will see it is for
25 medical uses listed under 400, 500, 600.

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1 The effect of this in mentioning
2 calibration or reference sources is that it
3 specifically excludes our transmission sources that
4 are now included in part 35, in 35.67 I believe. And
5 so we are recommending that the rule be changed in
6 32.74 to be for use as calibration, transmission, or
7 reference sources so that it parallels those sources
8 in 35.67.

9 MR. ESSIG: Dr. Howe, I am going to
10 interrupt just for a second. I am looking around the
11 room and not seeing --

12 DR. HOWE: What you have to --

13 MR. ESSIG: It was under a different tab.

14 DR. HOWE: Yes. It was under an earlier
15 tab.

16 MR. ESSIG: So it is under the
17 seedSelectron?

18 DR. HOWE: Yes or am I moving out of 1000?

19 MR. ESSIG: Or maybe out of 1000.

20 DR. HOWE: Yes.

21 MR. ESSIG: Yes. We are moving modalities
22 from 1000. It got misplaced.

23 DR. HOWE: That is where the slides are.
24 Okay? So the first item for this particular change
25 would be to add transmission.

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1 Yes, Ralph?

2 MEMBER LIETO: If I understand this right,
3 you are tieing it in to the 400, 500, and 600 uses,
4 correct?

5 DR. HOWE: No. If you read the part that
6 -- I don't have a pointer -- says, "Part 35 of this
7 chapter for use as a calibration or reference source,"
8 then there is an "or." The calibration or reference
9 sources are authorized under 35.67. So I am just
10 talking about the 35.67 uses right now.

11 CHAIRMAN CERQUEIRA: So the suggestion has
12 been made for a change. I mean, Jeff and Ralph, do
13 you see any problems with those changes?

14 MEMBER LIETO: I would definitely support
15 that.

16 CHAIRMAN CERQUEIRA: So do you want a vote
17 from the Committee on that? So is that a motion?

18 MEMBER LIETO: I would move for approval
19 of the change as suggested to section 32.74(a).

20 CHAIRMAN CERQUEIRA: A second on that?

21 MEMBER WILLIAMSON: (Raising hand.)

22 CHAIRMAN CERQUEIRA: Jeff? Okay. Second.
23 Any further discussion?

24 (No response.)

25 CHAIRMAN CERQUEIRA: Call the question.

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1 All in favor?

2 (Whereupon, there was a show of hands.)

3 CHAIRMAN CERQUEIRA: Opposed?

4 (No response.)

5 CHAIRMAN CERQUEIRA: Okay. Excellent. We
6 do have a quorum, by the way. I saw you.

7 DR. HOWE: You do have a quorum.

8 MEMBER EGGLI: What about calibration
9 sources that are used in other sections, like PET
10 calibration and transmission sources that really don't
11 fall under 400, 500, or 600?

12 MEMBER LIETO: That was my question she
13 just answered. If you notice, there is an "or."
14 Where it says, "400, 500, and 600," look at the line
15 above. It is restated to say, "Calibration,
16 reference, or transmission source or for the uses."
17 It would allow for gamma CAMs.

18 DR. HOWE: And this is specifically for
19 those byproduct material for persons licensed pursuant
20 to part 35. Okay?

21 CHAIRMAN CERQUEIRA: Good. Next?

22 DR. HOWE: The next, we are still looking
23 at the same part of the regulation, 32.74(a). Now we
24 are focusing after the "or." we are looking at for
25 the uses listed in 35.400 and 35.500, 35.600. The

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1 point here is the effect is that it specifically
2 excludes sealed sources and devices that are under
3 uses listed, 35.1000. And so we are recommending that
4 35.1000 be added to those.

5 This would only include those sealed
6 sources and devices that are under 35.1000. And
7 35.1000 had a radiopharmaceutical. It would not come
8 under 32.74 because it wouldn't be a sealed source
9 device. It would come under 32.72, which is where we
10 regulate radiopharmaceuticals and biologics and those
11 types of materials.

12 CHAIRMAN CERQUEIRA: Dr. Williamson?

13 MEMBER WILLIAMSON: I am a little confused
14 about the intent of this. These are sealed sources
15 actually used for intravascular treatment. They are
16 not calibration or reference sources associated with
17 it.

18 DR. HOWE: No. These are for the uses
19 listed under 400, 500, 600, or 1000. So these would
20 be your brachytherapy sources, --

21 MEMBER WILLIAMSON: I see.

22 DR. HOWE: -- your HDR units, your LDRs,
23 your GliaSites, your --

24 MEMBER WILLIAMSON: Okay.

25 CHAIRMAN CERQUEIRA: So, Jeff, you support

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1 that?

2 MEMBER WILLIAMSON: Yes.

3 CHAIRMAN CERQUEIRA: A motion to approve?

4 MEMBER WILLIAMSON: So moved.

5 MEMBER LIETO: Seconded.

6 CHAIRMAN CERQUEIRA: Discussion?

7 (No response.)

8 CHAIRMAN CERQUEIRA: Call the question.

9 All in favor?

10 (Whereupon, there was a chorus of
11 "ayes.")

12 CHAIRMAN CERQUEIRA: Opposed?

13 (No response.)

14 CHAIRMAN CERQUEIRA: Unanimous. Next
15 item?

16 DR. HOWE: Now we are going to move into
17 35. And I have got a number of proposed changes that
18 will address how we regulate and the information we
19 get from licensees under 35.1000.

20 35.12(d) addresses essentially how we
21 regulate 35.1000. And it was set up before we
22 actually implemented the rule. We believe at this
23 point that it doesn't accurately reflect what we are
24 doing.

25 First, it appears as if -- well, it is

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1 also 35.12(d)(1) that you have to meet the radiation
2 safety aspects not addressed in subparts A through C.
3 That seems to imply that the radiation safety aspects
4 are all addressed in A through C. I believe that it
5 is isn't clear that subpart M, which is your reporting
6 for medical events and embryo/fetus and nursing
7 infants also applies to 1000. So this is just to
8 clarify that.

9 We expect the 1000 users to comply with
10 subparts A through C and also the medical event and
11 the other reporting requirements. So it is just a
12 clarification. If you will let me continue, I will
13 show you proposed language afterwards.

14 There is a second element to 35(d). It
15 appears that, as I stated earlier, only the radiation
16 safety aspects are all found in subparts A through C.
17 What we are finding is that for some of these new
18 technologies, there are certain parts in A through C
19 that don't fit the new technologies.

20 We are also finding that most of our new
21 technologies fit almost exactly in subparts D, E, F,
22 G, H, which are the imaging localization, written
23 directives required, manual brachytherapy, remote
24 after-loaders, diagnostic devices. A through C are
25 the general categories in the regulation.

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1 MEMBER WILLIAMSON: So let me make sure I
2 understand what the problem is. The problem is that
3 the way one reads the current statement is that all of
4 the measures mentioned in A through C must apply. And
5 now what you want to do is introduce a fix that
6 somehow relieves the licensee of having to comply with
7 those provisions of A through C that don't have any
8 relevance to the 35.1000 modality under consideration?
9 I am sorry to be so dense here.

10 DR. HOWE: No. It's kind of the opposite.
11 There is an implication that A through C should apply
12 and apply without any changes. We are finding in some
13 of the emerging technologies that there are some parts
14 in A through C that don't apply to the emerging
15 technologies.

16 MEMBER WILLIAMSON: I thought that is what
17 I said.

18 DR. HOWE: It needs a revision to it. And
19 there is also in the supplemental information an
20 implication that the only information we need is the
21 things that are listed under (d)(1).

22 In fact, we are finding that some of the
23 written directive guidance needs to be modified for
24 the emerging technologies. We are also finding that
25 most of our emerging technologies fit almost exactly

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1 in the other categories.

2 And so what I am proposing is that we add
3 subpart M, in addition to A through C, and that we
4 also recommend --

5 MEMBER WILLIAMSON: What's subpart M? I'm
6 sorry.

7 DR. HOWE: Subpart M is the reporting for
8 medical events. Just to make it clear, that also
9 applies. The second part is that we revise 12(d) to
10 specifically include appropriate radiation safety
11 requirements in subparts D through H for a particular
12 1000 device. In the next slide, I will show you what
13 I think that particular revision would look like.

14 We would say in D, "In addition to the
15 requirements of paragraphs B and C, which is you must
16 submit an application and provide a description of the
17 facility and training experience, I believe, an
18 applicant for a license to amend the medical use of
19 1000 must include information regarding any radiation
20 safety aspects of the medical use of material that is
21 not addressed in subparts A through C and M of this
22 part. Commitments to follow radiation safety program
23 requirements in subpart D through H that are
24 appropriate to specific 35.1000 medical use." then we
25 would continue exactly the same wording as currently

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1 in the rule.

2 MEMBER WILLIAMSON: I think the original
3 way it is stated is so broad any radiation safety
4 aspects of the medical use of the material that is not
5 addressed is sort of --

6 DR. HOWE: It's too broad?

7 MEMBER WILLIAMSON: Even those that
8 haven't been imagined or mentioned anywhere in the
9 regulations I find this statement has always bothered
10 me.

11 DR. HOWE: Well, that was not the intent.
12 The intent was that if we have a specific element in
13 A through C and this one doesn't quite fit into how
14 that is described, there could be a modification to
15 somehow fit.

16 MEMBER WILLIAMSON: Somehow.

17 DR. HOLAHAN: I would like to add that if
18 you agree in concept, the wording will be --

19 DR. HOWE: It will be totally different.

20 DR. HOLAHAN: It may be because we will
21 come back to with the proposed rule at the time early
22 on in the process. And it may change.

23 DR. HOWE: And as you deliberate, you may
24 come to the conclusion later on that you don't believe
25 there is a change needed.

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1 CHAIRMAN CERQUEIRA: Ralph, you had a
2 comment?

3 MEMBER LIETO: Yes. I am a little unsure
4 as to what exactly is the intent to take something
5 that is currently listed in 1000 and state that it has
6 to meet all of the requirements of, say, subpart C
7 plus these things or is it to take it out of 1000 and
8 put it in subpart C with additional requirements?

9 DR. HOWE: Right now the basic radiation
10 safety program things, you need a radiation safety
11 officer, you need a written directive, you need a
12 program to ensure you are administering therapeutic.
13 All of that is in A through C, very general.

14 Those are general concepts. We aren't
15 going to go beyond what is there. But it may be that
16 this particular device doesn't fit the wording in this
17 particular part.

18 MEMBER SULEIMAN: I hear what you are
19 saying. And I read what you are intending. I agree
20 because it says, "any radiation safety aspects." It
21 is not saying, "other aspects." How can you
22 anticipate what may be unique about some new medical
23 device that maybe hasn't been addressed?

24 So I read this as sort of a catch-all to
25 some new emerging technology which has got some very

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1 unique characteristic that hasn't been addressed
2 specifically.

3 CHAIRMAN CERQUEIRA: Good.

4 MEMBER WILLIAMSON: Well, I agree some fix
5 is needed. Okay? The problems are there are aspects,
6 safety aspects, of the device which certainly aren't
7 captured in A through C and D through H and M that
8 need to be specifically mentioned, which you have done
9 in your guidance space. Okay. That is true.

10 There are also parts of these regulations
11 that may or may not apply in all of the sections A
12 through C, A through H, and M, though maybe the
13 general concepts are applicable.

14 I think, as I read it, though, it is very
15 confusing. And I think since you are planning to fix
16 it, if you could think of some way in more ordinary
17 language to express the intent so it is clear to
18 practitioners, for example, you may want to just
19 explicitly mention something to the effect that
20 radiation safety aspects, as mentioned by NRC in their
21 guidance for the appropriate device that aren't
22 mentioned in blah blah blah parts must be addressed in
23 the license application, somehow try to create
24 phraseology that connects more with what we perceive
25 to be the practical process for processing license

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1 amendments.

2 I think this is a very legalistically
3 written section that allows you the latitude to change
4 all of these things that perhaps according to the
5 Office of General Counsel, it is adequate. But as I
6 read it as an ordinary working individual, it seems
7 very obtuse what the intent is.

8 CHAIRMAN CERQUEIRA: So you have some
9 problems with the language, but you have no problems
10 with the addition of D through H and M as additional
11 requirements. Is that correct?

12 MEMBER WILLIAMSON: I just wish the whole
13 section were written in a more clear and concise form.

14 CHAIRMAN CERQUEIRA: Right. But I just
15 think given the lateness, I am just not certain it is
16 in our best interest.

17 MEMBER WILLIAMSON: No. I am making the
18 recommendation that the whole section be rewritten,
19 this whole paragraph be rewritten from top to bottom
20 to make the intention clearer.

21 DR. HOWE: But potentially we look at
22 35.12(d) and we make revisions, maybe not these
23 particular revisions, but we make revisions to more
24 accurately reflect --

25 MEMBER WILLIAMSON: You know, you are

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1 giving yourself the authority to exempt individuals
2 from specific 35 rule requirements, which aren't
3 applicable or meaningful for the new emerging
4 technology. Plus, you are leaving yourself the
5 authority to impose new ones via the licensing
6 process.

7 I agree. That is good to state, and it is
8 good to capture these other sections in here. I just
9 think if you could find a clearer way of describing
10 this --

11 CHAIRMAN CERQUEIRA: So are you making a
12 motion to approve the addition of D through H and M to
13 the new language that she is going to construct?

14 MEMBER WILLIAMSON: Subject to making the
15 intent of the paragraph clearer.

16 CHAIRMAN CERQUEIRA: Okay. Ralph, more
17 discussion?

18 DR. MILLER: Dr. Cerqueira, with regard to
19 motions, I just want to throw this out just to let you
20 know where are. Donna-Beth's presentation today I
21 think throws out some concepts to get a temperature
22 from the Committee. Okay? Anything we put out, what
23 she is trying to do is to articulate that by taking a
24 shot at what the language might be in a proposed
25 rulemaking.

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1 Anything that comes out of this I've got
2 to take back and prioritize all of the other
3 rulemakings that we have on the table. So where it
4 would come out priority-wise would be dependent upon
5 safety significance of the changes.

6 Given the lateness of the hour, I think we
7 need to get some feedback from you with the concepts.
8 Are we on the right track? Should we pursue this?
9 Should she pursue this? Do you agree with pursuing
10 this?

11 And then we would go to the rulemaking
12 branch and get it prioritized and go from there. How
13 soon that would be done would be dependent upon what
14 the priority would be.

15 Scott, did I say that right?

16 MR. MOORE: Yes, sir. Donna-Beth's slides
17 labeled "Potential Rulemaking" are just that. I am
18 throwing these out conceptually. We have what we
19 would call internally to the agency a user need memo
20 from Tom Essig's branch to my branch requesting
21 rulemaking on this. And that initiates the action.

22 CHAIRMAN CERQUEIRA: I understand. We are
23 just trying to give you feedback.

24 MR. MOORE: Right.

25 CHAIRMAN CERQUEIRA: Taking a vote

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1 sometimes I think just does force the Committee to
2 focus. I don't think there were any objections to
3 adding D through H and N. There were some concerns
4 about the specific language.

5 MR. MOORE: On this, what would help us is
6 a sense of where you are conceptually on the ideas.
7 And then with respect to the specific language on
8 these, we can certainly work it.

9 It is nowhere near proposed rule stage.
10 And priority-wise, it will probably rank out somewhere
11 in the medium to lower priority as a rule, probably
12 behind some of our security-related rulemakings.

13 CHAIRMAN CERQUEIRA: So have you got
14 enough feedback on this issue that you don't want us
15 to vote on it? I think everybody was in agreement.

16 MR. MOORE: I think that is up to you all,
17 but it sounds to me like conceptually you support the
18 idea. It sounds like you would like us to work on the
19 exact wording, especially any radiation safety
20 aspects, yes.

21 CHAIRMAN CERQUEIRA: Okay. That's good.
22 So, then, do you want to go to 35.41?

23 DR. HOWE: Yes. 35.41 is the requirement
24 for programs to assure that things that require a
25 written directive are administered in accordance with

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1 the written directive.

2 If you look at B, this says, "As a
3 minimum, you will have procedures required in A for
4 the following things." When you get down to 4, it
5 says that "You will have a procedure verifying that
6 any computer-generated dose calculations are correctly
7 transferred into the consoles for therapeutic medical
8 units authorized in 35.600."

9 I believe at this time that it should be
10 35.600 or 35.1000 so that if you have a therapeutic
11 medical unit and you have data being transferred into
12 the console, that you do need this, regardless of
13 where it is coming in the regulation.

14 CHAIRMAN CERQUEIRA: Jeff, do you have any
15 problems?

16 MEMBER WILLIAMSON: No.

17 CHAIRMAN CERQUEIRA: Any other comments?
18 (No response.)

19 CHAIRMAN CERQUEIRA: I mean, we are just
20 basically adding the 1000. And I think that is
21 certainly appropriate, emerging technologies. Okay.
22 35.610(d).

23 DR. HOWE: Do you want to go back, Ralph?

24 MEMBER LIETO: Well, I am trying to think
25 of where we might run into a problem. Are we

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1 concerned about 35.1000 applications involving
2 therapeutic treatments?

3 DR. HOWE: It only involves transferring.
4 You have got computer-generated dose calculations and
5 having them directly transferred into consoles of
6 therapeutic medical units.

7 So it is not all of 1000. It is just
8 those therapeutic ones with the computer-generated --

9 MEMBER LIETO: My concern was if, say, for
10 example, they were going to get into doing treatment
11 planning calculations for radiopharmaceuticals. And
12 you would have to do the same thing. I am just going
13 to be worrying about something that is really not an
14 issue right now, but this is potential.

15 CHAIRMAN CERQUEIRA: All right. Next?

16 DR. HOWE: So is everybody agreed on that
17 one?

18 CHAIRMAN CERQUEIRA: Yes.

19 DR. HOWE: The next issue is 35.610(d).
20 That is where a licensee is required to provide
21 instruction initially and at least annually. And then
22 it goes on to describe who it has to be given to and
23 people that use therapy units.

24 This is specifically for remote
25 after-loader units, gamma knife, and teletherapy

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1 units. We find that it is confusing to certain people
2 about the initial training. We think that there are
3 several different meanings to initial training. There
4 can be initial training when you get a brand new
5 device into a facility in which the initial training
6 should be provided by the vendor.

7 And then there is initial training when
8 you have an established program and you are bringing
9 a new person in. That initial training could be done
10 by the licensee. So what we are recommending is that
11 we add a new section to address vendor training and
12 distinguish it from the training a licensee provides,
13 initial training, and make that difference based upon
14 the licensee's experience with the unit; i.e., new
15 units or units with significant manufacturer
16 upgrading.

17 And so this would be an example of
18 recommended rule language, where we say "Vendor
19 training would be provided for all operators of a new
20 therapy unit or therapy unit" -- yes, Jim?

21 CHAIRMAN CERQUEIRA: Jeff?

22 MEMBER WILLIAMSON: Yes. I am trying to
23 think. In the 35.600, it doesn't specify what
24 training the vendor has to provide versus what the
25 licensee can provide without the vendor's support. Is

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1 that correct?

2 DR. HOWE: It doesn't address vendor at
3 all.

4 MEMBER WILLIAMSON: So my question is
5 right now it is left at the discretion and
6 responsibility of the licensee. So is that you
7 consider the current regulation inadequate now that it
8 is sort of left to the licensee based on their
9 judgment if an upgrade, for example, is significant
10 enough or they buy a new system, that they will get
11 the vendor training or not or make some other
12 arrangements that are suitable to themselves?

13 Right now it is a very nice, not very
14 prescriptive rule that allows the users a fair amount
15 of flexibility in determining what source they access
16 for the training. Do you really feel it is such a
17 problem that a more prescriptive rule identifying
18 exactly when the vendor has to be involved is
19 necessary?

20 DR. HOWE: We do believe for therapy
21 devices that are new, new technology, new therapy
22 devices, that vendor training is essential because the
23 vendor is really the only one that has the experience
24 with the unit at this particular time.

25 On certain new significant modifications

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1 to therapy devices, again, the vendor is the one with
2 the experience on what it is doing. We have actually
3 had a misadministration where the vendor was going to
4 provide training but didn't provide training before
5 first patient use and they didn't understand exactly
6 the new changes in the device from the preceding one.

7 MEMBER WILLIAMSON: Well, I guess I am
8 wondering. You now have a performance-based rule. If
9 you want to put more detail and complexity into it to
10 specify exactly when the vendor has to be involved,
11 why not leave it as a performance-based rule?

12 Okay. So there is one anecdotal
13 experience of where a licensee could perhaps have
14 benefitted from this, but in general, my perception
15 would be licensees are making good decisions when to
16 involve the vendors and when to make the changes
17 themselves. In the training and experience criteria,
18 there is now a role for the vendor in providing
19 experience for the authorized personages, the
20 physicist and the authorized user for 35.600.

21 I guess I am questioning the necessity of
22 this.

23 CHAIRMAN CERQUEIRA: Have there been
24 problems or are you just anticipating?

25 DR. HOWE: Yes, there have been problems

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1 and not only that, but one of the major differences in
2 new technologies and some of the older technologies is
3 that we do require vendor training in the guidance
4 because those are the people who have the experience.

5 CHAIRMAN CERQUEIRA: Right.

6 DR. HOWE: Moving it into the regulation
7 may make some of the new technologies less foreign to
8 the regulations. And we would already have vendor
9 training for the new devices.

10 CHAIRMAN CERQUEIRA: Yes. Ralph, you had
11 a comment?

12 MEMBER LIETO: I keep reading this, trying
13 to understand the exact issue that we are trying to
14 address in a long-term basis so that we are not just
15 trying to address this one incident that occurred.

16 I guess maybe if we change this to maybe
17 "vendor-authorized" because I am not necessarily
18 absolutely positive that you might not have the
19 licensee, an individual with a licensee or another
20 licensee that might come and provide that that is not
21 the vendor but maybe the vendor-authorized individual.
22 That is I think some fine tweaking here.

23 DR. HOWE: We kind of covered that.

24 MEMBER LIETO: Look for that. So that was
25 pretty much my --

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1 MEMBER WILLIAMSON: I think it is very
2 difficult.

3 CHAIRMAN CERQUEIRA: We have another
4 comment.

5 MEMBER SULEIMAN: I will keep it short,
6 but I think it does happen. I think, no matter how
7 new the technology or how familiar the users think
8 they are with the modified version of the new
9 technology, if you don't require it or mandate it,
10 there will be situations where it may be used before
11 it should be.

12 And so I think this is just sort of
13 putting it down as a regulatory requirement that thou
14 shalt not start using this unless you have proper
15 instruction.

16 By taking it out, somebody is going to
17 say, "Well, it wasn't required." I can give you some
18 examples, but it is human nature. They will feel
19 comfortable. They will think they know what to do,
20 and it will be used improperly.

21 CHAIRMAN CERQUEIRA: Jeff, do you have a
22 last comment?

23 MEMBER WILLIAMSON: Yes. I guess in the
24 spirit of performance-based regulation, I am opposed
25 to changing it from the relatively broad way it is

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1 written, which leaves a fair amount of discretion and
2 responsibility for the user to appropriately involve
3 the vendor.

4 I am thinking of situations where it is
5 very difficult to get 12 radiation oncologists or
6 physicists together at one time to have the vendor
7 give the training. I think that perhaps by safety as
8 not being marginalized in any way, for example, the
9 majority of individuals who operate the system get
10 vendor training. And then the physicist or lead
11 authorized user is able to sort of train as new
12 individuals on the new device others who follow. You
13 just create I think somewhat of a burden on everybody
14 for what I am going to speculate is a fairly small
15 number of incidents.

16 DR. HOWE: Now, we are not addressing the
17 "and others follow" because the "and others follow" is
18 in part 2. In other words, the licensee now has
19 experience with the unit. It is not new. It hasn't
20 had any major revisions. So that is the licensee.

21 MEMBER WILLIAMSON: But you have in number
22 one, "all operators." So that means if you miss one,
23 if one is sick that day on the one time the vendor can
24 come, you have created an incident now where the whole
25 operation is out of compliance because one operator

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1 was not here.

2 MEMBER SULEIMAN: I hear you. I think the
3 NRC staff should just make note of that and maybe
4 consider that.

5 CHAIRMAN CERQUEIRA: Doug and then Leon?
6 Do you have any comments?

7 DR. HOWE: So it may be more on wording.

8 MEMBER EGGLI: In support of Jeff's
9 comment, in new technology, train the trainer is a
10 very common vendor approach, where the vendor will
11 come out and train two or three people extensively for
12 a two or three-week period. And then those same two
13 or three people train everybody else in the
14 institution on that new piece of equipment.

15 It may be appropriate to have initial
16 vendor training of some portion of the staff, but it
17 is virtually impossible to get the vendor to train 100
18 percent of the staff. I am in support of Jeff'
19 comment.

20 MEMBER WILLIAMSON: Yes. And if you think
21 about the kind of training that is required for gamma
22 knife, it is very extensive and expensive. And if you
23 think about the sort of one or two-hour sessions the
24 vendor has, they are useful, but it is by no means a
25 replacement for licensee-initiated training and

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1 testing and observation of workers. So it is really
2 missed.

3 DR. HOWE: And I recognize the limitations
4 on putting all operators in there. We just really
5 would like to have vendor training provided at the
6 licensee's facility.

7 And then we generally have no problem as
8 a policy for vendor-trained individuals training
9 others. We do have policy problems when we get to the
10 other people who are three or four generations down
11 providing training on something new.

12 CHAIRMAN CERQUEIRA: I think you have
13 heard some of the concerns. It is difficult to get
14 everybody there. Ralph?

15 MEMBER LIETO: I don't interpret it that
16 they all have to be there at that time. It is just
17 that it has to be provided to them before they operate
18 the device. So if they are not there that first
19 whatever, then what I am interpreting is the vendor
20 has got to come back and get these others or, as it
21 says there, individuals certified by the device
22 manufacturer. He may train 20 people, and then he
23 certifies one of those people and they train the
24 others.

25 So, I mean, I guess basically I endorse

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1 it. And I think the wording can be massaged to
2 achieve I think Jeff's concerns.

3 CHAIRMAN CERQUEIRA: Good. All right.
4 Next?

5 DR. HOWE: As you know, we added a section
6 to each emerging technology up on the Web site that
7 allowed individuals that had authorization for the
8 35.1000 use that if the Web site guidance changed,
9 they could change their radiation safety program to be
10 in conformance with the new Web site guidance without
11 coming in for an amendment. They had to have approval
12 for that, essentially, in the tie-down condition of
13 the license.

14 The next step is to move this into the
15 regulations, make it clear that anybody with a 1000
16 use can revise their radiation safety program to
17 conform with the guidance as the guidance is being
18 updated without needing an amendment.

19 So this would involve revising 35.26 to
20 permit changes based on current 1000 guidance. And
21 this would probably look like this. The revision is
22 compliance with the license or is based on current
23 guidance for the 35.1000 medical use posted on the NRC
24 Web site. Once again, the wording is just a straw man
25 on there.

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1 DR. HOLAHAN: And I would like to add we
2 have to look at that seriously because I don't know if
3 it can be done because of guidance being changed. So
4 it is making our guidance into a requirement.

5 DR. HOWE: But what it does is the first
6 question came up because of intravascular
7 brachytherapy. Intravascular brachytherapy before it
8 moved into 1000, it was done by license condition. At
9 that point, we required the authorized user, the
10 cardiologist and the medical physicist, to be
11 physically present. Those were license conditions.
12 The licensee had to come in for amendments.

13 Now, under 1000, we no longer require all
14 three people to be physically present. So generally
15 as we relax the guidance, this allows licensees to
16 also relax their program to meet it without having to
17 ask for an amendment.

18 CHAIRMAN CERQUEIRA: Jeff?

19 MEMBER WILLIAMSON: Well, I think is very
20 clearly written and indicates the dynamic role of the
21 Web site and guidance. So if it could be legally done
22 this way to allow some sort of dynamic character to
23 the regulations, I am all for it.

24 I think this if it, again, passes muster
25 with your Office of General Counsel might indicate a

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1 model you could use to rewrite the earlier section
2 that I objected to, which mentions specifically the
3 role of the guidance Web site in indicating which
4 sections or provisions of A through H are to be
5 abrogated or to be enhanced in light of the specific
6 features of the new modality.

7 So I think if it is possible, this is
8 good. It is very clear. It relates in an obvious way
9 to the process. And everybody can understand it.

10 CHAIRMAN CERQUEIRA: Any other comments?
11 Usually if Jeff likes it, then --

12 (No response.)

13 CHAIRMAN CERQUEIRA: Okay. The last item,
14 35.2026?

15 DR. HOWE: And in 35.26, there was a
16 requirement to keep records of the change. And so
17 this is a conforming change to 35.2026, where
18 originally it asks that you keep a copy of the old and
19 new procedures in the effective date of the change.

20 And we would recommend that you would also
21 keep a copy of the appropriate 35.1000 medical use Web
22 site guidance that you were making your change based
23 on.

24 CHAIRMAN CERQUEIRA: It sounds
25 straightforward.

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1 DR. HOWE: And I think that is the end,
2 isn't it? Yes.

3 MEMBER SULEIMAN: Why five years?

4 DR. HOWE: Five years is the current I
5 think inspection frequency for most medical use
6 licensees. And that is in the current regulations.

7 Thank you very much.

8 VICE CHAIRMAN MALMUD: Thank you, Dr.
9 Howe.

10 NEXT MEETING DATE, AGENDA TOPICS, MEETING SUMMARY

11 VICE CHAIRMAN MALMUD: Can we schedule our
12 next meeting now?

13 MR. ESSIG: The piece of paper that you
14 were handed has ACRS and ACNW meetings on it. The
15 purpose in handing this out -- and we didn't have time
16 to explain it at the time -- this just shows you when
17 the room that we prefer to meet in, T2B3, is occupied;
18 that is, it is spoken for by either the ACRS or the
19 ACNW. And so, as you can see, September 8 through 11,
20 October 7 through 9, November 3rd through 6.

21 So if we meet in the latter half of
22 October I would think would be a good time because the
23 room would not appear to be spoken for in that time.
24 The ACNW is meeting in October, but they are meeting
25 in Las Vegas. So I would say any time after, say, mid

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1 October.

2 VICE CHAIRMAN MALMUD: Mid October?

3 MR. ESSIG: Yes.

4 VICE CHAIRMAN MALMUD: Which days of the
5 week?

6 MR. ESSIG: Probably Tuesday, Wednesday
7 seems to --

8 VICE CHAIRMAN MALMUD: Monday, October
9 11th is Columbus Day.

10 MEMBER WILLIAMSON: When is ASTRO? It is
11 always in October.

12 VICE CHAIRMAN MALMUD: I don't know.

13 MEMBER WILLIAMSON: I don't know either.

14 VICE CHAIRMAN MALMUD: October 12th and
15 13th good?

16 MEMBER WILLIAMSON: I don't know.

17 VICE CHAIRMAN MALMUD: Shall we not set
18 the date today?

19 CHAIRMAN CERQUEIRA: Is the 11th a
20 holiday? People tried not to travel.

21 MR. ESSIG: Yes. It is Columbus Day.

22 VICE CHAIRMAN MALMUD: The 11th is
23 Columbus Day.

24 MS. WILLIAMSON: If at all possible, let's
25 schedule it now because we don't know what is going to

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1 come up in the future. And we might just have to wind
2 up taking what we can get later.

3 VICE CHAIRMAN MALMUD: Then why don't we
4 try for the 12th and 13th of October,
5 Tuesday-Wednesday?

6 MR. ESSIG: Or maybe Wednesday-Thursday.

7 VICE CHAIRMAN MALMUD: Oh, I see.
8 Wednesday-Thursday, 13-14. Is that all right?

9 DR. HOLAHAN: And can you find out the
10 dates of the ASTRO meeting and get back to Angela or
11 Jeff?

12 MEMBER WILLIAMSON: Yes.

13 VICE CHAIRMAN MALMUD: So make it
14 Wednesday and Thursday, October 13th and 14th?

15 MR. ESSIG: And do we also want to pick a
16 date for, call it, a mid-cycle conference call?

17 VICE CHAIRMAN MALMUD: Yes.

18 MR. ESSIG: And that would be halfway
19 between now and October, so say about three months
20 out, four months out?

21 VICE CHAIRMAN MALMUD: Well, summer is a
22 problem.

23 CHAIRMAN CERQUEIRA: Towards the end of
24 May.

25 VICE CHAIRMAN MALMUD: End of May? All

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1 right.

2 CHAIRMAN CERQUEIRA: Or June.

3 VICE CHAIRMAN MALMUD: What about June?
4 Early June?

5 CHAIRMAN CERQUEIRA: It's just a
6 conference call. It's a conference call. It's not a
7 meeting.

8 MR. ESSIG: Yes, just an hour or two
9 conference call.

10 VICE CHAIRMAN MALMUD: What about
11 Wednesday, June 16th?

12 MEMBER EGGLI: That is the last day of
13 SNM. If you could make it Thursday?

14 VICE CHAIRMAN MALMUD: Thursday, June
15 17th?

16 MEMBER EGGLI: That would be after SNM.

17 VICE CHAIRMAN MALMUD: Okay. Yes. A
18 conference call. And that would be --

19 MR. ESSIG: You should probably schedule
20 it for the afternoon to --

21 VICE CHAIRMAN MALMUD: Afternoon.

22 MR. ESSIG: -- accommodate those that are
23 in the Pacific time zone.

24 VICE CHAIRMAN MALMUD: Great.

25 CHAIRMAN CERQUEIRA: What day are we

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1 considering?

2 VICE CHAIRMAN MALMUD: Thursday, June 17
3 at 1:00 Daylight Saving Time in the East.

4 DR. HOLAHAN: Excuse me? Dr. Malmud?

5 VICE CHAIRMAN MALMUD: Yes?

6 DR. HOLAHAN: May would work better if you
7 want to talk about the final rule going out because it
8 is planning on coming out approximately the end of
9 April. So that would give you time, a couple of
10 weeks, to look at it. So I would look at meeting
11 sometime in mid to late May.

12 MEMBER WILLIAMSON: That is a reasonable
13 situation under the circumstances, mid to late May.

14 MR. MOORE: I commented that the next
15 opportunity for comment on the draft final rule would
16 be when we issued to you in the agreement states in
17 draft final form for 30-day comment. We are
18 projecting that that will happen on April 26
19 approximately.

20 VICE CHAIRMAN MALMUD: So this should be
21 after that?

22 MR. MOORE: In between April 26 and
23 approximately May 26.

24 VICE CHAIRMAN MALMUD: How about Thursday,
25 May 20th in the p.m.? Thursday, May 20th? Thursday,

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1 May 20th, any objection?

2 CHAIRMAN CERQUEIRA: Staff should probably
3 send out notices on this so people can check their
4 calendars, talk to their spouses, too.

5 MEMBER WILLIAMSON: How about the 13th of
6 May, then?

7 VICE CHAIRMAN MALMUD: The 13th of May?
8 Is that better for everyone? Thursday, the 13th of
9 May, 1:00 p.m.?

10 DR. MILLER: Would that give you
11 sufficient time if you get the packages around the
12 beginning of May to be able to digest them?

13 MEMBER LIETO: Or you could use one as a
14 primary and the other as an alternate.

15 VICE CHAIRMAN MALMUD: May 13th is the
16 date. The 20th is the alternate.

17 MEMBER WILLIAMSON: So 1:00 p.m. Eastern?

18 VICE CHAIRMAN MALMUD: 1:00 p.m. Eastern
19 Daylight Time, which will allow us to bring in our
20 brethren in from the West Coast. Thank you.

21 MR. MOORE: Thank you.

22 MR. ESSIG: And is there a need to have a
23 notice to conference call within the next three weeks?

24 MEMBER WILLIAMSON: I think it is
25 possible.

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1 MR. ESSIG: Because we can go ahead and
2 schedule it and then cancel it if need be. If you
3 want to meet within the next three weeks, we should
4 take the action now, start the action tomorrow.

5 VICE CHAIRMAN MALMUD: That would be --

6 MR. ESSIG: If you want to do it on a
7 Thursday, that would be Thursday the what, 18th?

8 VICE CHAIRMAN MALMUD: Thursday.

9 MR. ESSIG: No. That is two weeks out.
10 Better make it whatever the Thursday is after.
11 Thursday, the 25th?

12 VICE CHAIRMAN MALMUD: I will be away.
13 March.

14 MEMBER EGGLI: I will also be away that
15 week.

16 MEMBER WILLIAMSON: March 25th I will be
17 away, too.

18 MR. ESSIG: You'll be away, too? Okay.
19 Well, that is not a good week, then.

20 VICE CHAIRMAN MALMUD: What about Tuesday?

21 MEMBER WILLIAMSON: Monday-Tuesday I will
22 be here.

23 VICE CHAIRMAN MALMUD: Tuesday afternoon,
24 the 23rd of March?

25 MEMBER WILLIAMSON: Yes. I think that

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1 could work.

2 MEMBER EGGLI: Is that the last week of
3 March?

4 VICE CHAIRMAN MALMUD: No. That is a
5 conference call Tuesday, the 23rd of March at 1:00
6 p.m.

7 MEMBER WILLIAMSON: I am leaving at 3:00
8 p.m. on a flight. I could do it earlier in the day,
9 but I can't do it at 1:00 o'clock.

10 MR. ESSIG: Is Monday okay?

11 MEMBER WILLIAMSON: Monday is okay.

12 VICE CHAIRMAN MALMUD: Monday afternoon?

13 MEMBER WILLIAMSON: Monday is okay.

14 VICE CHAIRMAN MALMUD: Monday afternoon,
15 March 22nd at 1:00 p.m.

16 MR. ESSIG: Okay. And what would we like
17 to have on the agenda so that we can put something in
18 the Federal Register?

19 MEMBER WILLIAMSON: I guess training and
20 experience for 35.300.

21 DR. HOLAHAN: And do you need to make sure
22 that the radiation oncologists are available?

23 MEMBER WILLIAMSON: Yes, yes. Good point

24 VICE CHAIRMAN MALMUD: And what about,
25 will we have any follow-up, then, on the issue at the

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1 hospital in Michigan?

2 DR. MILLER: Yes. You're going to need to
3 have a conference call to formulate the Committee's
4 view based on the subcommittee report in dose
5 reconstruction.

6 VICE CHAIRMAN MALMUD: Right, right. Is
7 that okay for you, Jeff, since you will have the dose
8 reconstruction task?

9 MEMBER WILLIAMSON: Is what all right with
10 me?

11 VICE CHAIRMAN MALMUD: That date, Monday,
12 the 22nd, to discuss it.

13 MEMBER WILLIAMSON: Oh, in addition to
14 this other item?

15 VICE CHAIRMAN MALMUD: Yes.

16 MEMBER WILLIAMSON: Yes, I guess. That
17 depends what information we have, I guess.

18 MEMBER LIETO: Give a status report?

19 MEMBER WILLIAMSON: We could certainly
20 give a status report at the very least.

21 MR. ESSIG: Jeff, the only other
22 information that I am aware of currently that you
23 haven't been already given would be results from any
24 insights from any interviews with the daughter. That
25 is all there is available.

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1 MEMBER WILLIAMSON: I think that is
2 correct. Also, if we would hear the factual testimony
3 of Ralph as well, I think, would be useful, what he
4 may be able to tell us.

5 VICE CHAIRMAN MALMUD: Do you have the
6 data that you need to evaluate, Jeff?

7 MR. ESSIG: Yes. I can get the data.

8 VICE CHAIRMAN MALMUD: Do you have the
9 data that you need to evaluate the dosimetry
10 calculations and the letter from Dr. Marcus and Dr.
11 Siegel?

12 MEMBER WILLIAMSON: Do I have the data
13 that I need? I mean, there is no data now. There is
14 an inspection report with the result. And there are
15 some arithmetic calculations and assumptions. And
16 there is the report by Marcus, et al., which raises
17 some general criticisms but is not much more
18 information. Right now there is no basis.

19 CHAIRMAN CERQUEIRA: I guess the only
20 other issue related to that is I think Dr. Malmud
21 mentioned that Ralph may be included on that
22 subcommittee, which is fine, but I think his
23 involvement by being employed at the hospital needs to
24 be sort of kept in mind and considered.

25 What is the feeling of the Committee and

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1 staff? Should he be on it? Should he not be on it?

2 MR. ESSIG: I believe my recommendation
3 would be that you not have him officially on the
4 Committee but that you could use him as a source of
5 factual information. He cannot participate in any
6 decision-making or any recommendations.

7 MEMBER WILLIAMSON: That was my request,
8 that we just be allowed to interview him and find out
9 what he knows.

10 MR. ESSIG: Certainly there is no problem
11 with that.

12 MEMBER LIETO: I could work on that task,
13 too, some part of it, with Dr. Malmud in terms of the
14 future recommendations.

15 MR. ESSIG: Sure, sure, no problem with
16 that.

17 CHAIRMAN CERQUEIRA: Thank you. The
18 meeting is now adjourned. Thank you.

19 (Whereupon, at 5:08 p.m., the foregoing
20 matter was adjourned.)
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