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Isotopes: OPEN SESSION

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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION
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4 MEETING
5 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
6 (ACMUI)
7 + + + + +
8 OPEN SESSION
9 + + + + +
10 THURSDAY
11 OCTOBER 14, 2004
12 + + + + +
13 ROCKVILLE, MARYLAND

14 + + + + +

15 The meeting came to order at 8:00 a.m. in
16 Room T-2B3 of Two White Flint North, Leon S. Malmud,
17 M.D., Chair, presiding.

18 COMMITTEE MEMBERS:

19	LEON S. MALMUD	Chairman
20	EDGAR D. BAILEY	Member
21	DAVID DIAMOND, M.D.	Member
22	DOUGLAS F. EGGLI, M.D.	Member
23	RALPH P. LIETO	Member
24	SUBIR NAG, M.D.	Member
25	SALLY W. SCHWARZ, RPh	Member

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1 COMMITTEE MEMBERS: (CONT.)

2 ORHAN H. SULEIMAN, Ph.D. Member

3 WILLIAM VAN DECKER, M.D. Member

4 RICHARD J. VETTER, Ph.D. Member

5 JEFFREY WILLIAMSON, Ph.D. Member

6 NRC STAFF PRESENT:

7 THOMAS H. ESSIG Designated

8 Federal Official

9 Linda M. Gersey NMSS/IMNS

10 Patricia K. Holahan, Ph.D. NMSS/IMNS

11 Merri Horn NMSS/IMNS

12 John Jankovich NMSS/IMNS

13 Charles L. Miller Ph.D. NMSS/IMNS

14 John Szabo, Esq. OGC

15 Sami Sherbini, Ph.D. NMSS/IMNS

16 Sandra Wastler NMSS/IMNS

17 Angela R. McIntosh NMSS/IMNS

18 Ronald E. Zelac, Ph.D. NMSS/IMNS

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P R O C E E D I N G S

(8:05 a.m.)

CHAIRMAN MALMUD: Good morning, ladies and gentlemen. We would like to get started so that we complete today's full agenda on time. There'll be a slight change in the program, and Mr. Essig will begin first with some administrative issues. Tom.

MR. ESSIG: Just a couple of follow-up items from yesterday. One is, there was a question asked on the ACMUI Member Handbook, and I believe it was Ralph Lieto that had asked the question about special government employees. We touched base with John Szabo from our Office of General Counsel, and his response is as follows; as to the member's question, ACMUI members are considered special government employees throughout their tenure and are subject to federal laws and regulations for special government employees. And then he goes on to say, which is, I believe, what you thought was the answer anyway, so we should clarify the handbook so that it just doesn't read only when you're attending meetings and that sort of thing. It's during the term of your appointment to the committee.

And then he goes on to say what is relevant is that when they are not performing services

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1 for the ACMUI, the member should not use their ACMUI
2 title or membership for any non-NRC purpose, unless
3 authorized; such as, using your ACMUI position to
4 benefit others. That was his response, and hopefully
5 that clarifies that matter. But I believe -- my
6 thought was we kind of suspected that was going to be
7 his response anyway, but this clarifies the issue.

8 A second administrative matter was
9 yesterday when we were talking about the nuclear
10 materials events database, and I believe Mr. Lieto
11 asked the broader question about searching of the
12 database and looking at these -- event information
13 that wouldn't strictly be a medical event, but it
14 would be something that had a clear connection to a
15 medical event; such as, a leaking radiopharmaceutical
16 package and that sort of thing.

17 My response would be yes, that would be
18 worthy of also looking at those events. I would
19 remind the members that they all have access to NMED,
20 and I sensed from the discussion yesterday that if Mr.
21 Lieto, and perhaps others, would be interested in
22 doing some systematic searches of NMED to ferret out
23 information of that type - namely, maybe a
24 transportation event or a leaking package and what
25 might be the trends there, I think that information

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1 would be certainly valuable.

2 I have two of my staff here in the
3 audience, Michelle Burgess - if Michelle would wave
4 her hand. She is in the blue over there on the left.
5 She is the NMED Project Manager, and any questions
6 that any of the members would have about either access
7 or how do I navigate once I get in NMED, she would be
8 happy to sit down with you on the telephone and walk
9 you through NMED. Her extension is 5868, so that
10 would be (301) 415-5868. And also, another member of
11 my staff who is knowledgeable in NMED is Ivelisse
12 Cabrera. Ivelisse, if you'd raise your hand. She's
13 sitting next to Michelle, and her extension is 8152.
14 And so either one would be available to help any of
15 the members navigate through NMED.

16 I think we might even consider, Mr.
17 Chairman, if you're agreeable, that since Mr. Lieto
18 expressed an interest in NMED, if he might want to do
19 some sort of pilot searches, if you will, and use that
20 as maybe feedback to the committee, and it might help
21 structure some of the committee's review of the
22 medical events to looking at some of these related
23 events, and then maybe even looking at the medical
24 events that were included in your package. So with
25 your okay, I would suggest Mr. Lieto being --

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1 CHAIRMAN MALMUD: If he has some time --

2 MR. ESSIG: I sensed the okay was already
3 given yesterday when he broached the subject, but I
4 didn't want to be too presumptuous.

5 And it seemed like there was a third
6 matter, but it will occur to me later, so I think that
7 takes care of the administrative items that I wanted.
8 I'm sorry. Charlie has one.

9 MR. MILLER: Yes. I had the occasion to
10 talk to Szabo this morning also. I ran into him, and
11 I specifically focused on the question that was raised
12 by you, Dave, concerning the travel. I think Tom's
13 answer with regard to the periods, during your whole
14 appointment period you're governed by that 24/7. He
15 said he doesn't necessarily agree with the law, but
16 we're bound to uphold it. So again, if you have any
17 questions, feel free at any time to give any of us a
18 call, or John Szabo directly. He's more than willing
19 always to answer any kinds of calls of that nature.

20 CHAIRMAN MALMUD: Thank you. And the next
21 item on the agenda is the presentation of the final
22 draft 10 CFR 35 T&E by Dr. Broseus.

23 DR. BROSEUS: Thank you all for having me.
24 I want to lead off very quickly, have as short as
25 possible presentation so you all will have plenty of

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1 time to discuss any issues that you might want to
2 bring to our attention with regard to rule making.
3 Let me just briefly go through the status of where
4 we're at.

5 The proposed rule, as you know, was
6 published on December 9th for a 75-day comment period,
7 which ended on February 23rd. Since that time, the
8 staff has been in the process to resolving comments
9 from the public, including the advisory committee, the
10 agreement states, and so on.

11 The draft final rule is now out for 30-day
12 comment by agreement states, and by the ACMUI. We're
13 doing this in parallel to keep things moving as
14 quickly as possible. The formal ending of the 30-day
15 comment period is October 18th.

16 As I go through my presentation, I'd like
17 to emphasize that I'm discussing the staff's approach
18 to the rule making. The issues before us are staff
19 discussion, and approval of our final recommendation
20 with the Nuclear Regulatory Commission's
21 commissioners.

22 Very quickly, as most of you know, I just
23 want to remind you that Subpart J, which was due to
24 expire this October, the staff published on September
25 16th an extension of the effective date for Subpart J

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1 to October 24th, 2005. The reference to the *Federal*
2 *Register* announcement is in your slides, if you need
3 it. This is going to allow time for a board to apply
4 for recognition of board certifications under the
5 forthcoming revisions to Part 35.

6 Let me briefly go through some of the
7 examples of key comments that we have on the proposed
8 rule. This is not meant to be an exhaustive listing
9 of the comments, by the way, but to pull out some
10 examples. The handout materials that were provided in
11 advance, including the rule making package, has a
12 detailed summary of the comments.

13 The first one that I'd like to mention is
14 a preceptor's comment that they should not be required
15 to attest to a candidate passing a board administered
16 exam, and on the use of the word "attest" versus
17 "certify" in preceptor statements. The staff believes
18 that the second comment is a good one. I meant to say
19 to the first one, and we'll go back to that in a
20 moment. That our final draft rule substitutes attest
21 or attestation for certify and certification in the
22 requirements for preceptor statements.

23 We feel that the comments that we received
24 from ACMUI and the public are valid in that regard.
25 And also, removes a little bit of ambiguity about what

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1 is certified versus attest. We have board
2 certifications and attestations as preceptors.

3 The next slide --

4 MEMBER NAG: I have a question about the
5 first part.

6 DR. BROSEUS: Sure. Yes, I'm coming back
7 to that right now.

8 MEMBER NAG: Okay.

9 DR. BROSEUS: Okay. An example of the
10 first one was flagged by commentators in proposed rule
11 35.390C, in which it appeared to apply - in fact, the
12 words did say that a preceptor would be attesting to
13 all of the requirements for board certification,
14 including the examination. And the staff agrees that
15 it's inappropriate to ask a preceptor to attest to a
16 passing of an exam. That's part of what a
17 certification is about, and so our draft final rule,
18 which you all had distributed to you, had that
19 requirement removed and reworded that. We also sought
20 comments on that, not just from ACMUI, but other
21 members of the public.

22 There also was a comment by ACMUI and
23 members of the public to allow for the authorization
24 of radiation oncologists who complete residency
25 programs under 390. One of the big issues here, I

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1 believe, for ACMUI and others was to make sure that
2 oncologists who are now able to perform therapies for
3 which a written directive is required, using material
4 for which a written directive is required, continue to
5 have that ability. They qualify under Subpart J, but
6 many of them do not qualify under what we have in the
7 proposed rule.

8 We took this into account and developed a
9 new Section 396, which provides for well-trained
10 oncologists to have an avenue to be approved for uses
11 under 390. A key requirement that we have in there is
12 to make sure that there's training and experience for
13 use of unsealed sources, unsealed byproduct material.

14 MEMBER NAG: May I?

15 DR. BROSEUS: Sure.

16 MEMBER NAG: You're saying the preceptor
17 should not be required to attest to candidate passing
18 board exam would be fine; however, this will
19 contradict your 396 because you are going to have
20 someone who became board certified, but may not have
21 had the 80 hours or may not have had a preceptor for
22 the unsealed source, and may require a separate
23 unsealed source preceptor.

24 DR. BROSEUS: That's okay.

25 MEMBER NAG: But then you're saying

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1 preceptor should not be allowed to attest candidate
2 passing board exam. Isn't that contradictory then?

3 DR. BROSEUS: The requirements -- there's
4 several conditions of 396, and I'd urge you to look
5 through them. But one of the key ones is that if an
6 individual is certified by a board for the other
7 sections where therapy has been done, the sealed
8 sources, brachytherapy or the high dose rate units -
9 if they are board certified and have the T&E for
10 unsealed sources, then they may be approved.

11 We can go back and look and make sure that
12 we haven't built in something that isn't appropriate.
13 If you have a particular observation, I'll make a
14 little note and get back to you.

15 MEMBER NAG: No. If you go back to your
16 previous slide, and if you look at that, in 396 you
17 really need the preceptor to certify that three
18 unsealed source, but here you are saying you are not
19 required to attest for a candidate passing board exam.
20 So if someone would pass board exam but needs an
21 additional attestation --

22 DR. BROSEUS: I understand.

23 MEMBER NAG: So you need to be careful how
24 you word that sentence, because otherwise you are
25 going to contradict yourself.

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1 DR. BROSEUS: So your comment is to make
2 sure that we're not requiring unnecessary attestation,
3 and just attestation to the training and experience
4 for unsealed sources. Is that correct?

5 MEMBER NAG: No. I think I'm trying to
6 say that the wording should be such that you don't
7 contradict yourself. I mean, your meaning is -- they
8 are well-meant, but the wording can be contradictory.
9 That's all I'm saying.

10 DR. BROSEUS: Okay. Thank you. We'll
11 note that.

12 CHAIRMAN MALMUD: WE also have a comment
13 from the public.

14 MS. FAIROBENT: Thank you, Dr. Malmud. My
15 name is Lynne Fairobent with the American Association
16 of Physicists. Dr. Nag, the origin of the comment
17 that generated I'm sure this first bullet on Roger's
18 behalf had to do with the fact that when a preceptor
19 is going to sign the preceptor statement, the
20 individual may actually have not completed the board
21 exam process. And, therefore, asking the preceptor to
22 attest that the individual has passed the exam was
23 premature, so that was the origin of that.

24 MEMBER NAG: I know the origin, but the
25 way it is put, it can become contradictory, and I'm

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1 trying to say before it becomes contradictory, you
2 need a preventative measure. I know what the
3 objective is and what it is meant to say, but the
4 wording may not be what is really meant to say.

5 DR. BROSEUS: Okay. Thanks for the
6 observation. We'll go back and look at that again.

7 CHAIRMAN MALMUD: Roger.

8 DR. BROSEUS: Dr. Malmud, there's somebody
9 --

10 CHAIRMAN MALMUD: Oh, Dr. Zelac.

11 DR. ZELAC: I'd just like to comment that
12 if my understanding of what 396 preceptor is attesting
13 to is simply the additional number of hours of
14 unsealed material training that the individual has
15 undergone, period. The individual who would be
16 applying for authorization would, in addition to that
17 preceptor statement, submit either a copy of their
18 board certification, for which no additional
19 attestation would be required. Is that correct,
20 Roger?

21 DR. BROSEUS: Yes. I'm re-reading our
22 draft right now, and I believe that the concern that
23 Dr. Nag expressed is not there. However, I would
24 encourage you that if you see something there that we
25 haven't seen, to annotate it and call it to our

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1 attention because we want to have a rule that's out
2 there that's clear and understandable, and is not
3 internally contradictory. Okay. So thank you for
4 looking at this very closely.

5 CHAIRMAN MALMUD: Roger, may I ask for a
6 concrete example. Let's say that there is a radiation
7 oncologist, board certified, who now wishes to use
8 unsealed sources, but did not have experience in
9 unsealed sources during his or her residency training.
10 How many hours of training does that individual
11 require be attested to?

12 DR. BROSEUS: Under 396, it's 80 hours.

13 CHAIRMAN MALMUD: Eighty hours.

14 DR. BROSEUS: Yes.

15 CHAIRMAN MALMUD: Thank you. Dr.
16 Williamson.

17 MEMBER WILLIAMSON: Yes, I have some
18 questions too about the meaning of 396. This is meant
19 to apply for any radionuclide and form of
20 administration other than oral. Is that the correct
21 --

22 DR. BROSEUS: It's written for parenteral
23 administration.

24 MEMBER WILLIAMSON: Which means what in
25 the NRC?

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1 DR. BROSEUS: I'd go back and look at the
2 dictionary, but I believe it means administration by
3 injection. It's not oral.

4 MEMBER WILLIAMSON: So it would cover, for
5 example, installation of P-32 radiochromic --

6 (Simultaneous speech.)

7 DR. BROSEUS: We didn't say
8 intravascularly. We didn't say venous or anything
9 like that. We used parenteral. My understanding
10 parenteral would include like --

11 CHAIRMAN MALMUD: I believe parenteral is
12 anything except oral.

13 DR. BROSEUS: That's how I would interpret
14 it, yes.

15 MEMBER WILLIAMSON: And so if the -- is
16 this to be done on a radionuclide by radionuclide
17 basis, or if, for example, a radiation oncologist
18 qualifies for say P-32 intra abdominal installation,
19 and then subsequently wants to do Zevelin or something
20 else - is there a need for the individual to do
21 anything else, or is this actually --

22 DR. BROSEUS: The rule doesn't say that.
23 The rule says -- it doesn't name a radionuclide, and
24 the intent in Part 35 now is to have more general
25 rules that cover broader aspects. You shouldn't have

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1 to come in for a license amendment if somebody -- you
2 know, I could conceive of circumstances where that
3 might be, but that's not the intent of the rule. The
4 intent of the rule doesn't say for P-32 or abdominal
5 sites or whatever. It isn't narrow, it's broad, for
6 which a written directive is required for parenteral
7 administration, period.

8 MEMBER WILLIAMSON: And I guess then that
9 a radiation oncologist then by complying with 396 and
10 getting 80 hours of training and experience, and then
11 doing what is it - 392 for thyroid radioiodine
12 treatment? Is it 392 or 394?

13 MEMBER EGGLI: Depending on whether you're
14 doing a benign or malignant -- 394 is malignant.

15 MEMBER WILLIAMSON: So then by -- or if
16 they wanted to do 392, as well, then three times 80
17 hours and they would be able to have the equivalent
18 authorization, authorized user privileges as --

19 MEMBER EGGLI: It would be three times 80
20 hours.

21 MEMBER WILLIAMSON: Okay. That was going
22 to be my follow-up question, is that for multiple --
23 how would you handle the case where a physician wanted
24 to do both radio Iodine and more general radionuclide
25 therapy - would you want just one 80-hour training?

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1 DR. BROSEUS: It sounds like it's coming
2 under --

3 MEMBER WILLIAMSON: Yes.

4 DR. BROSEUS: -- now if it's really broad.
5 It depends upon what the particular application is.
6 I could foresee using material that would fall under
7 the requirements for 396, and if they wanted to do a
8 certain level of activity with I-131, they'd have to
9 meet 392 or 394.

10 MEMBER WILLIAMSON: Yes. So that would be
11 another 80 hours, or could the same 80 hours be used,
12 and effectively the additional requirement for the
13 radiation oncologist would be to have three supervised
14 radio Iodine treatments for thyroid carcinoma?

15 DR. BROSEUS: Well, the requirements for
16 case experience are in there, and so if a person
17 didn't have the case experience required for 392, they
18 would have to pick that up.

19 MEMBER WILLIAMSON: But they wouldn't need
20 an additional 80 hours of training and experience.

21 DR. BROSEUS: That's not the intent of the
22 working group.

23 MEMBER WILLIAMSON: What is the intent of
24 the -- in terms of trying to qualify for multiple
25 authorized user privileges.

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1 DR. BROSEUS: Well, I think the intent is
2 for an individual who is using byproduct material for
3 which a written directive is required, to have
4 experience with unsealed sources for which a written
5 directive is required. So they're aware of the safety
6 requirements, the hazards, the cautions associated
7 with these higher levels of activity, so if they have
8 a spill or whatever, that they could take care of it.
9 Think about this for a moment. Sometimes a physician
10 is his own radiation safety officer, or her own
11 radiation safety officer. It isn't to require 240
12 hours. It's to have an appropriate amount of training
13 and experience for the type of use you're going for.
14 And it doesn't say P-32 and 396. Okay.

15 CHAIRMAN MALMUD: Dr. Eggli.

16 MEMBER EGGLI: To qualify under 396, I
17 don't remember -- I don't have it in front of me. Do
18 you have to be a 400 or higher authorized user to
19 qualify for unsealed sources?

20 DR. BROSEUS: You don't have to be
21 authorized in the other types of uses.

22 MEMBER EGGLI: Okay. Because --

23 DR. BROSEUS: What it does do is admit, if
24 a person is board certified for those types of uses,
25 they may use that board certification as evidence of

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1 their T&E.

2 MEMBER EGGLI: But one of the issues
3 though is, there are only two kinds of administration,
4 basically. There's oral administration and parenteral
5 administration, and if I can come in under 394 and
6 396, I can do 80 hours of training, and I can bag the
7 700 hours in Part 300, so why the heck would I ever
8 want to worry about Part 300, because I can circumvent
9 Part 300 all together by doing 392, 394, and 396.
10 I've got everything available under Part 390.

11 MEMBER WILLIAMSON: May we should multiply
12 the 80 times --

13 MEMBER EGGLI: No, I'm not trying to
14 suggest that. But I think there's a potential
15 inconsistency there. And if you limited 396 to those
16 who are certified at 400 or higher, then I have no
17 problem with 396.

18 DR. BROSEUS: I'm sorry. Would you repeat
19 what you just said.

20 MEMBER EGGLI: To qualify to use unsealed
21 sources under 396, if you have to be an authorized
22 user of 400 or 600, then I have no problem with 396.
23 But if anybody can go an 80-hour pathway and get into
24 396 without being an authorized user in 400 or 600,
25 then I have a problem.

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1 CHAIRMAN MALMUD: But you have to be board
2 certified.

3 MS. CHIDAKEL: If I could clarify; now
4 this is a technical discussion. I know this is a
5 technical discussion.

6 CHAIRMAN MALMUD: Would you please
7 introduce yourself.

8 MS. CHIDAKEL: I'm Susan Chidakel. I'm
9 the Office of General Counsel Senior Attorney. I
10 don't know if you all have the draft final rule in
11 front of you or not, but if you will look at the draft
12 final rule, it says that the licensee shall require an
13 authorized user for the administration requiring a
14 written directive to be a physician who is an
15 authorized user under 490, 690, or before October
16 24th, 2005, 940 or 960, or certified by a medical
17 specialty board whose certification process has been
18 recognized under 490, 690, or before October 24th, 940
19 or 960. So I don't know if this answers your
20 question. And then in addition, has completed these
21 80 hours and so forth. I don't know if this resolves
22 your question or not.

23 MEMBER EGGLI: It does. Thank you.

24 DR. BROSEUS: I think we're covered here,
25 because there is not an alternate pathway also.

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1 MEMBER EGGLI: Okay. I'm happy with that.

2 DR. BROSEUS: Okay. Great. But thank you
3 for attending to that, because that's something I
4 don't believe we necessarily thought about in the
5 working group.

6 CHAIRMAN MALMUD: Dr. Williamson.

7 MEMBER WILLIAMSON: Well, I think it's an
8 excellent idea doing this 396, and resolves a lot of
9 the complexity and arguments that we've had over the
10 390. The only suggestion I would make to you to
11 consider is to fold into this a parallel definition of
12 acceptable board certification, on the assumption that
13 the American Board of Radiology will eventually adapt
14 and require the 80-hours and three cases as part of
15 the certification process in the future, so that then
16 the additional requirements --

17 DR. BROSEUS: Well, if ABR has
18 certification recognized for the other uses and a
19 person comes in with 80 hours, they would meet the
20 requirements of 396, so I think there's sufficient
21 there now. Now they could add 80 hours and create a
22 new certification, but 396 does not need a new
23 certification. There's not a new certification.

24 MEMBER WILLIAMSON: Yes, I understand
25 that. I'm suggesting you could potentially structure

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1 396 to be the same as the other rules, which would
2 have both an alternate pathway and a board
3 certification pathway, which would then, at that point
4 if and when American Board of Radiology adapts and
5 makes it clear that --

6 MEMBER EGGLI: I think the American Board
7 of Radiology intends that it's diplomats should be
8 certifiable for all 390 uses.

9 MEMBER WILLIAMSON: That's my
10 understanding, as well.

11 CHAIRMAN MALMUD: May I suggest, in
12 listening to all these questions, that it might be
13 most useful if there were a spreadsheet which had
14 matrices in it, including certification by the
15 American Board of Radiology, the American Board of
16 Physicists in Medicine, the American Board of Nuclear
17 Medicine, the American Board of Radiation Oncology,
18 and the American Boards of other specialties in one
19 column, indicating what the requirements are for those
20 individuals to achieve satisfactory compliance with
21 NRC regulations for the performance of tests involving
22 unsealed sources, so that it would be very clear to
23 any user what his or her requirements are, because if
24 this committee, which has worked on it with you for
25 months, if not years, remains confused, the public-at-

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1 large, particularly the users, are going to be
2 extraordinarily confused. And it doesn't seem to be
3 clear yet to us as a group, as to what the
4 requirements are going to be for individuals who will
5 have completed training by October, who will complete
6 training after October, and what the additive numbers
7 are, though you've clarified an issue certainly for us
8 this morning.

9 I think a spreadsheet would be most
10 useful, and that would be something that anyone could
11 look at and say well, this individual qualifies. I'm
12 not speaking about the credentialing process in the
13 hospital. That's separate. I'm talking about NRC,
14 satisfying NRC regulations.

15 DR. BROSEUS: I think I would refer that
16 to our Material Safety and Inspection Branch for
17 consideration in developing guidance with the rule.
18 I think at the point we're at, to develop something at
19 this point, we're trying to get this rule out so these
20 things will be in place, but I think a potentially
21 good suggestion for explaining things and how the rule
22 works, and so I would expect the MSIB to take this
23 under advisement as a suggestion. There's been a hand
24 back here for quite some time.

25 CHAIRMAN MALMUD: Yes, I'm sorry. Could

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1 you introduce yourself, please.

2 MR. MOORE: Yes, sir. Dr. Malmud, I'm
3 Scott Moore. I'm the Chief of the Rulemaking and
4 Guidance Branch. I'm Tom's counterpart. We can
5 certainly work towards getting such a spreadsheet, but
6 as Roger just noted, I don't think we would be able to
7 provide that within the time period that we're asking
8 for comments back from the ACMUI.

9 We put this item on the agenda primarily
10 so that the ACMUI can prepare comments back to us
11 within the time period that we need them, and have
12 asked you for them, which is October 18th.

13 I just heard Dr. Williamson make a
14 suggestion to us with regard, I believe, to 396. What
15 we really need for the ACMUI to do is to make those
16 suggestions to us as a body in writing, and we have
17 another hour and a half for you all on the agenda to
18 prepare such comments in writing to us to work
19 together as a group, to decide what you want to make
20 in comments back to us, the agency, if you want to
21 make any such comments on the draft final rule.

22 Within our time frame, we're asking for
23 the agreement state comments back by the 18th, and for
24 us to stay on schedule, we need the advisory committee
25 comments back also by the 18th. We can continue to

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1 provide comments throughout the next hour and a half
2 and discuss the rule, but I do need to let you all
3 know that we need the ACMUI's comments to go forward,
4 and that's the time schedule that we're working
5 against.

6 CHAIRMAN MALMUD: So you need comments by
7 the end of today.

8 MR. MOORE: We need them back by the 18th,
9 sir.

10 CHAIRMAN MALMUD: Dr. Diamond, I think you
11 were next, and then Mr. Lieto.

12 MEMBER DIAMOND: Ladies and gentlemen,
13 obviously what we have here are some very substantive
14 changes in the regulations, and in this pre-decisional
15 material, as you can clearly see, even we as very
16 experienced members who have been working with those
17 regulations, I've been involved for six years myself.
18 I think Dr. Williamson for nine years. There are very
19 important questions related to how the regulations are
20 being interpreted. There's absolutely now way it is
21 appropriate for us to come to a consensus opinion for
22 you by October the 18th, absolutely no way whatsoever.

23 What ought to be done is that these pre-
24 decisional regulations ought to be released to the
25 stakeholders, to the public, at this time, so that

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1 everyone can take a look at them. Good guidance is
2 not to supplant bad rulemaking, and I think we need to
3 get this out to the stakeholders. These are very
4 substantive changes.

5 My understanding, for example, is that a
6 radiation oncologist in practice who's currently not
7 licensed to, for example, use some of these materials,
8 will not be grandfathered if he or she wishes to use,
9 let's say Zevelin radio immuno therapy in the future
10 without going through a fairly proscriptive set of
11 tasks. And I think that in the grand scheme of
12 things, we have lost our main focus.

13 When this process started several years
14 ago, one of the key elements was that we all agreed
15 that board certification would be the default pathway
16 to authorized user status. Now we're learning that
17 because of the way the hours are enumerated, that
18 board certification in radiation oncology, for
19 example, by the American Board of Radiology would not
20 necessarily accomplish that task because of how the
21 700 hours are accomplished.

22 We had Donna-Beth yesterday tell us that
23 we needed 700 hours of classroom laboratory experience
24 - to paraphrase - exclusively and specifically related
25 to unsealed radio isotope material. My question to

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1 her is what are you going to talk about for 700 hours
2 in classroom laboratory exclusively related to that.
3 It makes no sense at all to me. And the point related
4 to that is it's a different interpretation of how
5 you're counting hours that now leads some members of
6 the staff to say that the ABR Boards in Radiation
7 Oncology or not satisfying the requirements and,
8 therefore, we need to create this new 396. So as you
9 see, gentlemen and ladies, I have some serious issues
10 with the substantive and interpretive changes that we
11 see before us. And I believe the correct approach is
12 to release this pre-decisional material to the public
13 for public comment. And after discussion, I'd be
14 happy to make a motion to that effect.

15 CHAIRMAN MALMUD: Thank you, Dr. Diamond.
16 Mr. Bailey. Excuse me. Mr. Lieto was waiting in
17 line.

18 MEMBER LIETO: I have two comments, one a
19 general question. At the teleconference, I believe
20 that one of the committee members had requested that
21 we have before us a version of the proposed rules
22 redlined, strikeout, underlined edition-type document
23 so that we could see where the changes were in
24 relationship to what had been proposed from last year.
25 Has that been made available, or is that available?

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1 MR. MOORE: I could address that. The
2 request at the teleconference was wherein the draft
3 rule was issued in final that a redlined strikeout be
4 prepared at that time.

5 MEMBER LIETO: No, that was not the
6 understanding I think at the teleconference. I'd be
7 glad if board members here --

8 MR. MOORE: I disagree with you.

9 MEMBER LIETO: Well, I guess I'd like to
10 ask the committee members, because that's been one of
11 the biggest problems in coming before this group, is
12 that we get this document which is what's supposed to
13 go to the *Federal Register*, and we have repeatedly
14 said that it's very difficult to look at things out of
15 context with a specific rule, and that in order to
16 understand all the nuances that go into the changes
17 that the working group is recommending, especially
18 with these changes of 396 and some of these other
19 things regarding grandfathering and so forth, it's
20 very important for us to understand what the working
21 group is intending to put in there, and be sure that
22 our understanding is correct. It's just plain
23 difficult to look at it through this part, and just
24 like happened a little bit earlier. There was a
25 misunderstanding about what the working group was

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1 intending or has put in there versus what the
2 committee members have.

3 I've been on here through this T&E, and
4 this has been a request repeatedly from committee
5 members. And if I'm wrong, I'd like one of the
6 committee members to let me know, but that's one of
7 the things that I think really would aid. I would
8 heartily support Dr. Diamond's statement about the
9 realization that we're going to go through all these
10 changes in an hour and a half, come to a consensus for
11 the NRC working group, I think is really unrealistic.
12 And I think a lot of committee members that I've
13 talked to didn't even recognize the October 18th
14 deadline. Okay. That that was going to be the
15 expectation, that we're going to spend less than two
16 hours, come out with a consensus document over all
17 these changes, and then walk out of here with this is
18 what the ACMUI wants to do, I think is a little
19 unrealistic; especially not having a good working
20 document to work from.

21 CHAIRMAN MALMUD: Thank you, Mr. Lieto.
22 The next was Mr. Bailey.

23 MEMBER BAILEY: Yes. I'm not sure that
24 ACMUI is aware that the Organization of Agreement
25 States has petitioned the NRC on this very item, and

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1 this petition has now been accepted. And it seems
2 that assuming that NRC will take the petition with
3 some seriousness, that were going to end up in another
4 rulemaking process almost immediately.

5 The agreement states, all of them signed
6 off that they wanted this petition, that they're not
7 happy with the way the current rule is written with
8 regard to T&E. It may not be -- the agreement states
9 may not agree with the physician members on T&E, but
10 at least we think it needs to be clear, and it needs
11 to be based on some sort of information, some value
12 judgments on really how many hours. It was asked, how
13 do you spend 700 hours? I personally do not know.

14 We have begun to look at what is the
15 rationale for the number of hours being required, and
16 for which groups? And I think maybe it's totally
17 premature to go forward with this rule at this time
18 until we have had more comment.

19 MS. CHIDAKEL: Excuse me, if I may
20 interject here.

21 CHAIRMAN MALMUD: This is Susan Chidakel.

22 MS. CHIDAKEL: Yes. I wanted to sort of
23 clarify and sort of focus on what we're doing here, if
24 I may, from my perspective.

25 The rule did go out for comment to the

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1 public, the proposed rule, with major changes went out
2 for comment and was published in the *Federal Register*,
3 and we have received the comments back, so the public
4 did have an initial comment period to review the major
5 changes of the T&E.

6 The main thing that is changing now with
7 our draft final rule is in response to the comment
8 that we should have a breakdown of the hours, a
9 specification of division up of the, say for example,
10 700 hours between on the one hand classroom and
11 laboratory, on the other hand work experience. So
12 this is the main thing, and I do believe this is the
13 main thing that we need ACMUI's input on right now,
14 because the other changes, while there have been
15 changes made in this draft final rule, I think the
16 majority of the basis of the rule as it was, the
17 proposed rule basically was essentially very similar
18 to what we are coming out with now with the draft
19 final rule, with the exception of this hour issue.

20 Now with regard to the hour issue, bear in
21 mind that we not affecting the board certification
22 pathway. We are not breaking down the hours between
23 classroom and laboratory and work experience with
24 regard to board certification. The proposal for the
25 breakdown of the hours goes only to the alternate

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1 pathway. And I think is what we - excuse me, I see
2 someone shaking his head. Do you disagree with what
3 I've said?

4 MEMBER NAG: Yes.

5 MS. CHIDAKEL: Please.

6 CHAIRMAN MALMUD: This is Dr. Nag.

7 MS. CHIDAKEL: Well, basically that was
8 the emphasis that I wanted to put on this, and we do
9 need ACMUI's input on that particular issue, in
10 particular. That is the whole point and the whole
11 focus, as I see it, of our discussion this morning, so
12 that I want to make sure that we're not going to go
13 into all other directions and not resolve this issue,
14 because the rest of the rule did go out, like I said,
15 for public comment with the exception of the 396.
16 This is true, that was added, and other changes that
17 I consider were relatively minor, but the main change,
18 and the main thing we need ACMUI to look at is the
19 division over the hours. And again, bear in mind the
20 division of the hours only goes to the alternate
21 pathway, does not go to the board certification.

22 CHAIRMAN MALMUD: If you'd remain at the
23 microphone.

24 MS. CHIDAKEL: Sure.

25 CHAIRMAN MALMUD: The issue that both Dr.

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1 Nag and Dr. Eggli are going to raise, I believe, is
2 this; the board certification pathway is not
3 independent of the alternate pathway since if an
4 individual does not pass his boards at first taking,
5 that individual will have to have documented that the
6 individual received a certain number of hours of
7 training in the course of preparation for the board
8 certification; that is, during the residency program.
9 Therefore, the residency program must include the
10 requirements of the alternate pathway, or the
11 individual physician will not be able to meet NRC
12 standards.

13 MS. CHIDAKEL: The individual always, of
14 course, has the option to do the alternate pathway.
15 Let me just -- I don't want to be facetious.

16 CHAIRMAN MALMUD: Excuse me. You are
17 incorrect, if I may say so. The individual does not
18 have the option of the alternate pathway when in the
19 course of his residency training, where he fully
20 expects to become certified within a year or so of
21 completing the residency, those requirements were not
22 met by the residency because though the current
23 regulations indicate that only the alternate pathway
24 must have the numerical requirements, the residency
25 will not have prepared the individual unless the

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1 residency meets the alternate pathway requirements.

2 MS. CHIDAKEL: I understand. I understand
3 what you're saying. I did hear the same argument
4 during the telecon.

5 CHAIRMAN MALMUD: It's not argument, it's
6 a fact.

7 MS. CHIDAKEL: And I understand -- well,
8 forgive me, I'm sorry. We're talking about semantics
9 here. I understand the discussion. I understand the
10 point that you are making.

11 If I may, and I'm not trying to be
12 facetious or anything else on this issue - while I
13 understand the problem, this is not a problem that's
14 unique to the medical profession, frankly speaking.
15 I'm an attorney. I went all through law school. I
16 took four years, or 3-1/2 years, or three years of
17 whatever it was to go through law school and meet all
18 of these tough requirements and pass my law school
19 exam. If I don't pass my bar, I have the same
20 problem, so that this is - you're shaking your head,
21 but it's true. I cannot practice law really before a
22 court if I'm not bar certified, which is essentially
23 the same thing as being board certified.

24 MEMBER EGGLI: That's wrong. There are
25 boards who don't allow their candidates to take the

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1 exam until they've been in practice for more than a
2 year.

3 MEMBER DIAMOND: Under the new
4 requirements for radiation oncology, radiation
5 oncology residents who graduate their programs, they
6 will take their written boards in the fall after they
7 finish training. And if they pass that, they will
8 take in the spring, following completion of training,
9 the oral boards; thus, for a person who has completed
10 training on schedule, has completed the examinations
11 and passed them sequentially, one will not be board
12 certified for essentially four years, so every single
13 resident coming out of training will not be board
14 certified for a minimum of one year, and during the
15 first year of practice by default would have to fall
16 under the alternate pathway.

17 MS. CHIDAKEL: I understand. I see what
18 you're saying.

19 MEMBER DIAMOND: And because of the way we
20 are enumerating these hours with the 700 being
21 specifically and exclusively devoted to the unsealed
22 radioisotopes which makes no sense to me, there's
23 going to be --

24 MS. CHIDAKEL: This problem -- this was
25 never -- I never heard this problem explained before.

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1 What I heard in the telecon was the idea that people
2 would be failing their boards and, therefore, would be
3 out of luck. I never heard this discussion --

4 MEMBER DIAMOND: The other issue, just for
5 your information again - this is not the world in
6 which you function - is the boards set failure rates
7 that unfortunately are probably artificially high, and
8 they do that for a number of reasons. The failure
9 rate for the Part 1 Written Boards is somewhere around
10 30 percent, so you have some very, very highly
11 educated well-trained people that are failing simply
12 to meet the criteria of the curves. The fail rates
13 for the orals - Subir, what do you think - they are
14 probably around the same?

15 MEMBER NAG: Thirty percent.

16 MEMBER DIAMOND: So you're talking about
17 large numbers of extremely qualified people who are
18 not passing on their first go-around. There's really
19 no stigma associated with it. It's kind of the way
20 the game is played.

21 MS. CHIDAKEL: Let me see if I can
22 understand your position then. Are you saying that
23 you don't feel there should be any change as far as
24 specification of hours, either in the alternate
25 pathway or the board certification path?

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1 MEMBER DIAMOND: I think the main issues,
2 if I may, are that -- my sense is that the NRC staff
3 is interpreting the enumeration of hours differently.
4 And based upon that different interpretation, the
5 American Board of Radiology for Radiation Oncology
6 certification would not meet all the requirements that
7 are being enumerated and, therefore, we're falling
8 into this alternate pathway problem. That's number
9 one.

10 Number two, all of the residents coming
11 out of training now will not be board certified for at
12 least a year and, therefore, will all fall into the
13 alternate pathway matrix.

14 CHAIRMAN MALMUD: Dr. Nag.

15 MEMBER NAG: Okay. I do have a few
16 comments. Although this was out for public comments
17 a couple of weeks ago, this was not conveyed to the
18 ACMUI, so the ACMUI has not had a chance to look at it
19 in detail. One thing would have helped would have
20 been an email that this is being out and have that
21 sent to us. But one of the things is that next month,
22 I am giving on how do you get certified. And because
23 of that specific reason, I had to talk with NRC
24 officials to gain some of the insight and, therefore,
25 I do have a little insight because of that. But the

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1 ACMUI members have not had that chance for the
2 interaction, so I do support Dr. Diamond's proposal
3 that we be given more time to be able to analyze and
4 understand this. We could do it, perhaps, as a
5 subcommittee or any other way you need a two week
6 notice, because otherwise you will not have a chance
7 to discuss this among ourselves.

8 With this alternate pathway of 396, a
9 board certified radiation oncologist can become an
10 authorized user of the 390 requirement, but will
11 require 80 hours of unsealed sources extra. Now the
12 board at the moment is not requiring that 80 hours,
13 but once it does, it will solve the problem. I think
14 one of the problems you are seeing right now of making
15 a spreadsheet is that the board requirements are
16 changing, and they have not finalized what the exact
17 requirements are, because of this situation. The NRC
18 is making some of these requirements, and then the
19 board has now to see whether it can meet these
20 requirements. For, for example, right now the
21 American Board of Radiology does not require a
22 separate 80-hour as noted, although it may be
23 incorporated as part of the program in many of the
24 programs. Now the board has to make a separate
25 decision whether they are going to make that 80-hours

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1 incorporated within that training program. So at the
2 moment, we can't even make a spreadsheet. So I think
3 with all of the confusion going on, I do support Dr.
4 Diamond's proposal.

5 MR. MOORE: Dr. Malmud.

6 CHAIRMAN MALMUD: Who just said Dr.
7 Malmud?

8 MR. MOORE: I did.

9 CHAIRMAN MALMUD: Okay.

10 MR. MOORE: This is Scott Moore. Dr. Nag
11 just recommended that an email would have helped. I'd
12 like to point out that Sandy Wastler did send an
13 email. We have a 30-day comment period for agreement
14 states and ACMUI built into the rulemaking process to
15 comment on rules. We have a very tight deadline for
16 complex rules, and this is certainly one of them.

17 Sandy sent out an email to all members of
18 the ACMUI at the start of the 30-day comment period.
19 The 30-day comment period ends on October 18th, and it
20 was sent to agreement states at the same time. Each
21 of you received an email from Sandy at the start of
22 the 30-day comment period, and we asked for comments
23 back from the ACMUI at the end of the 30-days, which
24 is October 18th. So in response to what Dr. Nag just
25 brought up, we did send the email.

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1 CHAIRMAN MALMUD: I think Dr. Broseus was
2 next.

3 DR. BROSEUS: I have a couple of
4 observations. One of them is sort of parallel to
5 Scott's, but not quite the same. The working group
6 feels a tug both ways, but we feel it's very important
7 to get this rule out as soon as possible. And if the
8 rule were reopened for public comments, that would
9 cause quite a lengthy delay in getting this rule on
10 the books, and getting stability into the regulation
11 in this particular area.

12 The second observation is that I believe
13 if we come back and focus on some of the key elements
14 here, that it is possible to move forward
15 productively. 396, if it were in redline, in a
16 redline strikeout, will all be redlined because it's
17 new. And I have a copy here which I can circulate to
18 people - in fact, I'll pass it around. Dr. Nag asked
19 for this yesterday, but if you could bring questions
20 you have to me about these particular areas, I think
21 we could focus on them.

22 One of the comments that Dr. Diamond made
23 related to the interpretation of the 700 hours, and
24 differing messages that you received from the staff.
25 I've touselled with those very issues when we were

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1 developing guidance in 2002 before the current rule
2 was issued, and so my own personal opinion is that a
3 comment coming back from ACMUI that recognizes that
4 and calls that to our attention, we can go back and
5 look at it in the supplementary information how to
6 address these differing views and clarify them because
7 the steady message has been from the NRC, and the
8 people developing the rule and the guidance that are
9 guiding this forward is to have reasonable rule, have
10 it clear, and not have different interpretations that
11 cause problems.

12 So once again, I would just say anything
13 that we can come out of this meeting with about
14 October 18th that would move this forward is important
15 because it may be the Commission would not grant us
16 the privilege of extending the rule if that were a
17 recommendation in order to go forward. Thank you.

18 CHAIRMAN MALMUD: I think Dr. Williamson
19 was next.

20 MEMBER WILLIAMSON: I think maybe with
21 regard to Dr. Diamond's suggestion, we need to think
22 through the different parts of the rule, 100, 200,
23 300, 400, and 600, and ask the question for radiation
24 oncology and other boards potentially, too, if the
25 number of hours of training and experience in the

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1 alternate pathway is a problem. So if one looks at
2 the 490, the alternate pathway for brachytherapy,
3 manual brachytherapy requires 200 hours of classroom
4 and laboratory, and 500 hours of supervised experience
5 which I think the word is involves, it doesn't say
6 exclusively devoted to, but involves the handling and
7 preparation of sources.

8 Do Dr. Diamond and Dr. Nag think that the
9 current four year residency complies would allow an
10 applicant to satisfy that requirement for the
11 alternate pathway for manual brachytherapy?

12 MEMBER DIAMOND: This is Dr. Diamond. To
13 answer your question, Jeff, I believe that many of the
14 programs currently satisfy all of those requirements,
15 and for those programs that do not, relatively minor
16 additive changes would satisfy that requirement.

17 MEMBER WILLIAMSON: Okay. Let's go to
18 600 now. Do Dr. Diamond and Dr. Nag think that the
19 rule as written, which again the alternative pathway
20 requires 200 hours of classroom and laboratory, plus
21 500 hours involving, and then again a slightly
22 modified laundry list of technical tasks associated
23 with high dose rate and teletherapy. Do you think an
24 individual that has successfully completed a four year
25 residency to date in radiation oncology could comply

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1 with the requirements of the alternative pathway?

2 MEMBER DIAMOND: This is Dr. Diamond.
3 Once again, by the way I account for hours, the answer
4 would be yes.

5 MEMBER WILLIAMSON: The third question -
6 396.

7 MEMBER NAG: You haven't asked me.

8 MEMBER WILLIAMSON: Oh, I've asked both of
9 you.

10 MEMBER NAG: You haven't given me the
11 chance to answer.

12 MEMBER WILLIAMSON: I'm sorry. You're
13 right.

14 MEMBER NAG: It will depend on how the
15 hours are interpreted. That's what I'm trying to tell
16 you; that if you are saying that the 500 hours include
17 your experience in handling of radioisotope, that
18 includes the 600, but also includes the 400 - yes,
19 then you will meet it. But if someone says yes, you
20 have the experience in manual brachytherapy on the
21 400, that was the 500 hours. Now you have to show me
22 a separate 500 hours for the use in 600. That will be
23 very difficult in some of the training programs that
24 don't have their own HDR. But if it did comprise a
25 part of the overall training, yes, there is no problem

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1 meeting it. So that was my reason for asking the NRC
2 how are you affecting these hours.

3 MEMBER WILLIAMSON: And let me finish with
4 my third question, and then I'll shut up. The 300 now
5 requires 700 hours, and I think it is not -- in the
6 alternate pathway it is distinguished between, of
7 course, classroom and laboratory, and supervised work
8 experience. I think it is by NRC's own admission that
9 radiation oncologists today would not satisfy that,
10 but the 396 pathway does seem to provide a solution
11 for practicing radiation oncologists that have either
12 in their residency or in subsequent practice acquired
13 that experience to be able to easily comply and do
14 what they're doing, and someone who has never had that
15 - well, two weeks of training and three cases is some
16 barrier, but it doesn't seem to be a completely
17 unreasonable one for someone who hasn't had that
18 experience. So do you think that, does it matter
19 whether 300 requires 700 hours now? That's my
20 question.

21 MEMBER NAG: Yes. I think the -- I mean,
22 I did discuss this with the NRC officials because I am
23 going to be talking about this in a meeting, so I had
24 to clarify for my own understanding before I say it to
25 the general radiation oncology community. The general

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1 radiation oncologists will not be able to meet the 300
2 requirement of 700 hours, but because they can qualify
3 under the 400 and the 600, then they can add the 396
4 and qualify by that log, so that is not a problem.
5 The one problem would be that until the board -- until
6 the American board of radiology requires an 80-hours
7 of unsealed sources built into that program, they will
8 have to somehow show that they have the 80-hours of
9 separate unsealed source somewhere, so that may be
10 slightly difficult, but not impossible.

11 MEMBER WILLIAMSON: So I guess the
12 question is, is whether the issue raised by Dr.
13 Diamond, which is certainly a frightening prospect, is
14 valid.

15 CHAIRMAN MALMUD: Thank you. Dr. Zelac,
16 I believe, had his hand next.

17 DR. ZELAC: Thank you, Dr. Malmud. I'd
18 like to point out several things that I think are
19 pertinent to the discussion. First, in terms of the
20 total number of hours required in the different
21 modalities there have been no adjustments from the
22 current rule. And there was clearly extensive
23 discussion involving the advisory committee, the
24 various boards, the public when the current rule was
25 adopted, so if we're talking about, for example, the

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1 700 hours, that has been on the books for two years
2 now, and apparently is not providing an impediment to
3 people achieving authorized user status.

4 Secondly, I'll wait until Dr. Diamond is
5 finished, because this I think is -- Dr. Diamond, I
6 wanted you to --

7 MEMBER DIAMOND: I'm listening.

8 DR. ZELAC: Okay. Particularly hear this.
9 Since we are talking about now unchanged requirements
10 from the current rule, it's appropriate to take a look
11 at the statements of consideration that went along
12 with the publication of the current rule with regard
13 to things like the 700 hours, and where one acquires
14 it, and what qualifies for requiring it. And there
15 are two places in the statements of consideration for
16 the current rule that are applicable. One was to the
17 290 requirements, for which there are 700 hours, and
18 the second was for therapeutic utilization.

19 Quoting from the *Federal Register*, "We
20 recognize that physicians in training will not
21 dedicate all of their time specifically to the subject
22 areas in 35.290" - not talking about 700 hours there -
23 "and will be attending to other clinical matters
24 involving the diagnostic use of material under the
25 supervision of an authorized user; example, reviewing

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1 case histories or interpreting scans. Even though
2 these clinical matters are not specifically required
3 by the NRC, this type of supervised work experience
4 may be counted toward the supervised work experience
5 to obtain the required 700 hours." That's one area.

6 The second has to do with training and
7 experience requirements for sealed byproduct material,
8 and the quote here from the Statements of
9 Consideration, "The NRC agrees that concurrent
10 training should be allowed for the clinical and work
11 practical experience requirements in 35.490 and
12 35.690. Therefore, we revise the regulatory text to
13 allow for concurrent work and clinical experience."

14 MEMBER DIAMOND: This is very helpful
15 information, Ron, because listening to you, that
16 Statement of Consideration is much closer to how in my
17 mind I enumerate for these hours, the same way I would
18 believe our Chairman does, and perhaps the entirety of
19 the committee. And also, sounds to me different than
20 what I heard yesterday. And I would go back to Jeff's
21 series of questions when he was asking do the training
22 programs satisfy these hours. And based upon those
23 Statement of Considerations with respect to 300 level
24 uses, I would say that many of the training programs
25 already do satisfy those hours, and the ones who do

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1 not probably could meet them with very minor changes.

2 DR. ZELAC: The other last point that I
3 would make with respect to -- in response to what Dr.
4 Williamson had brought up is, if you look at what the
5 board requirements are versus the alternate pathway
6 requirements for 190 and 290, it was built into the
7 board requirement meeting the requirement in the
8 alternate pathway, except for again in terms of the
9 numbers of hours have to be met. We have been
10 careful, however, in the rewrite in the working group
11 to try to not put additional requirements - and this
12 is the issue that's been raised by Dr. Malmud -
13 additional requirements that would apply specifically
14 to the board certification pathway. So the dilemma is
15 there, and I think it's perhaps somewhat unavoidable
16 from the way we're approaching this if, in fact, we
17 are going to go down the pathway of specifying
18 training -- excuse me, classroom and laboratory
19 subgroup of the total experience required.

20 DR. BROSEUS: Excuse me for interrupting,
21 but I want to supplement what Ron said by noting that
22 in the supplementary information for the draft final
23 rule, we have brought forward this discussion he just
24 quoted into the supplementary information, and added
25 a bit to it just to clarify that the NRC's intent is

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1 to make sure that radiation safety training is
2 adequately addressed, because we're also dealing with
3 the didactic hours issue, and so that discussion is in
4 the supplementary information.

5 MEMBER WILLIAMSON: A point of
6 clarification. What is supplementary material?

7 DR. BROSEUS: Okay. I'm talking jargon -
8 excuse me. The Statements of Consideration - it's the
9 front part --

10 MEMBER WILLIAMSON: Is this the thing that
11 we heard --

12 DR. BROSEUS: Yes. It's the first part of
13 that. At the end of that is the rule text, but the
14 supplementary information has a discussion for
15 rational rule change and comments and responses.

16 MEMBER WILLIAMSON: Do the stars refer to
17 the current Part 35 published in --

18 DR. BROSEUS: Pardon me?

19 MEMBER WILLIAMSON: Do the stars refer to
20 the *Federal Register* version of the rule published
21 April 24th, 2002, or some other version of the rule?

22 DR. BROSEUS: Let me give you a specific
23 answer, a correct answer to that. Okay? The stars
24 refer to text which is in the current rule which is
25 not up here. The only thing that we put in there is

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1 where rule text is changed. Current rule text
2 includes what was published in 2000, some minor
3 corrections put in to correct typographical errors in
4 the draft final rules published since then, and the
5 extension of Subpart J. That is current rule language
6 now, and so what you see here is changes from current
7 rule language. Current rule language on the books
8 legally.

9 MEMBER WILLIAMSON: My question is if I'm
10 looking at this *Federal Register*, April 24th, 2002 -
11 am I accurately reading these stars.

12 DR. BROSEUS: No.

13 MEMBER WILLIAMSON: No.

14 DR. BROSEUS: No. What I just said -
15 April, 2002 does not take into account the most
16 current rules on the website here, and in January of
17 this year the *Federal Register* published Title 10,
18 which includes the typographical error updates and so
19 on.

20 DR. HOLAHAN: But those are minor changes,
21 so basically what you see in the rule text before you
22 is the current rule with some modifications, like
23 minor corrections.

24 MEMBER NAG: You very well clarified the
25 390, 490, 690. Could you do similarly for the 390,

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1 that is, are you going to allow overlap in that 700
2 hours of training for the 390? The 390, 490 - you
3 were very clear. I thought I knew what 390 was, but
4 the 700 would be separate for unsealed source, but if
5 you're having -- if you're allowing overlapping 490
6 and 690, and ultimately 290, why are you not allowing
7 overlap in that 390?

8 DR. BROSEUS: I have a note for myself to
9 go back to the working group that says clarify in the
10 supplementary information the meaning of these hours
11 and look at this overlap, and we'll discuss that in
12 the working group, and make sure we have an
13 appropriate statement there.

14 CHAIRMAN MALMUD: Okay. So Dr. Nag will
15 get that information clarified by you, Dr. Broseus, or
16 Dr. Zelac?

17 DR. BROSEUS: We'll take it as a comment
18 on the draft final rule in our development of the
19 final supplementary information.

20 MEMBER NAG: If that 390 can be clarified
21 that there is overlap, then you don't even need 396
22 because the --

23 CHAIRMAN MALMUD: Let see, I'm trying to
24 see who was next. Mr. Bailey.

25 MEMBER BAILEY: We have a real problem,

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1 and when I say "we", I think most of the states do.
2 When we go to adopt these NRC rules, we have to meet
3 a standard of clarity. These regulations fail
4 miserably on clarity, and I hope -- I mean, it's
5 obvious that if we're having this much trouble, it's
6 going to be very difficult for lawyers in the Office
7 of Administrative Law in the 33 states to accept these
8 regulations as being clear.

9 The second thing that we have to do is we
10 can't have interpretations in the regulations and
11 standards that you're going to apply an interpretation
12 of the regulations and Statements of Consideration.
13 Those are called underground regulations in most
14 states.

15 Thirdly, when you add a provision such as
16 you've done with 396, that is a - and I never can say
17 this word - substantive change in the regulations, and
18 we would have to go back out for public consideration
19 of those brand new requirements. So these regulations
20 as they're being proposed now will be extremely
21 difficult for many, many states to adopt. And because
22 they're not clear, we're just making a machine for
23 misunderstanding of requirements from state to state.

24 CHAIRMAN MALMUD: Thank you, Mr. Bailey.
25 That was the concern that I was raising earlier. I

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1 think that from the Office of Counsel, Ms. Chidakel,
2 pointed out the process has been adhered to, and I
3 accept that personally. I can't speak for the whole
4 committee. However, clarity is not there. It is
5 simply not there. Here we are, months of discussion -
6 we don't understand it. How is someone in another
7 state going to understand it? How is anyone in a
8 position of authority who doesn't deal with this
9 regularly going to understand it? There is no clear
10 guideline that is able to be looked at in one or two
11 pages and a conclusion drawn. That's my concern; that
12 we will bring embarrassment upon ourselves and the NRC
13 in passing regulations that are so cloudy that no
14 intelligent educated Ph.D. who hasn't been involved -
15 or M.D. - who hasn't been involved in these issues for
16 months can understand them. That's my concern. But
17 I'm speaking for myself here, and next, Dr. Diamond.

18 MEMBER DIAMOND: Let me give you an
19 example of that. I've just been reading the 396
20 language, if I could ask everyone here to take a look
21 at this, please. The construction - this is the
22 alternate pathway for the unsealed byproduct material
23 requiring a written directive. The construction, as
24 I'm reading it, is A, or B, plus C. Okay. A, or B,
25 plus C is the construction. A is essentially the

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1 grandfather clause for A use, who became A use prior
2 to October, 2005. B is individuals who are certified
3 by the boards prior to October, 2005, and C.

4 As I understand this, for a resident, for
5 example, who finishes his or her radiation oncology
6 training in the spring of 2006 or 2007, 2008 it is not
7 humanly possible for that person to ever give
8 parenteral administration of unsealed byproduct
9 material unless there's a typographic error.

10 MEMBER WILLIAMSON: I think if I could
11 clarify, it's really A or A Prime, or B, or B Prime,
12 and C, so within the A clause and B clause it
13 distinguishes between satisfying Subpart J versus the
14 current regulation, so I think on a technical point,
15 I don't think the concern is warranted.

16 MR. MOORE: Dr. Malmud, Scott Moore. If
17 the advisory committee's comment is that the additions
18 with regard to didactic hours in 396 or any changes
19 since the proposed rule are not clear, those types of
20 comments would be helpful to us, because they give us
21 some direction as a group, as a writing group on what
22 we can do with respect to the draft final rule. And
23 if you can in particular point out the areas that
24 aren't clear or give us directions on how to clarify
25 them, those would be helpful.

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1 I would note that with regard to the
2 public comments on the proposed rule, and also on the
3 agreement state comments, Mr. Bailey, on the proposed
4 rule, I don't recall that we got comments that the
5 rule itself wasn't clear, so with regard to what went
6 out and was commented on in the proposed rule stage,
7 I don't recall that we got comments back saying it
8 wasn't clear.

9 MEMBER DIAMOND: This is Dr. Diamond. But
10 again, getting back to my question which was premised
11 on clarity - let's take the hypothetical example of a
12 radiation oncology resident graduating from a program
13 in 2006. That individual will not be able to sit for
14 his or her boards until 2007, so obviously not board
15 certified at that point. This individual will not
16 satisfy Paragraph A, nor will they satisfy Paragraph
17 B. And because the construction -- Jeff, if I'm
18 wrong, please explain how I'm wrong.

19 MEMBER WILLIAMSON: Okay. A resident who
20 graduates and is not board certified would be able to
21 become an authorized user of 490 or 690 under the
22 alternate pathway, and therefore, they would satisfy
23 the first part of Clause A. It is an authorized user
24 under 490 or 690, and then the "or before October
25 25th" this is for the previous people - but if they

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1 become by whatever pathway a 400 or 600 AU, they
2 satisfy A.

3 MEMBER DIAMOND: So you're saying that the
4 commas before and after "or", that that should be
5 October 24, 2005 - I see, that's how you're
6 interpreting the --

7 MEMBER WILLIAMSON: Yes. That's --

8 MEMBER NAG: For 940 and 960.

9 DR. BROSEUS: Let me expand. October,
10 2005 is capturing people. You can come in under
11 Subpart J. Subpart J disappears October, 2005, and so
12 everything that comes after the "or" disappears in
13 2005. But a person could use either pathway up to
14 that point.

15 MEMBER DIAMOND: So again - so, Jeff, that
16 hypothetical individual, the day he or she finishes
17 his training will already have AU status obviously
18 under 490 and 690.

19 MEMBER WILLIAMSON: Even before they --

20 MEMBER DIAMOND: If they're in training,
21 right.

22 MEMBER WILLIAMSON: After three years if
23 they have the 700 hours mixture of didactic and
24 supervised training, just as fellows in current
25 training programs can become AUs through the action of

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1 the Radiation Safety Committee. I don't think that --
2 it's not going to be a big problem.

3 CHAIRMAN MALMUD: Who is next? Mr. Lieto.

4 MEMBER LIETO: Yes. I have a point, just
5 to be sure I understand, a couple of questions for
6 clarification for Roger. The intent as to what is
7 going to be published would be the final rule. Is
8 that correct? There's not really going to be any more
9 public comment. Is that correct?

10 CHAIRMAN MALMUD: That's correct.

11 MEMBER LIETO: Okay. A specific question
12 related to 396. A physician, ABR certified under 290
13 wants to come in and be approved for parenteral
14 applications, therapy applications - he would not be
15 able to be qualified under the board certification
16 route. I mean, he would not be able to be qualified,
17 period. Right?

18 DR. BROSEUS: If I recall correctly from
19 previous discussions in this advisory committee, many
20 times the training that a person has under 290 is
21 going to get them close to or qualify them for 300
22 use, and so you don't have to worry about 396. Ron,
23 we talked about this before. Do you want to expand
24 upon that?

25 CHAIRMAN MALMUD: Dr. Zelac.

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1 DR. ZELAC: I think the point to be made
2 is that 396 was intended very specifically for
3 radiation oncologists to be able to use unsealed
4 material that required a written directive. For those
5 who have been trained specifically not for radiation
6 oncology, essentially for nuclear medicine, it would
7 be expected that those individuals would satisfy the
8 requirements for 390 if they intended to use materials
9 for which a written directive was required.

10 The last point to be made is that some of
11 the training that such individuals, and a large part
12 of it, actually, that individuals would receive under
13 the 290 would be applicable to the requirements under
14 390, a lot of the basic information would cross over.
15 Specific information relating to, if you will,
16 therapeutic use, use of unsealed materials in
17 therapeutic quantities would have to be added to the
18 training such individuals would receive before they
19 would qualify for 390 use.

20 MEMBER LIETO: Mr. Chair, a follow-up
21 point. I guess the reason I was asking is that there
22 may be a number of areas where nuclear medicine
23 physicians don't want to deal with Iodine, nor have
24 that authorization or those restrictions on their
25 license. Okay? I shouldn't say restrictions, but

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1 that latitude on their license, and want to only deal
2 with the non-Iodine therapy applications.

3 DR. BROSEUS: Well, they could apply for
4 just whatever they need. They don't have to apply for
5 --

6 MEMBER LIETO: Well, that's kind of my --

7 DR. BROSEUS: That's not an issue.

8 MEMBER LIETO: Well, that's my point, is
9 that if a physician comes in who's board certified and
10 is approved under 290, what you're saying is that he
11 has to come under 390 or that's it, because if you
12 look at A and B, it doesn't allow anybody who's board
13 certified and approved under 290 to come in and get
14 396.

15 MEMBER NAG: Well, I think the confusion
16 is 396 was meant only for people for radiation
17 oncologists, basically only for people who qualified
18 under 400 and 600 who solved the problem that the
19 radiation oncologists may not handle the unsealed
20 sources. The 396 has nothing to do with nuclear
21 medicine physician, so when you're talking about 396,
22 only refer to radiation oncology training.

23 CHAIRMAN MALMUD: That is my
24 understanding, as well, Dr. Nag.

25 DR. BROSEUS: That's it.

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1 CHAIRMAN MALMUD: And Dr. Broseus confirms
2 that. Does that answer your concern, Mr. Lieto?

3 MEMBER LIETO: Well, you answered my
4 question. Yes.

5 CHAIRMAN MALMUD: Thank you. I think that
6 Sally Schwarz, you were next.

7 MS. SCHWARZ: I just wanted to ask a
8 question.

9 CHAIRMAN MALMUD: I couldn't hear you.
10 I'm sorry.

11 MS. SCHWARZ: Sally Schwarz. I'm just
12 concerned about the authorization for nuclear medicine
13 physicians under 390. Actually, that's what I'm
14 concerned about, and I think that's what Dr. Eggli was
15 going to raise, as well.

16 CHAIRMAN MALMUD: All right. Then we'll
17 pass to Dr. Eggli.

18 MEMBER EGGLI: Okay. Actually, Jeff asked
19 his questions with respect to 400 and 600 users.
20 Nobody has so far asked the same questions for 100
21 series users, 200 series users, or 300 series users.

22 When I look at the -- there are a lot of
23 different boards who qualify people in these areas.
24 When I look at the American Board of Nuclear Medicine,
25 I have no problem assuming that the American Board of

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1 Nuclear Medicine will hit the training mark. My big
2 problem is the vast 70 percent of all nuclear medicine
3 in this country is practiced by diplomats of the
4 American Board of Radiology, and the American Board of
5 Radiology trains people in a wide variety of imaging
6 modalities, and the training allowed is governed
7 largely by the regulations. So as the American Board
8 of Radiology looks at trimming its previously 1,000
9 hour training for a radiologist in nuclear medicine to
10 700 hours, it's hard to get everything in.

11 And the biggest problem that I'm seeing
12 here is the 200 hour requirement for 300 uses. First
13 of all, I have a son who attends a well-known college
14 in the northeast. They spent three hours a week in
15 class, 15 weeks in a semester, so that about 45 hours
16 for a college course. Two hundred hours is 4-1/2
17 college courses devoted to issue of safe handling of
18 radiopharmaceutical strikes me as a little on the high
19 side for safe handling. No, actually it strikes me as
20 wildly on the high side for safe handling.

21 The other issue is, now I only get these
22 people - first of all, I think I'm the only person
23 sitting at this table who trains people for 300 uses
24 or 200 uses. I only get these people for 700 hours.
25 If I now lose five weeks, which is 40 hours a week of

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1 their time to didactic training and safe handling, I
2 now have less than three months to teach them clinical
3 nuclear medicine and make them competent.

4 I think this rule will have the unintended
5 effect of impairing the clinical experience of
6 diplomats of the American Board of Radiology in
7 clinical nuclear medicine, and that may have a
8 limiting effect on how they perform clinically, and
9 maybe a greater hazard to public safety than the hours
10 of training.

11 I sat down and designed a didactic
12 radiation safety program for my residents, including
13 every conceivable topic, plus supervised what I would
14 call laboratory experiments where we set up
15 experiments on the use of the equipment and safe
16 handling, and we monitor them in a laboratory
17 environment, much like you would have gone to a lab
18 section in a college course. I came up with 50 hours
19 of training, and I think 50 hours actually for Part
20 200 uses is very appropriate, and I think something
21 closer to 100 hours for Part 300 would be appropriate.
22 Because again, for 300 uses, we talk about the broad
23 uses of so many radiopharmaceuticals.

24 Now I've got two basically - I have orally
25 administered therapies, and I have parenterally

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1 administered therapies. And for orally administered
2 therapies, those we're only going to do radio Iodine,
3 they have an 80-hour requirement of training right now
4 on the alternate pathway. And again, the argument
5 that I'm not going to have to train the alternate
6 pathway is specious because I'm going to for the
7 reasons that Dr. Diamond described, I'm going to have
8 to train everybody to alternate pathway rules.

9 Now we're saying that we need another 120
10 hours of training, of didactic training to handle one
11 other category of administration, which is basically
12 beta emitters administered parenterally. And the
13 safety issues don't change if I put it in a joint, if
14 I inject it into the peritoneal cavity, if I inject it
15 intravenously, whether it's really a coloital beta
16 emitter or in solution - none of the safety issues
17 that I need to train for changed, so I've got two
18 categories of therapy that I need to train for under
19 Part 300, oral administration and parenteral
20 administration.

21 I think NRC has recognized that there are
22 two broad categories of therapeutics in the way
23 they're now describing Part 396. So I think 200 hours
24 is unnecessarily excessive, and will - since I'm only
25 going to get them for 700 hours, is going to limit my

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1 ability to make them clinically competent. And I
2 think that is going to damage healthcare in the United
3 States.

4 DR. BROSEUS: Mr. Chairman.

5 CHAIRMAN MALMUD: Dr. Broseus.

6 DR. BROSEUS: We're moving into the other
7 topic, which I did want to address, and if I just
8 might present a couple of slides to talk about that,
9 and then we can come back to some of the other issues.
10 And that is, we did have a teleconference on October
11 5th to talk about the issue of - I'm going to put
12 quotes around - "didactic hours", and we presented
13 recommendations that came forward from our working
14 group, which are appearing on the slide behind me now,
15 which has the subdivision, including the 200 hours of
16 didactic training that Dr. Eggli just mentioned. And
17 one of the objectives of the working group today is to
18 get any recommendations that ACMUI may have about what
19 is the proper number of hours.

20 Additionally in that meeting, we heard
21 some discussion about definition of what the hours
22 are. And, for example, in those sections in Part 35
23 dealing with T&E, the term "didactic" isn't used.
24 What we have is classroom and laboratory training,
25 except for individuals to qualify as nuclear

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1 pharmacists. And for that particular category in the
2 current rule, and in the proposed rule which we
3 published, there was a reference to didactic hours
4 requirement for nuclear pharmacists.

5 Now the working group has been thinking
6 about these issues, especially since the telecon, and
7 it would be also useful if you feel there's a need to
8 look at the definition more to get some feedback, and
9 a basis if you think there's a need to change the
10 definition.

11 Now the working group was considering
12 eliminating the term "didactic" from pharmacy for the
13 requirements for nuclear pharmacist, and substituting
14 the term classroom and laboratory hours to make it
15 clear. And so what I'm suggesting is that as we move
16 forward, and it's 9:32, that we also would benefit if
17 you have comments about what the proper balance of
18 hours is, a basis for a change, and Dr. Eggli
19 suggested some, as well as is there a need to look at
20 the definition of didactic hours, that is classroom
21 and laboratory hours, which is what most people I
22 think mean by that term, if there is a need to
23 elucidate that, should it be in definitions and rule
24 space, or in supplementary information. You, Dr.
25 Malmud, pointed out that one could get into a slippery

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1 slope if you start defining things, and so on.

2 I'd also like to - since I got the chair
3 back - just mention, we've already talked about our
4 closing period for comment being October 18th. We
5 plan right now to hopefully have this rule go to the
6 Commission by mid-November, and would anticipate
7 publication in 2005. Thank you for letting move on a
8 little.

9 CHAIRMAN MALMUD: Certainly. Dr.
10 Williamson is chomping at the bit.

11 DR. BROSEUS: I'm at your disposal.

12 MEMBER WILLIAMSON: I wanted to ask a
13 question to Mr. Bailey, who has gone away, so perhaps
14 I should -- I'll just ask. I'll ask, I think, a
15 follow-up question to what Dr. Eggli has presented.

16 In radiation oncology, which is a 4-year
17 program, I think the 200 hours, while not absolutely
18 required by the ABR, I think is met by virtually most
19 of the diplomats. And this is met not just by courses
20 that deal with sealed sources and brachytherapy. They
21 have a long radiation physics sequence. They have
22 radiation biology. They also have probably formal
23 instruction in statistics and design of clinical
24 trials and interpretation of clinical studies, et
25 cetera; as well as numerous sessions on radiation

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1 safety dealing with more specific devices and programs
2 that they have.

3 For the 700 hour training program you
4 administer, I assume these are diagnostic radiology
5 residents who also get a similar broad didactic
6 training experience in radiation physics, radiation
7 biology, and what happens if you get inadvertent
8 exposures to fetuses and so forth, teratology which is
9 equally applicable to external sources of radiation
10 and internal in terms of the basic principles. So you
11 really have to give 200 hours of your 700 hour
12 segment.

13 MEMBER EGGLI: If I look at the diagnostic
14 radiology physics curriculum, I come up with another
15 50 hours of didactic training in the rest of physics
16 for radiology, so for our radiology residents now have
17 actually planned a roughly 100 hour course; 50 of
18 those hours, which as we look at it, we felt were
19 relevant to the nuclear medicine requirements, and 50
20 hours that we thought were probably not relevant to
21 nuclear medicine requirements because they deal with
22 devices and don't fall under what we thought was the
23 spirit of the regulation.

24 CHAIRMAN MALMUD: Dr. Nag.

25 MEMBER NAG: Dr. Broseus, you had in your

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1 previous slide, you had the requirement for 35 up to
2 35 390, could you enumerate now for 490 and 690 in one
3 slide. That way we can show the whole thing. I mean,
4 that again - 700 and 200, but my question is that
5 someone who has this 200 has -- included in that body
6 of knowledge is the requirement partly of the 390, so
7 in the 396 you are asking for additional 80-hours
8 specifically for unsealed sources. And that is the
9 specific requirement. It's not part of your
10 overlapping requirement.

11 For someone who has spent 200 hours in
12 didactic to then have another 80-hours that is
13 separately for unsealed which is partly covered in the
14 radiation oncology training, but hard to dissect out
15 that there was 80-hours built within that 200 hours -
16 is going to be an excessive requirement for a board
17 certified radiation oncologist, because when you are
18 trying -- I give my course in brachytherapy, and my
19 course is probably one of the more extensive in
20 brachytherapy in the country. And I can accomplish
21 that within a period of two to three years in about 80
22 hours that is all about the specific brachytherapy
23 things. So that includes some of the requirements in
24 handling liquid or unsealed source also. So if you
25 ask me how many hours did I give last year on

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1 specifically unsealed source out of my 200 hours,
2 that's very difficult to dissect out, so I think that
3 80 hours additional for 396 is very, very -- it's
4 probably an over-burden.

5 DR. BROSEUS: Would you like me to address
6 the first question, which is how many hours for 490
7 and 690 it's 200 hours.

8 MEMBER NAG: I know, 200 and 700.

9 DR. BROSEUS: Okay.

10 MEMBER NAG: What I meant was having it on
11 that so someone can look at it and automatically see
12 it. I mean, I know how many hours it takes.

13 CHAIRMAN MALMUD: Excuse me. May I
14 interrupt. I just want to clarify Dr. Broseus'
15 answer; that the total hours for 490 and 690 is 700,
16 of which 200 would be didactic in each case. Is that
17 what you said?

18 DR. BROSEUS: Classroom and laboratory
19 training.

20 CHAIRMAN MALMUD: Thank you. Now the
21 second question - Dr. Nag's question. Well, actually
22 it's a point. You're making a point that you believe
23 the 80 hours of additional training for the handling
24 of unsealed sources for radiation oncologists who are
25 otherwise fully trained and will have had already

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1 completed physics training, which includes some hours
2 that overlap into unsealed sources, that the 80-hour
3 requirement may be excessive.

4 MEMBER NAG: Yes. I mean, basically at
5 that point the only extra thing you need to know is
6 what do you do in terms of a liquid spill that we
7 generally do not handle in a sealed source, although
8 we partially do, so there is really very little extra
9 knowledge required to then be able to handle unsealed
10 source.

11 CHAIRMAN MALMUD: Dr. Diamond.

12 MEMBER DIAMOND: Just to clarify
13 something; so you're asking about grandfathering of
14 board certified radiation oncologists who are not
15 licensed for 300 level uses.

16 MEMBER NAG: Right.

17 MEMBER DIAMOND: And you feel that a
18 radiation oncologist who's been in practice 10 or 20
19 years, who has never been licensed to give Strontium
20 or Iodine, or P-32, that that individual can start
21 giving these agents, or Zevelin, or whatever - going
22 from zero to that level in less than 80 hours.

23 MEMBER NAG: In less than 80 hours,
24 because you have already the body of knowledge on what
25 to do for therapy. Now you have to get the additional

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1 requirement on what to do if you have a spill. In 80
2 hours, what are you going to teach someone, a
3 curriculum that will cover 80 hours.

4 MEMBER DIAMOND: If I may respond to focus
5 this discussion just towards the radiation oncology
6 community for a minute. My feeling is, is that I
7 would be satisfied if the following exists. I'll be
8 satisfied if it is either in the Statements of
9 Consideration or in other manners that the spirit that
10 Ron Zelac mentioned for 490 and 690, and which was
11 mentioned elsewhere today regarding the enumeration of
12 hours, if that is in that same spirit, I would be
13 happy, because what that means is that an individual
14 going through the board pathway, which we intended all
15 along to be the AU pathway, if that individual, once
16 he or she becomes board certified, can satisfy all the
17 300 level uses. So if that spirit is interpreted in
18 that manner, I'm very happy in that regard, number
19 one.

20 Number two, recognizing that every single
21 radiation oncology resident coming out will have to
22 fall under 396 until he or she becomes board certified
23 at a minimum, I think that that is okay, as well,
24 because during the course of his or her training, he
25 or she will easily have satisfied the 80-hour

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1 requirement, and you need to, of course, have the
2 three cases which is not a big deal. And they've
3 already satisfied Paragraph A by virtue of their other
4 training, so that's good.

5 The third scenario is what Dr. Nag is
6 mentioning - what about those radiation oncologists
7 who are Aus, have been in practice for many years, but
8 are not licensed for 300 level uses. In that
9 particular case, I do think that individual needs
10 additional training. Is the number 80 hours? I don't
11 know. Is the number 5 hours? No.

12 Quite honestly, my opinion, for that
13 physician who has not been doing any of these uses and
14 may have been out of practice for 10 or 20 years, I
15 really don't have a big problem with the 80 hours,
16 Subir. I really don't. So anyway, to bring this to
17 focus, I think if we can come to consensus on the
18 spirit of enumeration, that will satisfy a major
19 issue. We now have clarification for the 396
20 alternate pathway use that these residents coming out
21 of training or folks who have not yet passed their
22 boards because they failed the first time or two, will
23 be taken care of.

24 And as far as the grandfathering issue for
25 folks that have never been licensed for 300 level

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1 uses, I personally believe they do need additional
2 training. And I think we can discuss what the number
3 is - is it 80, is it maybe a little less than 80, but
4 certainly not, in my opinion, going to be 5 or 10.

5 MEMBER NAG: No, I think, David, you are
6 somewhat mistaken. A person who had finished their
7 residency, just finished their residency and became an
8 authorized user in 490 and 690, will still require 80
9 hours to be able to do the 390. And that will require
10 that you have to demonstrate an additional 80 hours,
11 and that is excessive because that person has recently
12 finished training, and many of those 80 hours were
13 already included in that 490 training.

14 MEMBER DIAMOND: By my understanding,
15 Subir, and please, staff, correct me if I'm wrong - by
16 my understanding, those 80 hours should easily have
17 been satisfied during the residency program. In other
18 words, that person, the day he finishes training, does
19 not need to then go and take an additional 80-hour
20 course. All you need to do is have attestation that
21 those 80 hours were satisfied during your 4-year
22 residency. Am I correct on that?

23 MS. SCHWARZ: That's correct.

24 MEMBER DIAMOND: Okay.

25 CHAIRMAN MALMUD: Thank you. Sally.

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1 MS. SCHWARZ: I still have concerns about
2 the 200 hours for the nuclear medicine physicians.
3 That's a concern of mine that I believe that that 200
4 hours is too high in terms of nuclear medicine
5 physicians in additional training.

6 MEMBER EGGLI: I would like to speak to
7 the logic of that. This is Dr. Eggli. My
8 understanding of the way the regulation is written, as
9 the subparts get higher numbers, those are both
10 greater complexity and higher risk for the patient.
11 But yet, as we look at Part 300 T&E requirements, Part
12 400 T&E requirements, and Part 600 T&E requirements,
13 they are identical.

14 If, in fact, there is an escalation in
15 risk and complexity of therapy as we go from Part 300
16 therapies to Part 400 therapies, to Part 600
17 therapies, then again it seems that the requirement
18 for 200 didactic hours in Part 300 is excessive
19 because it, in fact, matches the didactic requirement
20 for what are acknowledged to be higher risk and more
21 complex therapies that a Part 300 user could not do.

22 DR. BROSEUS: I'd like to just interject,
23 that when you get to the 300 level, the split starts
24 to become the form. The 300 is unsealed, 400 and 600
25 is sealed. And so you may have equal level of

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1 complexity doing Zevelin, and dealing with some of the
2 things that Dr. Nag was talking about --

3 MEMBER EGGLI: I would, in fact, argue
4 that there is a different level of complexity. And,
5 in fact, you argue that - "you" being NRC staff -
6 argued that when you put the spheres into
7 brachytherapy, because you considered them more
8 complex than could be covered. And again, it looks to
9 me for all practical purpose, like a 300 material, so
10 that again, I think your own logic system says that
11 there is greater complexity and higher risk in manual
12 brachytherapy.

13 CHAIRMAN MALMUD: Excuse me. Did you want
14 to respond to that, Dr. Broseus?

15 DR. BROSEUS: One thing I want to say is
16 that the major split at that level is the physical
17 form.

18 CHAIRMAN MALMUD: Dr. Zelac, did you want
19 to respond to that?

20 DR. ZELAC: Yes, I'd like to make a point.
21 For 490 use and for 690 use, in addition to the
22 classroom and laboratory, plus work experience which
23 are common among 390, 490, and 690, the additional
24 risk levels that you speak of are dealt with by the
25 additional requirements for 490 and 390 in the

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1 alternate pathways to have three years of supervised
2 clinical experience. That doesn't appear for the 390,
3 so the higher risk levels that are associated with 490
4 and 690 are covered in the requirements by the
5 additional clinical experience of three years.

6 CHAIRMAN MALMUD: Thank you. Does that
7 clarify it? Does that satisfy your concern?

8 MEMBER EGGLI: No. My concern that 200
9 hours in Part 300 uses is excessive is not satisfied.

10 CHAIRMAN MALMUD: So your point is that
11 the 200 hours for 490 and 690 may be valid, but if
12 that's the case, your argument is that the 200 hours
13 for the 390 is excessive by comparison.

14 MEMBER EGGLI: Yes.

15 CHAIRMAN MALMUD: All right. Your
16 argument has been heard. Yes. Is it Mr. Moore or Dr.
17 Moore? I'm sorry.

18 MR. MOORE: Mr. Moore.

19 CHAIRMAN MALMUD: Mr. Moore.

20 MR. MOORE: I guess an other thing to
21 consider is that there is a very large group of
22 stakeholders that recommended something in the range
23 of 200, and that's the agreement states for the 300
24 series. And that's something we have to consider.
25 The working group certainly looked at that, and they

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1 looked at numbers less than 200, or slightly less than
2 200, but arrived at the recommendation of 200 to the
3 agency, which segues into the comment that Mr. Bailey
4 made regarding to the petition.

5 I do want to let the ACMUI know that there
6 is a petition. It has been docketed. It's from the
7 Organization of Agreement States, many, many agreement
8 states signed onto it. It has been accepted by the
9 agency as a petition. I think it's premature to say
10 that it will result in a separate rulemaking. There
11 are a number of options that the agency has in how to
12 deal with petitions. They range from addressing it as
13 a comment, to handling it as an absolute separate
14 formal rulemaking in parallel to this rulemaking. It
15 certainly deals directly with these issues of didactic
16 hours, both for the alternate pathway and for boards,
17 so it overlaps entirely with the issues that are here.
18 But it's a very formal mechanism in the rulemaking
19 process, and we will treat is very formally as an
20 agency, so the committee needs to know about that.

21 I guess I'd like to also go into something
22 that will maybe take this above the technical
23 discussion that we're having. The rule is due to the
24 Commission by the staff in mid-November. That due
25 date is non-violable unless the Commission gives us

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1 relaxation in the date. We would need a strong basis
2 for an extension to that date, and so we're looking at
3 a due date to the Commission about a month from now.

4 If the ACMUI believes that additional time
5 is needed for the ACMUI to review and comment back to
6 us, or for the public to look at again for that
7 matter, then we would need you to provide us a comment
8 to that effect. One option you have is to make that
9 comment to us as a body, but beyond just telling us
10 that you need additional time to do that, I think you
11 would be well served in telling us the basis for
12 needing that additional time, because we would
13 certainly need to tell the Commission why we would
14 need the additional time. And then it's up to the
15 Commission to decide whether they're going to give the
16 staff additional time before we present the rule to
17 the Commission.

18 In addition, we've certainly heard you,
19 the body, saying today that public comment -
20 certainly, Dr. Diamond raised this - is needed on some
21 of the more significant areas, like 396. We checked
22 with our Office of General Counsel. The comments that
23 came in during the public comment period and the
24 changes that were made by the staff subsequent to the
25 public comment period, namely, the addition of 396 and

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1 this addition of didactic hours, don't pass the
2 threshold for going out for public comment again in
3 terms of significance, so we're not legally required
4 to go out for public comment again.

5 That said, if the ACMUI believes that we
6 should go out for public comment again, that's
7 certainly a comment that you can give us, and you can
8 make a recommendation that we should do so. Again, I
9 would recommend that you give us a reason for going
10 out for public comment again, and the staff would
11 certainly take that into consideration, and inform the
12 Commission that you recommended that, and the
13 Commission would take that under advisement.

14 CHAIRMAN MALMUD: Thank you, Mr. Moore.
15 Perhaps I --

16 MR. MOORE: Charlie may have additional
17 comments about that.

18 MR. MILLER: I want to make some comments,
19 but Ralph has had his hand up, and if he has a point
20 he wants to make --

21 CHAIRMAN MALMUD: Well, rather than doing
22 that at the moment, may we get back to Mr. Moore's
23 observation, because there are two issues that have
24 arisen, Mr. Moore - one came from Mr. Bailey, and that
25 is his view, meaning the view of the states that Part

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1 396 is, in fact, from their view a substantive change.
2 That's the term that he used.

3 Counsel for the NRC, you tell us, feels
4 that it's not a substantive change, so there seems to
5 be a disagreement between the states and Counsel for
6 the NRC as to what constitutes a substantive change.
7 But NRC has the final say, and I will defer to you in
8 a moment, then there is no substantive change because
9 NRC has the final say. But Mr. Bailey did say, and I
10 was taking down notes as he was talking, that the
11 states regard 396 as a substantive change and want it
12 to go public. That comment will come forward from the
13 ACMUI, namely, a protest that the states regard 396 as
14 a substantive change which has not had adequate
15 opportunity for public comment. That's one point.

16 The second point is that Dr. Zelac agrees
17 with us, though it was not his presentation, that
18 there is a dilemma in the board versus alternate
19 pathway in the fact that the alternate pathway does
20 dictate to the boards that which they should teach in
21 order for a graduate of the boards to qualify for
22 practicing, even though that individual may not have
23 had the opportunity to, or may have failed taking the
24 board certification exam the first time. And I would
25 point out to you, which is a matter of concern to me,

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1 that if we graduate a number of physicians after four
2 years of college, four years of medical school, four
3 years of residency training in radiation oncology to
4 enter a field that is nationally under-supplied and
5 create a roadblock to that individual practicing in a
6 small town in a rural state, as represented by the
7 states, we will have created a great embarrassment for
8 us, the NRC, and I am sure it will reverberate in
9 Congress, because this is a field which is terribly
10 short of individuals. The number of training programs
11 in radiation oncology is not enormous to begin with,
12 the number of graduates is not enormous, the shortage
13 is great. These individuals are not incompetent
14 because they didn't pass the boards. They simply
15 haven't passed the boards. There's a cut-off point,
16 so I believe that we have to look at this very
17 carefully, both for the public good - mainly the
18 patients, as well as for those individuals who have
19 spent so many years in training. And with all due
20 respect, it's not quite analogous to passing the bar
21 exam. There are differences, though there are
22 similarities. Now I defer to distinguished Counsel.

23 MS. CHIDAKEL: Thank you. I just want to
24 clarify a couple of things. First of all, please note
25 I did not say that 396 was not a substantive change.

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1 Actually, I specifically mentioned that 396 was one of
2 the only changes, the only real changes that I saw to
3 the rule from the time that the rule was proposed. I
4 specifically said that.

5 I didn't pass on the issue of whether it
6 was a substantive change. In that connection, let me
7 raise - since we were talking about the Office of
8 General Counsel's view on republication in the *Federal*
9 *Register*. The test is whether the change is such that
10 it is so far from what was proposed that the person
11 who read the rule would not have been given proper
12 notice that they could comment on that issue. I know
13 that's kind of complicated, but what I'm trying to say
14 is the decision was made that this was not outside the
15 whole area of T&E, of training and experience, which
16 was the focus of the rulemaking, so that is why I'm
17 talking about the hours now - the hours issue now,
18 396. That is why the decision was made by OGC
19 management that this was not necessary, legally
20 necessary to be republished. As I believe Scott
21 pointed out, certainly that doesn't mean we can't
22 republish it if there are policy issues, if the ACMUI
23 wants to come out and make that argument and have a
24 basis, and give us reasons why they feel that this is
25 not -- while it isn't legally necessary, you know,

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1 certainly you can make an argument as to why you think
2 it's a good idea. But that is the issue. And the
3 issue is that we didn't see anything in the changing
4 in the hours issue that was totally, completely
5 outside of the scope of the proposed rule. Does your
6 answer your question?

7 You made another point. I'm sorry that it
8 has escaped me now.

9 CHAIRMAN MALMUD: There were two issues.
10 One was with respect to 396, and the other was with
11 respect to the dilemma created by establishing
12 criteria for the alternate pathway which would be
13 applicable to all residency training programs because
14 a certain number of people who complete their
15 residency successfully do not pass their board
16 certification within a year. By the time they've
17 graduated from the residency, completed the residency,
18 if you will; and, therefore, they would be limited in
19 their employment opportunities to very large
20 institutions where they'd be under the umbrella of
21 someone else, leaving the smaller facilities,
22 particularly those represented by the states which are
23 very often in smaller cities, uncovered by graduating
24 fellows.

25 DR. BROSEUS: I put on my health physicist

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1 hat for a minute.

2 CHAIRMAN MALMUD: Please do.

3 DR. BROSEUS: And those are exactly the
4 people that sometimes the health physicist is
5 concerned about. Many serve as their own RSO, and
6 that's in the rule. So the concern is to make sure
7 they have sufficient training. Now if they could get
8 it with less hours and it applies to unsealed sources,
9 I'm assuming that these individuals, even though
10 they're not board certified, can go out and practice
11 medicine, and that's not our concern. Okay. They're
12 a licensed physician. That's all it takes in the
13 rules. So the real question then is what is a
14 sufficient number of hours - and if we can focus on
15 that today and by the 18th, and satisfy both needs,
16 we've gotten home.

17 CHAIRMAN MALMUD: Dr. Diamond.

18 MEMBER DIAMOND: To answer Dr. Malmud's
19 question regarding do we think this needs to be
20 published for comment - based upon the discussions we
21 had earlier, my personal feeling, and this is not
22 represented by necessarily the radiation oncology
23 community. This is my personal feeling. My personal
24 feeling is that if the Statements of Consideration do
25 reflect what I believe is a logical enumeration of

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1 hours, given all of the potential algorithm pathways
2 that we talked about, that with respect to the
3 radiation oncologists and 300 level uses, I can live
4 with this.

5 CHAIRMAN MALMUD: Thank you. Dr. Miller.

6 MR. MILLER: If you will indulge me - as
7 a layman, I've listened to this discussion for about
8 an hour and a half now, and I think it's been a lot of
9 discussion, debate, whatever you might want to call
10 it. At the risk of sounding obnoxious, I hope I
11 don't, but what we have to understand is the
12 Commission has given the staff a challenge of
13 stabilizing the medical regulations. I think we all
14 agree - Dr. Diamond made a statement early, bad
15 regulation - if I remember the quote - with good
16 guidance is not the way to go. So no one wants to put
17 out - the staff certainly does not want to put out bad
18 regulations.

19 That said, Dr. Broseus and the working
20 group and members of my staff have been working
21 extremely hard over the last couple of years to try to
22 come up with regulations that will meet what NRC feels
23 needs to be done with regard to regulating the
24 community. However, taking in all stakeholder's
25 comments, I'm drawn to the conclusion that there is no

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1 regulation that we can promulgate in this area that is
2 going to satisfy everyone.

3 The agreement states have expressed some
4 serious concerns with regard to the regulations. Part
5 of what the agreement states dilemma is, they are co-
6 regulators with us, and in talking to many members of
7 the agreement states, I think their preference would
8 be to have something that's more prescriptive, that
9 would allow them to regulate.

10 In talking to members of the medical
11 community, I think people want flexibility so that
12 it's not so prescriptive, that people are limited in
13 what they can do, so that creates somewhat of a
14 dilemma to satisfy our stakeholders.

15 With regard to the dates, the schedules
16 for the promulgation of the rule, I don't want the
17 staff to come across as being bureaucratic, and we
18 have to meet this date come hell or high water. We're
19 going to meet it regardless of what people's views
20 are. However, my concern is for those of us in the
21 room who are old enough to have taken FORTRAN in
22 college and used it as a computer language, I don't
23 want to get stuck in an infinite do-loop in trying to
24 get this rule out, and that's what I feel that we're
25 getting to. We can't continue to have bring me a

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1 rock, comment on it. Bring me a rock, comment on it.
2 We have to be able to reach a point that we can get a
3 rule that's meaningful, that puts people in place that
4 we are satisfied are qualified to do this job, but not
5 put such a burden on the industry, if I may call it
6 that for this aspect of it, that they can't practice.

7 So if we were to go to the Commission, and
8 I don't know the Commission's view of that, because
9 the Commission gets very anxious to not to want to
10 delay rulemakings. If I were to go to the Commission
11 and ask them for more time, I'd have to be able to
12 articulate why that time is needed, what's going to
13 come out of it for the general good, and give them
14 some rigid answers as to why at the end of that time
15 we're going to come up with a product that's better.

16 The product that's better in my view would
17 need to have a consensus, at least by the staff, the
18 committee - I don't know if we can get a consensus
19 with the agreement states - that what we've come up
20 with is workable. And if we were to go out and ask
21 for more time, make further changes to the language as
22 Roger and the working group have crafted it, I would
23 ask the committee to have the involvement to the
24 extent that whatever is recrafted is liveable with the
25 committee, so that we don't have to come back here in

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1 six more months and continue to debate the issue as we
2 have for the last couple of years.

3 That said, as time marches on, part of the
4 reason we had to extend Subpart J was we were unable
5 to draw a conclusion over the past year, and
6 promulgate a rule that would give boards enough time
7 to do what they need to do with regard to
8 certification. My fear is we're going to end up in
9 that same dilemma again this year. That's a dilemma,
10 and what do we do about it? So that's the world that
11 I see that we, the regulator, live in. How can we get
12 through it?

13 CHAIRMAN MALMUD: Thank you. Are you
14 going to address the comments that Dr. Miller made,
15 Dr. Lieto?

16 MEMBER LIETO: Yes, and then some. I
17 guess what I see as a problem is the sort of like
18 almost less than a week deadline that we have, where
19 we are -- with what Mr. Moore said, we're kind of
20 really, from my perspective, being put into a corner.
21 All right. And we don't have an alternative.

22 I think if we could maybe have a few more
23 weeks to address these changes, because I'd like -
24 again, this is my opinion - what I see are three major
25 areas of what looks to me as changes in this piece

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1 here. One has to do with the radiation safety
2 officer, which appears to have met the intent of the
3 ACMUI, but again I'm going to come back to this - I
4 want to see this in the context of the whole Part 35.
5 The training and experience, which probably is the
6 number one issue that is before this group, and the
7 grandfathering aspect, especially with respect to
8 authorized medical physicists.

9 I think if we - again my opinion is that
10 if we could have all these changes, including the
11 proposed by the working group, before us and maybe in
12 a teleconference in the next week or so with the
13 committee, or maybe even a subcommittee if the Chair
14 deems appropriate, to look at all these changes, and
15 then get back to the committee as a whole, we might be
16 able to address these within a matter of two, three,
17 four weeks at most.

18 Now I don't know if that's unreasonable.
19 I mean, if that's too long, then I guess we're painted
20 into a corner, and I don't have a suggestion. So
21 that's a suggestion. I do still have some points to
22 make on the hours, and Dr. Eggli's issue about 390
23 hours. So I don't know if we want to address that
24 comment that I --

25 CHAIRMAN MALMUD: Well, why don't you

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1 finish your comments, and then we'll move on to the
2 next one.

3 MEMBER LIETO: I tried to -- I think
4 there's some -- trying to understand where the working
5 group came from in terms of the number of hours that
6 are proposed in here. I think what have been also --
7 the 392s, and 94, and 96 in here also, but if you look
8 at Subpart J, which is the current where we're at
9 right now, if I am interpreting 930 right now
10 correctly, it requires 80 hours of training and
11 experience, plus 13 thyroid cases, is the way
12 currently is the 390 requirement. And that the 80
13 hours would be the didactic portion of training and
14 experience.

15 If we look at the proposed 390, we've now
16 gone up from 80 hours to 700 hours, and 200 of those
17 700 hours, which were 80 before; in other words, we've
18 gone from 80 to 200 hours of didactic training,
19 laboratory and classroom experience. If we look at
20 the 392 and 4, which are the thyroid in the parenteral
21 requirements requiring 80 hours for thyroid, 80 hours
22 for the other - which comes out to 160 hours if you
23 wanted to sort of go back the route of I want to get
24 parenteral, and then I want to get thyroid without
25 going the 390 route. Basically, I'm trying to get to

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1 some type of an equivalency.

2 The 200 hours still is almost a factor of
3 one-third higher, just even using that relationship.
4 So it gets, I think if we're even trying to keep
5 things at even scale, the 200 hours is probably a
6 factor of maybe two or close to that high. In other
7 words, maybe something like 100 to 120 or 30 hours
8 might be more appropriate for the 390 aspects, and
9 bring it more into line what we're requiring for the
10 other uses. But not having sort of a sense of where
11 these numbers came from originally, other than they
12 were just proposed by, I'm assuming the OAS. Is that
13 correct? Is that where the numbers are - okay. So
14 that might be maybe a starting point to suggest in
15 adjusting the 200 hours, if that's one of the things
16 we wanted to achieve right now.

17 CHAIRMAN MALMUD: Does that complete your
18 comment?

19 MEMBER LIETO: Yes, thank you.

20 CHAIRMAN MALMUD: May I -- oh, Dr.
21 Williamson.

22 MEMBER WILLIAMSON: I have a comment, too,
23 which I think is relevant. I think I agree with Dr.
24 Diamond that from radiation oncology and medical
25 physics point of view, this seems to me to be a great

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1 improvement, and within the limits of my sort of
2 ability to digest the details of legalistic language,
3 I think it's resolved many of the major concerns that
4 our community has had.

5 Having said that, I'm a strong believer in
6 the dictum that the devil is in the details, and there
7 are changes of commas and ands, and ors that are very
8 difficult to follow. And I have not been able to
9 descend to that sort of level of detail, and indeed
10 working with others outside of this group is the best
11 way I think to shake down this regulation and
12 determine whether there are small bits.

13 The second point is, it does seem like a
14 substantive issue of the 200 hours in 390 is a
15 significant concern, and could cause harm to our
16 colleagues' practice in therapeutic nuclear medicine.
17 And I would defer to Dr. Eggli's recommendation that
18 the definition of the additional hours or whatever be
19 better calibrated to the actual teaching practices
20 that are now used in the program, that exist -
21 assuming that we accept the premise that what is being
22 done now is an adequate standard of educational rigor.

23 And I guess the third point I wanted to
24 make is that I would like to follow-up on a question
25 Mr. Bailey has -- a challenge Mr. Bailey has put

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1 before us. He's made, in addition to the -- he's
2 indicated the agreement states are dissatisfied with
3 the current final regulation on three grounds. I
4 think the issue of substantiveness is clear. Then
5 there's the issue of vagueness, and I guess the charge
6 that the regulation is not clear.

7 Now I spent three hours reviewing this on
8 my way here, and within my limitations I thought it
9 was reasonably clear. Of course, I have some
10 questions - I am not a lawyer, and I'm not an expert
11 in regulatory affairs. I'm an amateur, but it does
12 seem like the nature of this regulation has a certain
13 level of complexity that is essentially the bottom
14 line. You have to distinguish between Subpart J,
15 which was a temporary regulation, and what happens in
16 the future. That's a sort of a required element of
17 complexity, when you have a two-track system where the
18 boards are not hard-wired into the regulatory
19 language, they need to have complying regulations to
20 define what are appropriate boards that is going to
21 introduce an element of complexity that you simply
22 cannot dispense with, if that's the approach that is
23 going to be taken. You have a set of criteria for the
24 boards, and you have a set of criteria for the
25 alternate pathway. I think that there's a consensus,

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1 maybe the agreement states don't share it, but that
2 the nature of the boards is such that their
3 requirements are not written in the language of the
4 alternate pathway, and that public health, which is an
5 important goal - not just public safety, but public
6 health requires that the system of health care
7 education not be disrupted, unless there's really and
8 overriding concern. So grant that.

9 So having been through this, I mean I
10 guess I would ask Mr. Bailey to expand on this, and
11 tell us what is wrong with this regulation. And
12 secondly, since the 700 and 200 hours has been put
13 into the alternative pathway, what is the concern of
14 the agreement states?

15 DR. BROSEUS: Mr. Chairman, I must beg for
16 a short break.

17 CHAIRMAN MALMUD: Dr. Broseus asked for
18 a short break, and I think that's a reasonable thing
19 to ask for at 10:15. Does Mr. Essig agree?

20 MR. ESSIG: I want to give Dr. Broseus the
21 relief that he's seeking. However, I have one point
22 with regard to the agenda. We had allocated time for
23 the committee to write a memo, and I realize we
24 obviously aren't at that point. But what I wanted to
25 raise is there are four items remaining on the agenda

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1 for today. One of them, namely, the abnormal cross-
2 criteria, we desperately want to seek feedback from
3 the committee, so I would like to keep that on the
4 agenda.

5 Another agenda item is on the National
6 Source Tracking System, which was an information brief
7 for the committee. We could do that at another time.
8 We are prepared to do it, we can do it another time,
9 so that would save us some time there. We have two
10 hours allocated for Dr. Vetter to present the ICRP-
11 2005 recommendations. That is something that perhaps
12 we could do in abbreviated form. The purpose of it
13 was for Dr. Vetter to seek the committee's views,
14 because he is representing the committee next week at
15 an ACNW working group which is convening for a day,
16 and he wants to make sure that he carries any concerns
17 that the committee had. Now I realize that some of
18 you maybe have little or no interest in the ICRP-2005
19 recommendations, and others do have some, and so I
20 just raise that as maybe an item that we could either
21 -- we could shorten or handle it in some other way.

22 CHAIRMAN MALMUD: Dr. Vetter indicates
23 that he may not require the two hours, and it could be
24 handled in a lesser period of time.

25 MR. ESSIG: Okay.

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1 CHAIRMAN MALMUD: I just asked him that
2 question while you were speaking.

3 MR. ESSIG: Okay. Fine. And then the
4 fourth item is the tail-end, sort of the wrap-up to
5 make sure we have agreement on the action items, and
6 that kind of thing. I guess a break is in order, but
7 after we come back then I would like to still keep on
8 the table, if we could, the notion of whether or not
9 some thoughts can come forth in a collective manner
10 from the committee for the rule that we've been
11 talking about.

12 CHAIRMAN MALMUD: Well, having listened to
13 all of the opinions, I think that we probably can.
14 We'll do that after the break.

15 (Whereupon, the proceedings in the above-
16 entitled matter went off the record at 10:17 a.m. and
17 went back on the record at 10:35 a.m.)

18 CHAIRMAN MALMUD: You're all invited to
19 come back to the table for reconvening. Dr. Broseus
20 is ready.

21 DR. BROSEUS: Thank you for the break.

22 CHAIRMAN MALMUD: I enjoyed sharing it
23 with you.

24 (Laughter.)

25 CHAIRMAN MALMUD: It was not joint. It

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1 was sequential.

2 May I do a little introduction to the
3 reconvening of the last session?

4 MR. ESSIG: You may, but I just want to
5 make one point first, which is the adjustment in the
6 agenda.

7 CHAIRMAN MALMUD: Yes.

8 MR. ESSIG: The abnormal occurrence,
9 criteria discussion which we want to see the views of
10 the committee, I had talked with Ms. Jones, and she's
11 agreeable to come back at one o'clock.

12 CHAIRMAN MALMUD: Thank you.

13 In the latter part of the last session and
14 during the break, I had the opportunity to speak to
15 some of the members of the committee, and if I may, I
16 would like to summarize what might be an appropriate
17 action at this point.

18 Let's just review for a moment the
19 material on Dr. Broseus' slide. Nuclear pharmacy,
20 35.55, total hours 700, didactic 200, in vitro 35.190,
21 total hours 60, didactic eight, diagnostic only
22 35.290, 700 hours including 80 didactic, and then
23 therapeutic and diagnostic 35.390, 700 total hours,
24 200. That's unsealed.

25 Then if we had extended, if Dr. Broseus

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1 would give us editorial permission to extend his
2 table, the next line would be 35.396, 80 hours
3 specifically for unsealed sources applying only to
4 Board certified radiation oncologists. Is it Board
5 certified or Board eligible?

6 DR. BROSEUS: Board certified.

7 CHAIRMAN MALMUD: Board certified
8 radiation oncologists.

9 DR. BROSEUS: Or authorized users.

10 CHAIRMAN MALMUD: Or AUs, plus three
11 cases.

12 Then we have 35.490 and 25.690, each of
13 which would have 700 hours in the first column, 200
14 hours in the second column, and that's sealed, more
15 complex, to include classroom laboratory work and
16 three years of clinical experience.

17 Does that summarize factually what would
18 appear in that table or what does appear in that
19 table?

20 DR. BROSEUS: Sounds right to me.

21 CHAIRMAN MALMUD: Thank you.

22 Now, the real issue that seems to be
23 percolating around the table is the issue of didactic
24 hours, not the issue of total hours, and here we come
25 back to the definition of didactic, which we raised in

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1 an earlier session.

2 Didactic includes a classroom and
3 laboratory experience. No one has an argument with
4 that as long as laboratory experience includes
5 clinical laboratory experience. When I'm in a
6 clinical laboratory with a resident, I'm instructing
7 the resident. The resident is essentially functioning
8 in a training role.

9 The proof of that is that I could probably
10 do three to five times as much work without the
11 resident present as I am with the resident --

12 (Laughter.)

13 CHAIRMAN MALMUD: -- because I am
14 instructing the resident.

15 DR. BROSEUS: I thought it was a patient.

16 CHAIRMAN MALMUD: And Dr. Eggli and Dr.
17 Diamond and Dr. Nag all have the same experience. So
18 that is didactic time. It's a one-to-one didactic
19 time, much better than sitting in the classroom with
20 600 students in a 101 course in college, which is
21 certainly didactic by anyone's definition.

22 So I think that the issue arises for the
23 definition of didactic, and the concern, quite
24 frankly, that's coming from various members of the
25 committee is that no one in this room but a lower

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1 level employee of minimal experience becomes overly
2 enthusiastic and decides that the training program at
3 Harvard or at Yale or at Washington University or at
4 Hopkins does not have 200 hours of classroom time.
5 Hence it does not meet the requirements of the NRC,
6 and that that employee's citing of that program can
7 escalate into something which would be embarrassing to
8 everyone involved.

9 So the question really is not any of the
10 issues that we've reviewed, but the issue, again, of
11 what is didactic. If didactic includes instruction in
12 the classroom, in the laboratory, and clinical
13 laboratory, everything on the table is acceptable, I
14 believe, to everyone who has raised a concern about
15 this, including the states who wanted to have these
16 numbers of hours as they are.

17 Now, is that acceptable to the staff here
18 of NRC? What do you consider to be didactic?

19 DR. BROSEUS: Let me discuss some of the
20 issues that have come up. One of them is expressed in
21 a concern from the states that the 700 hours includes
22 the classroom laboratory training in safety related
23 items that are enumerated, for example, 390, under
24 little Roman i. Little Roman ii is supervised
25 clinical experience loosely termed. Okay?

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1 The concern of some states is that that
2 time over there would be used to count when they're
3 not really learning safety. That's the idea, and so
4 if there is a definition or re-definition, they have
5 to be careful about that.

6 You know, I personally believe from my
7 experience as a health physicist -- and is there
8 something we can do with the ringing on the speaker,
9 please? It's driving me nuts -- that a physician, for
10 example, or a pharmacist working with a physician or
11 a supervisory nuclear pharmacist is learning safety in
12 the clinic lab, you know, but some of the arguments
13 are, well, the use in time reading scans and call that
14 classroom and laboratory training, and so that's the
15 concern, I believe, that people have.

16 Also, you know -- I'm sorry. That's all.

17 CHAIRMAN MALMUD: Well, then you and I
18 agree, if I interpreted what you say correctly, that
19 when a physician and/or physicist and/or radiochemist
20 or pharmacist is working with the resident in
21 providing care to a patient while being instructed in
22 safe handling of radioisotopes in, for example, doing
23 lymphocytography in the separating of the dose into
24 its various syringes in gloving, in indicating what
25 the radiation exposure might be to both the worker and

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1 to the patient from this, that that is didactic
2 training on a one-to-one basis, much more valuable
3 than sitting in a classroom with 400 students in a
4 Physics 101 course. This is one-to-one didactic
5 training by a fully qualified professional.

6 If we accept that as didactic, then a
7 portion of the time that we are spending with the
8 residents is, in fact, didactic. I can't imagine any
9 better training.

10 MR. MOORE: Dr. Malmud, this is Scott
11 Moore.

12 I think the intent of the staff is that
13 with regard to classroom and lab, a portion of the
14 time that's spent on rad protection instrumentation,
15 rad physics, chemistry, and rad bio, if it's performed
16 in, say, a nuclear medicine hot lab, if it's performed
17 in a scan room, if it's performed in an I-191
18 administration room, if it's focused on those issues,
19 radiation protection instrumentation, rad physics,
20 chemistry, or rad bio would count as didactic
21 training.

22 CHAIRMAN MALMUD: Now, having said that,
23 Mr. Moore, is there any indication to the training
24 program directors that this, in fact, NRC policy that
25 would be accepted so that when perhaps a lower level

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1 employee of a region comes into a department and
2 challenges whether or not this is didactic, there is
3 an NRC statement that what you just said is true?

4 MR. MOORE: I think it's up to us to make
5 that clear in the final rule. The staff's preference
6 would be to make that in the statements of
7 consideration, which Roger refers to as the
8 supplementary information. The reason the staff would
9 prefer to put that in the statements of consideration
10 is because we're concerned about unintended
11 consequences by putting it into the rule itself.

12 CHAIRMAN MALMUD: Amen. So am I.

13 MR. MOORE: The terminology that is used
14 in the current rule is classroom and laboratory. We
15 have taken a broad interpretation of classroom and
16 laboratory, and I think we can put text in the
17 statements of consideration that reiterate what I just
18 said, that we've taken a broad interpretation of
19 classroom and laboratory, and we consider classroom
20 and laboratory to include, you know, the nuclear
21 medicine hot lab, the scanning room, patient rooms, as
22 long they cover the required topics in rad safety and
23 protection, instrumentation, rad physics, chemistry,
24 radiation biology in those locations.

25 CHAIRMAN MALMUD: Having said that, may I

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1 ask the members of the committee if they are,
2 therefore, with that definition, willing to move
3 forward with approval of the current recommendations?

4 Would someone wish to make a motion?

5 MEMBER DIAMOND: I believe there's a
6 question.

7 MEMBER SULEIMAN: Sorry. I want
8 clarification.

9 CHAIRMAN MALMUD: Okay.

10 MEMBER SULEIMAN: You know, the sign is
11 changing where you're doing computer training, remote
12 site training.

13 DR. HOLAHAN: On-line training.

14 MEMBER SULEIMAN: That's right. On-line
15 training. Would that be considered part of the
16 didactic classroom?

17 CHAIRMAN MALMUD: If it's related to
18 radiation safety training, if it is radiation safety
19 training. If it's simply transmitting images which
20 has nothing whatsoever to do with radiation protection
21 and radiation safety, in my mind -- and I speak for
22 myself, not for the group. I haven't polled them on
23 this -- I wouldn't consider that radiation safety
24 training.

25 On the other hand, if it relates to the

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1 calculation of doses, if it relates to the correct --
2 to the standardization of instrumentation, if it
3 relates to the correct checking of a dose in a well
4 counter, to the calibration of a well counter, the
5 answer is absolutely.

6 PARTICIPANT: We would agree with Dr.
7 Malmud's response.

8 CHAIRMAN MALMUD: Dr. Vetter.

9 MEMBER VETTER: In the spirit of moving
10 forward, I am inclined to agree with these, but I must
11 say and from personal experience in being involved in
12 the training of residents that on the whole they are
13 very, very smart people, and it simply does not take
14 200 hours to give them the training in the area of 300
15 uses. That's simply a lot of time.

16 What do we do? We give them reading
17 assignments. We'll give them NCRP 116 and some other
18 things and then they come back and we'll discuss that
19 together, but I just want to say they're very smart
20 people, and you can give them this information in much
21 less than 200 hours.

22 DR. BROSEUS: Does your training program
23 include laboratory time exercises with the geiger
24 counter?

25 MEMBER VETTER: All of these things, oh,

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1 yes, all of these things.

2 CHAIRMAN MALMUD: I think that Dr. Eggli
3 was next.

4 Dr. Eggli.

5 MEMBER EGGLI: Yeah, and again, I need to
6 stay say that I think 200 is way too long and we need
7 to look at a proportion of time. I had these
8 residents for 1,000 hours. Then 200 hours represented
9 a portion of that total 1,000 hours. It represented
10 20 percent.

11 Now that I have these residents for 700
12 hours, 200 hours on safety represents a significantly
13 larger portion of their time and, again, compromises
14 my ability to make them clinically competent as well
15 as safe.

16 And I think we need to try to maintain
17 some sort of balance here. I think 200 hours is
18 really way more than it takes to train them in safety,
19 and I need to train a well rounded, clinically
20 competent, safe nuclear medicine physician, and this
21 new regulation -- and, again, I realize this is
22 alternate pathway, but I have to train to alternate
23 pathway -- this new regulation will hamper my ability
24 to make them clinically competent.

25 DR. BROSEUS: This is draft right now.

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1 Let me emphasize that. So what is your the
2 irreducible minimum?

3 MEMBER EGGLI: Truthfully, I think for 200
4 uses 50 hours is adequate, and for 300 uses 100 hours
5 is adequate.

6 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

7 MEMBER LIETO: I was just going to make a
8 motion to the committee. It seems like the whole
9 stumbling block here is this number of hours for 390.
10 I think we're all in agreement pretty much with
11 everything else. So I'd like to make a motion that
12 the committee propose 80 hours of didactic training
13 and experience for 35.390 authorized uses, plus the
14 already stated 12 varied therapy cases.

15 CHAIRMAN MALMUD: Is there a second to
16 that motion?

17 MS. SCHWARZ: I second the motion.

18 CHAIRMAN MALMUD: Dr. Schwarz seconds the
19 motion.

20 Is there discussion of that motion? I'm
21 sorry. Sally.

22 MS. SCHWARZ: From my perspective
23 certainly what we're trying to teach is safe handling
24 of isotopes. With 290, nuclear medicine physicians
25 receive a significant amount of training to handle

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1 unsealed sources.

2 To move from the unsealed sources in
3 nuclear medicine to the therapeutic
4 radiopharmaceuticals that are also trained in nuclear
5 medicine, I believe that they certainly have within
6 that 80 hours a significant amount of time in terms of
7 the safe handling of unsealed radioactive sources.

8 They are different types, and there are
9 different considerations, but I think that the total
10 80 hours is a sufficient amount of time to cover what
11 is required.

12 CHAIRMAN MALMUD: Dr. Nag.

13 MEMBER NAG: Yes. Well, one possible good
14 thing you could do is then you could eliminate now the
15 396 because 396 requires a -- no, requires a Board
16 certified radiation oncologist to have 80 hours.

17 MEMBER EGGLI: Specifically for unsealed
18 sources.

19 MEMBER NAG: Right, and then if they can
20 qualify under 396, they will also now be able to
21 qualify under 35.390 or 35.390 will have --

22 MEMBER EGGLI: No, No.

23 MEMBER NAG: Why not?

24 MEMBER EGGLI: Because the 700 hours.

25 MEMBER NAG: but the 700 is -- I agree

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1 with what you said before. The 700 can overlap
2 between the different training modalities.

3 MEMBER WILLIAMSON: The 700 for unsealed
4 radioactive sources. I think you would be making a
5 big mistake to oppose these.

6 CHAIRMAN MALMUD: Mr. Lieto.

7 MEMBER LIETO: I would disagree with Dr.
8 Nag because 396 only addresses parenteral
9 applications. Three, ninety includes both that plus
10 the oral. So 390 would be a much larger application
11 of unsealed radiopharmaceuticals.

12 CHAIRMAN MALMUD: There's a motion on the
13 table.

14 I beg your pardon?

15 DR. BROSEUS: You're shooting yourself in
16 the foot if you put 396 up.

17 CHAIRMAN MALMUD: There is a motion on the
18 table for approval and discussion.

19 Mr. Moore?

20 MR. MOORE: With respect to the
21 discussion, I guess an important factor that everybody
22 needs to be aware is that the agreement states in the
23 proposed rule, I believe it was Alabama and Iowa did
24 recommend a specific number, 200 of didactic hours in
25 comments on the proposed rule, and they may have

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1 recommended in the petition itself 200 hours also.

2 And so if the ACMUI does pass such a
3 motion, then the staff will have to consider the
4 motion relative to the comments on the proposed rule
5 and also the petition itself. So Mr. Bailey may have
6 some comments relative to that.

7 CHAIRMAN MALMUD: Dr. Diamond.

8 MEMBER DIAMOND: I would defer to Mr.
9 Bailey.

10 CHAIRMAN MALMUD: Mr. Bailey is looking
11 for something.

12 MEMBER BAILEY: Go ahead. Let me find the
13 paper.

14 MEMBER DIAMOND: Because there's a motion
15 on the table, I'd like to discuss it further.

16 Ralph, if I may be clear, in your motion
17 it would be 80 hours specifically of didactic for 390
18 in the context of a total of 700 hours; is that
19 correct?

20 MEMBER LIETO: That's correct.

21 MEMBER DIAMOND: Thank you.

22 MEMBER NAG: Again, on that same thing,
23 now you are having a 390 for 80 hours, 390. This
24 includes both the parenteral and the oral
25 administration for unsealed sources.

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1 MEMBER DIAMOND: That's correct.

2 MEMBER NAG: In the 396 pathway, you are
3 now having a radiation oncologist who has done oral
4 therapy to now require also the same number of 80
5 hours only for the parenteral portions. So that does
6 not really match. I mean, I would say in that case
7 that for the 396 you would probably require a letter
8 number than the 80.

9 CHAIRMAN MALMUD: That doesn't address the
10 motion on the table, which we'd like to move forward
11 first. Are you addressing the motion on the table,
12 Ralph?

13 MEMBER LIETO: Yes. I would like to also
14 point out that 390 requires 12 cases total. In other
15 words, three cases of each of the four different
16 classes of radiopharmaceutical therapies, whereas in
17 396 it only addresses three cases of any one form of
18 the parenteral.

19 So from the standpoint of the clinical
20 case documentation, 390 is, again, more varied and has
21 a wider range of requirements than the 396.

22 CHAIRMAN MALMUD: Thank you.

23 The motion on the table is to reduce the
24 200 didactic under 35.390 to 80. Is everyone happy
25 with the number 80 or -- oh, more discussion. Mr.

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1 Bailey.

2 MEMBER BAILEY: I was just going to
3 respond. I quickly looked through the petition and
4 whereas 200 is referenced, I only see it specifically
5 in reference to the pharmacist, and that the petition
6 really asks for simply some numbers to be put in.

7 And I know these numbers have been tossed
8 around, but as late as October 5th, there was no -- it
9 was the first time there was really a poll on whether
10 or not the agreement states agreed with these numbers.
11 So I don't know that the agreement states have agreed
12 on these numbers because the poll has not been
13 tabulated to my knowledge, and I know at least one
14 state, since it was me, did not agree with the numbers
15 and, in fact, suggested that basically the equivalent
16 of what I considered one graduate health physics
17 course, three lecture hours and four hours of lab for
18 one semester or about 120 hours would be an
19 appropriate amount of training in the health physics
20 radiation protection.

21 Now, people have come back and made
22 arguments for 200, but those arguments are a little,
23 to my way of thinking, a little weird in that they are
24 comparing what an agreement state person who goes to
25 the Oak Ridge five-week course gets.

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1 So I don't think we're talking about an
2 equivalent situation.

3 I also want to take this opportunity.
4 When I spoke before about clarity and all, I was
5 speaking not for the agreement statements in a poll
6 that had been taken, but as a personal opinion having
7 worked for two agreement states and how we adopted
8 regulations. I wanted the record to be clear.

9 CHAIRMAN MALMUD: Thank you for clarifying
10 that.

11 Dr. Diamond, did you have a comment?

12 MEMBER DIAMOND: Yes. I would just
13 comment that given that 390 does require 700 total
14 hours, given the requirements for three cases for each
15 of the four classes, I think it would be reasonable to
16 keep the 700 total hours and proceed in a favorable
17 fashion with the reduction of 200 hours didactic to 80
18 hours of didactic, given that I do not believe this
19 would have any negative impact on public safety.

20 CHAIRMAN MALMUD: Any further discussion
21 of this item on the table?

22 If not, may we vote? All in favor of
23 this?

24 (Show of hands.)

25 CHAIRMAN MALMUD: Any opposed?

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1 (No response.)

2 CHAIRMAN MALMUD: Any abstentions?

3 (Show of hands.)

4 CHAIRMAN MALMUD: It carries with
5 unanimity except for one abstention. So the
6 recommendation is that the table presented by Dr.
7 Broseus be amended for 35.390 to show 700 hours in
8 Column 1 and 80 hours in Column 2, recognizing that
9 that's plus 12 cases, three of each type of the four,
10 and this is for unsealed sources.

11 DR. BROSEUS: I might make a small
12 correction. Twelve cases are not required in all
13 situations. It was a footnote which grants us at
14 least three cases in Category G2, also satisfies
15 Category G1. So one can get away with nine cases.

16 CHAIRMAN MALMUD: I stand corrected
17 because your table didn't specify that. You are
18 correct.

19 DR. BROSEUS: Yeah. Secondly, we had a
20 motion. I've recorded that to go back to the staff
21 with. It's useful also though to have a strong basis
22 for this. What is the committee saying in terms of a
23 basis of sufficiency of 80 hours?

24 CHAIRMAN MALMUD: That which I have heard,
25 and please, anyone augment or change my comments if

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1 you wish, is that Category 35.290, which is diagnostic
2 only, includes 700 plus 80 of didactic, and the
3 therapeutic application on top of the diagnostic is
4 generally covered in the 80 hours that are presented
5 in the diagnostic. Since the therapeutic relates
6 primarily to the use of beta emitters, the same
7 radiation safety practices apply, as do for the gamma
8 emitters, though there's recognition that beta and
9 gamma emitters are different and that the radiation
10 burdens from them are different, and that the
11 shielding for them is somewhat different.

12 And, therefore, 80 hours would represent
13 an adequate number of hours. It is also the number of
14 hours which is used in nuclear radiology training
15 programs currently, as documented by Dr. Eggli, who
16 has a nuclear radiology training program and
17 represents 80 hours of training, which is the rough
18 equivalent of three courses of three hours a week in
19 any college program.

20 Tricia.

21 DR. HOLAHAN: Could I ask a question?
22 Two-ninety (35.290) training is 80 hours as well. So
23 would you envision any differences in the 290 training
24 versus the 390 training, Dr. Eggli?

25 MEMBER EGGLI: I can speak to that

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1 question only in that I think, again, the group we're
2 talking about are diplomats of the American Board of
3 Radiology because the other training programs would
4 probably for 390 encompass easily the 200 hours.

5 But diagnostic radiologists train in 12
6 different modalities, and therefore, their time is a
7 little bit more limited.

8 It is my understanding that it is the
9 intention of the American Board of Radiology to have
10 their training programs train residents in diagnostic
11 radiology for certification or licensure for uses
12 under Subpart 300, and therefore, it may be moot
13 whether the requirements for 200 or 300 are different,
14 given that the Board intends that all of the residents
15 should be trained to the level of Part 300 uses.

16 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

17 The other comment is, I believe, that 390
18 does not require the 12 cases of varying types, that
19 290 doesn't require them and 390 does.

20 MEMBER EGGLI: Yes, that's correct.

21 CHAIRMAN MALMUD: So that's a difference.

22 DR. HOLAHAN: Yes, but the argument that
23 the agreement states made, and correct me if I'm
24 wrong, but they felt that there was a risk with 390
25 uses that there wasn't associated with the 290 uses.

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1 MEMBER EGGLI: And the only thing I would
2 say is that 80 hours for uses under Subpart 200 is
3 probably excessive, but again, since it's the intent
4 to train everybody to at least the 300 level, it's
5 unimportant.

6 But if you feel it's important to make the
7 distinction, then I have no problem with reducing the
8 number of hours under Part 290 T&E requirements, which
9 I actually did suggest a few minutes ago, that I
10 thought 50 hours would be more than appropriate at
11 Part 290 T&E, but again, I believe that the American
12 Board of Radiology intends to train all of its
13 diplomats under the rules of Subpart 390, and
14 therefore, the distinction may be more theoretical
15 than real.

16 CHAIRMAN MALMUD: But there is a
17 distinction in the requirement for the cases between
18 290 and 390.

19 MEMBER EGGLI: Yes.

20 CHAIRMAN MALMUD: Does that answer your
21 question, Dr. Holahan?

22 DR. HOLAHAN: Yes.

23 CHAIRMAN MALMUD: Dr. Broseus?

24 DR. BROSEUS: I missed something. You
25 attributed to Dr. Eggli a comment about 80 hours is

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1 required by ABR, but I didn't really hear a number.

2 MEMBER EGGLI: No, I don't believe I said
3 a number.

4 DR. BROSEUS: What is the requirement? Do
5 you know?

6 MEMBER EGGLI: For ABR?

7 DR. BROSEUS: Yeah.

8 MEMBER EGGLI: Right now ABR is waiting
9 for NRC to say something. As a matter of fact,
10 there's a lot of uncertainty in ABR training programs
11 right now waiting for this final regulation. I can
12 tell you that because there are 12 modalities out
13 there that diagnostic radiologists have to train for,
14 that wherever NRC sets the threshold, that will be
15 what the training programs require.

16 It used to be that we trained our
17 residents to \$1,000 because that's what was required
18 for NRC authorized user status under Parts 290 and 390
19 previously. Now if it's going to be 700 hours, then
20 the ABR requirement will be 700 hours, and it's just
21 a necessity because there are 12 modalities.

22 And if the training requirement becomes 80
23 hours for subpart 390 T&E requirements, then that is
24 what the American Board of Radiology will suggest to
25 its training programs that they ought to offer.

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1 DR. BROSEUS: Let me ask one more devil's
2 advocate question, and that is where you're describing
3 a scenario in which medicine becomes more complex and
4 there are more applications and more and more and
5 more, and therefore, being the devil's advocate. This
6 tells me that the physician who's doing that needs
7 more radiation safety, not less, and so maybe somebody
8 should add hours to the total training program to make
9 sure there's enough radiation safety rather than
10 trimming the safety part to make sure there's enough
11 time for clinic.

12 I emphasize devil's advocate.

13 MEMBER EGGLI: Keep in mind that we are
14 providing almost as many hours again in physics
15 training that is pertinent to the other modalities in
16 radiology, such as CT, plain film, and all of the
17 other areas where ionizing radiation issues, and
18 again, that is, we have designed our program. We
19 designed 100 hours of classroom lecture. Half of
20 those would fit the description in the regulation for
21 nuclear medicine. The other half we considered to be
22 more limited to other forms of diagnostic radiology
23 and not directly applicable to the handling of
24 unsealed sources.

25 There was some crossover, but at least 40

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1 percent did not readily cross over. So we're
2 providing far more physics training, health physics
3 training to our resident than will satisfy NRC because
4 we have other modalities where we're training these
5 kinds of issues where we didn't see a direct
6 crossover.

7 Now, maybe we should have been more
8 generous in our own internal definition and said it
9 all crosses over, but we didn't do that. We separated
10 diagnostic radiology physics from nuclear medicine
11 physics.

12 CHAIRMAN MALMUD: Dr. Broseus, does that
13 satisfy your devil's advocacy question?

14 PARTICIPANT: Well, I think what I'm
15 hearing is that you're using the term "physics," which
16 some people may interpret as principles of physics
17 more broadly to include health physics, radiation
18 safety related topics; is that correct?

19 DR. BROSEUS: Yes.

20 CHAIRMAN MALMUD: Dr. Williamson?

21 MEMBER WILLIAMSON: Yeah, I'm worried now
22 that this motion for 80 hours is based on a
23 misunderstanding of what the 200 hours are allowed to
24 be. Okay. The 200 hours, it doesn't say they have to
25 be on radiation safety and only the physics, narrow

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1 physics that's relevant to radiation safety.

2 If I read what it says, it says radiation
3 physics and instrumentation. It doesn't say that
4 learning to use instrumentation to determine a dose
5 for X-ray computed tomography can't be counted. You
6 know, it says radiation physics. It says radiation
7 biology. This could be any kind of radiation. It
8 doesn't even specify that it has to be ionizing
9 radiation biology. It could be, for example,
10 ultraviolet light biology.

11 PARTICIPANT: And we do count the
12 radiation biology in the --

13 MEMBER WILLIAMSON: Now, mathematics
14 pertaining to the use of measurement of radioactivity
15 and then, you know, chemistry of byproduct material
16 for medical use is more specific, but I'm asking, I
17 guess, if in this calculation of hours the sort of
18 broadness of what is allowed to be counted has been
19 considered.

20 CHAIRMAN MALMUD: I imagine that question
21 is directed to Dr. Eggli.

22 MEMBER WILLIAMSON: It is.

23 MEMBER EGGLI: And we tried to consider
24 that, and we did consider that there was an area of
25 overlap. Probably about 30 percent of our lectures

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1 overlapped the two areas where we have obligation to
2 train, and then we had an area where we thought there
3 was clearly not an overlap, and as we are looking at
4 coming up with total hours, that's where we were
5 running into trouble, is coming up with total hours.

6 And, again, I think we have a fairly
7 comprehensive program, and if you look at the total
8 amount of time we have, it's certainly equivalent to
9 a semester long college course.

10 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

11 Mr. Lieto has a question.

12 MEMBER LIETO: I wanted to clarify just a
13 question or point. The wording in the original
14 proposal says "has completed 700 hours of training and
15 experience including a minimum of 200 hours of
16 classroom and laboratory training in basic
17 radionuclide handling techniques applicable to the
18 medical use of unsealed byproduct material."

19 So the 80 hours that we're referring to or
20 that the motion, the approved motion took place is in
21 that definition. So the more general definition of
22 physics and safety in X-ray and CT would not have been
23 applicable the way that the definition is for that
24 section.

25 So I would say that we're fine in what we

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1 proposed.

2 CHAIRMAN MALMUD: Thank you.

3 Now, the motion was passed with unanimity,
4 one abstention. May we move on to the next item? And
5 does this satisfy the NRC's need to bring this forward
6 to the next step?

7 DR. BROSEUS: I'd just like to make one
8 clarifying comment. I'm not sure that Dr. Williamson
9 was serious about including ultraviolet, but we're
10 talking about ionizing radiation here. While it's not
11 defined in Part 35, it is defined in Part 20.
12 Radiation means ionizing radiation.

13 CHAIRMAN MALMUD: Thank you for clarifying
14 that for the record, Dr. Broseus.

15 May we move on?

16 Thank you. It has been a most stimulating
17 session, which has come to a resolution.

18 MR. MILLER: I think we can all agree on
19 that.

20 MEMBER NAG: Now that we have had no 390,
21 what I'd like to bring up for a brief discussion here
22 is 396. Eighty hours is a submission for unsealed
23 sources (phonetic) both for parenteral and for oral
24 administration. Am I right? Yes, no?

25 MEMBER EGGLI: Three, ninety or 396?

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1 MEMBER NAG: Three, ninety.

2 MEMBER EGGLI: Three, ninety.

3 MEMBER NAG: So 80 hours submission for
4 both the oral and for the parenteral. With 396 we are
5 only going to do parenteral because the 396 under the
6 parenteral for those who are Board certified in
7 radiation oncology who have now already spent quite a
8 lot of time in therapy and now need to know about
9 unsealed sources for the parenteral administration
10 only.

11 For that group of people, are you going to
12 need the same eight hours that you require for
13 somebody who is learning both about thyroids and about
14 parenteral administration, yttrium (phonetic), and so
15 on, or my proposal is that for somebody who already is
16 an expert on handling radioactive material in the
17 source, but the parenteral only 80 hours is excessive.
18 If you want me to put a number, I would say it has to
19 be less than 80. Whether 60 or 40, I think we can
20 deliberate, but if the APR rate is going to be
21 sufficient for only a limited component of that, by
22 definition it should be somewhat less.

23 CHAIRMAN MALMUD: Does anyone else wish to
24 address that or do you want to make that as a motion
25 and see what the response is?

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1 MEMBER NAG: If you want me to make a
2 motion, I would make a motion that for 396, the
3 didactic component of that be 60 hours.

4 CHAIRMAN MALMUD: Is there a second to
5 that motion?

6 Not hearing a second, we will --

7 MEMBER EGGLI: I'll give him a second.

8 CHAIRMAN MALMUD: You're going to give him
9 a second?

10 MEMBER EGGLI: Sure.

11 CHAIRMAN MALMUD: Dr. Eggli gives you a
12 second, which now opens it up to discussion. Dr.
13 Broseus.

14 DR. BROSEUS: It would be helpful to
15 include in the motion if possible, not to make it too
16 complex, a basis for this of sufficiency.

17 MEMBER NAG: The basis is that for the
18 entire scope of unsealed sources, including the
19 parenteral and the oral administration, we are
20 requiring 80 hours. What percentage of that is oral
21 and what percentage of that is for parenteral is hard
22 to say, but allowing for overlap and so forth, I would
23 say, you know, that is why we bring it down. Instead
24 of half-half, I'm looking at 760 rather than, you
25 know, 40 and 40.

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1 CHAIRMAN MALMUD: The point might be made
2 that in providing the therapeutic application of
3 radionuclides, one often does a diagnostic test first
4 with another isotope or a lesser amount of the same
5 isotope.

6 In addition, it may come to pass that the
7 oral administration of a therapeutic or diagnostic
8 isotope would be associated with the use of a
9 therapeutic isotope in the future, and for that reason
10 it would be safer to leave a number at 80.

11 And we recall that under Part 35.396, it
12 specifically says 80 plus three cases. Under 35.390,
13 it's 80 plus 12 cases. So there is a difference, and
14 in the sense that we don't know what will evolve in
15 the future, it might be best to leave it as it is.

16 However, that is open for discussion.

17 Dr. Williamson.

18 MEMBER WILLIAMSON: Well, I think in
19 practice, complying with the 80 hours, you know, given
20 the extensive base of didactic training that radiation
21 oncologists get, you know, much of the physics and
22 instrumentation would be applicable.

23 I think that in practice the incremental
24 burden would be very small. I think the only case
25 that I can think the 80 hours would affect, you know,

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1 a very direct way in the way you're thinking would be
2 those that fail the recency of training test. I've
3 forgotten which paragraph. It is in Part 35, but it
4 seems to me that someone who is seven years beyond
5 their residency training and has not had experience
6 with radionuclide therapy probably would, in fact,
7 have to have 80 hours' worth of training in order to
8 add this new credential.

9 MEMBER NAG: Basically that is what I was
10 thinking of.

11 MEMBER WILLIAMSON: And, you know, I'm not
12 sure that someone who is out away from this for ten
13 years, speaking as a physicist, whether it would be
14 such a bad thing that they repeat, you know, this much
15 training.

16 CHAIRMAN MALMUD: Mr. Lieto, you had a
17 comment?

18 MEMBER LIETO: Well, I was going to state
19 that I would oppose reducing the 80 hours because I
20 think there are more radiation safety considerations
21 associated with the administration of parenteral
22 radiopharmaceuticals than oral, and also it would
23 remain consistent with what we have in 392 and 394 as
24 requirements for all administrations. So I would like
25 to just keep it as is.

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1 CHAIRMAN MALMUD: Thank you.

2 Any other comments?

3 (No response.)

4 CHAIRMAN MALMUD: If not, should we call
5 the vote on it?

6 MEMBER NAG: I withdraw my motion.

7 CHAIRMAN MALMUD: The motion is withdrawn.
8 Thank you, Dr. Nag.

9 MR. MOORE: Dr. Malmud, point of
10 clarification. This is Scott Moore.

11 When you're talking about moving on to the
12 next subject, are you talking about moving on to the
13 National Source Tracking System or are you talking
14 about moving on to the next subject within Part 35
15 T&E?

16 CHAIRMAN MALMUD: Is there another subject
17 under 35?

18 PARTICIPANTS: Yes.

19 CHAIRMAN MALMUD: Then we'll move on to
20 the next part of 35 T&E. Is that what you wanted to
21 do?

22 We have a member of the public who wishes
23 to make a comment on Part 35.

24 DR. WHITE: Thanks.

25 Jerry White, American Association of

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1 Physicists in Medicine.

2 I'm impressed with the great attention to
3 detail that you've given to the training requirements
4 for various physicians, but there are some T&E issues,
5 I think, that we made comments on regarding authorized
6 medical physicists, grandfathering of authorized
7 medical physicists, and RSOs for medical physicists,
8 and I'd just like to ask the ACMUI if they have had
9 the opportunity to consider those, and if the changes
10 might be substantive, if there could be some way that
11 -- I know the paper copy of these changes is not
12 available, but if there were some oral discussion that
13 you might want to have or have some way to have other
14 eyeballs look or know about these changes.

15 CHAIRMAN MALMUD: We have several
16 physicists here who have not commented yet. Dr.
17 Williamson, we haven't heard from you for a while.

18 (Laughter.)

19 MEMBER WILLIAMSON: Well, I think that,
20 you know, I have reviewed this, and I think for RSO --
21 I think. I say this very tentatively because it is a
22 complex regulation. I don't think it is unclearly
23 written, but I know how disastrous the misplacement of
24 a comma and the transposition of an "and" or "or" can
25 be, and I would think that it would serve the

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1 regulated community and the NRC to have a few more
2 eyes look closely and analytically at these various
3 revisions because while they may not be substantive
4 according to the letter of the Administrative
5 Procedures Act, nonetheless, we have had mistakes in
6 the past that have been very embarrassing, and I would
7 think that we should find some way to on a short-term
8 basis make these pre-decisional document public or
9 available to people who wish to look at it.

10 I think this would help the ACMUI in
11 crafting its final memo to have some additional input
12 from expert reviewers. So I would ask that we figure
13 out some way, if necessary, reading this into the
14 public record or making a motion to append it to the
15 meeting summary which must be posted in ten days or
16 simply taking the common sense step of putting it on
17 the Web so that those people who wish to see it can
18 see it.

19 CHAIRMAN MALMUD: Thank you.

20 MEMBER WILLIAMSON: I think it can only
21 help improve the final product to have some unforeseen
22 or unanticipated consequence or, you know, mistake
23 revealed.

24 CHAIRMAN MALMUD: Thank you.

25 Dr. Vetter, do you have a comment?

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1 MEMBER VETTER: Yes. I don't have the
2 test in front of me, but when we reviewed this prior
3 to our conference call, it appeared to me that the
4 question that Jerry raised about RSOs has been
5 adequately answered. That is, there was a gap for
6 those physicists who qualified under ABR, and now
7 there is one of the "ors" that says if you have a
8 Master's degree in physics and two years of
9 experience, you will qualify as the RSO, and I think
10 that takes care of ABR's concerns, doesn't it,
11 relative to RSO?

12 CHAIRMAN MALMUD: Dr. White, you raised
13 the question.

14 DR. WHITE: Dr. Vetter, I just have to say
15 I don't know because without seeing the actual text,
16 it's just so hard to respond. Sorry.

17 MEMBER VETTER: Okay. Point well taken,
18 but in my opinion it does take care of it.

19 CHAIRMAN MALMUD: So Dr. Vetter reassures
20 you, Dr. White, that in his opinion it is taken care
21 of, though you haven't seen the text, Dr. White.

22 Mr. Lieto.

23 MEMBER LIETO: I would like to also
24 support Jeff's recommendation that we release this
25 predecisional document for people to look at. I

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1 think, you know, Jerry White's, you know, comment
2 being a point that the medical physics community would
3 like to see that this is addressed.

4 I do agree with Dick though that I think
5 it does answer the concern. I have an additional
6 question regarding the RSO preceptor issue.

7 CHAIRMAN MALMUD: Before we go on to your
8 additional question, is there any objection to
9 distributing this document?

10 Dr. Miller.

11 MR. MILLER: The committee is certainly
12 within its rights to make such a recommendation if you
13 so choose. We recognize that will be a recommendation
14 if you choose to make it that the staff will have to
15 take to the Commission itself for approval, and if the
16 Commission were to approve it, and I think what I'm
17 hearing is a recommendation.

18 To put it out for public comment again, to
19 put it out just for the public to look at and as a set
20 of eyes serves no purpose in my view with regard to
21 trying to reach a final product unless there's a view
22 that you would want to seek as a committee the
23 public's views on this before we go forward.

24 And I go back to my comments this morning
25 of we've got to get to a point where we're not stuck

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1 in an iterative process that we can't get out of. At
2 what point in time do we move forward?

3 So you know, with that, the question
4 becomes does the committee think at least from the
5 staff's perspective that the rule should be put out
6 for public comment and, if so -- and I need General
7 Counsel's help on this, Susan, if you can listen --
8 I'm going to ask a question if you'll indulge me of
9 our representative from the Office of General Counsel.

10 If we were to consider putting the rule
11 out for public comment, could you limit it to some
12 portion of the rule or do you have to put the whole
13 thing out again for public comment?

14 MS. CHIDAKEL: The reason I was just
15 talking to Sandy when you called my attention to your
16 questions is that I need to take these issues back to
17 the Office of General Counsel. I'm not really
18 prepared at this point to answer those questions, and
19 I raised the issue of Sandy.

20 I think, you know, these are
21 recommendations you can make, but I think I need to go
22 back to my management and have these issues resolved.

23 MR. MILLER: Exactly. I mean, before we
24 could act on the recommendation, we would have to get
25 approval.

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1 MS. CHIDAKEL: You would have to get an
2 official opinion from the agency.

3 MR. MILLER: Scott is trying to get a
4 point in here, I think.

5 MR. MOORE: Yes. If I may, there are
6 rulemaking mechanisms whereby we can make
7 predecisional rulemaking -- maybe I should call it
8 draft rulemaking -- available for the public to see.
9 The Office of Nuclear Reactor Regulation is using that
10 mechanism, namely, posting it on the Web, for the
11 public to see.

12 If the ACMUI believes that we should do
13 so, you know, it's certainly within your prerogative
14 to make such a motion and pass it. This has certainly
15 been such a controversial rule and that mechanism has
16 not been used within NMSS very frequently. You know,
17 we would certainly consider it, and may consult with
18 the Commission before we would do so.

19 MR. MILLER: Well, we would consult with
20 the Commission, yes.

21 MR. MOORE: Okay. Please recognize that
22 the Commission itself has not seen this language
23 that's before you. So you're seeing a draft final
24 rule that the Commission itself has not seen.

25 So you know, if you want to pass a motion

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1 that either it be made public so that you can share it
2 and talk to your counterparts and colleagues or that
3 it be made public and it be commented on again, that's
4 certainly all within --

5 MR. MILLER: Scott, so that they're clear
6 on the motion that they need to make --

7 MR. MOORE: I think Dr. Suleiman had a
8 comment.

9 MEMBER SULEIMAN: I have. I need some
10 clarification. What we're talking about that the
11 public hasn't seen that's pre-decisional, will that be
12 published as the final rule to take effect after a
13 certain amount of days or is that going to be
14 published as proposed rulemaking?

15 MR. MOORE: I can answer that. If it goes
16 out now without any change in process, after we would
17 get your comments, we would -- and the agreement
18 states' comments, we would send it up to the
19 Commission in mid-November. The Commission would
20 eventually vote on it as Roger's last slide showed,
21 and it would go out as a final rule. It would not go
22 out again for public comment.

23 MEMBER SULEIMAN: Okay, all right.
24 Interesting.

25 CHAIRMAN MALMUD: Does that answer your

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1 question, Dr. Suleiman?

2 MEMBER SULEIMAN: At some point NRC will
3 determine whether there have been substantive changes
4 to the document, whether, in fact, you'll reconsider
5 and go back and propose it as a new rule because it's
6 up to your --

7 MR. MOORE: No, no. I can answer that.
8 I checked with the General Counsel yesterday, and the
9 General Counsel's office yesterday actually, Stu
10 Treby, was of the opinion that it did not need to go
11 out for public comment. I don't think "substantive
12 comments" is the actual phrase. I think Susan gave
13 the correct legal threshold.

14 MS. CHIDAKEL: And please let me clarify.
15 He's not the General Counsel.

16 MR. MOORE: Okay. The General Counsel's
17 Office.

18 MS. CHIDAKEL: For the record, his
19 position is the Assistant General Counsel for
20 Rulemaking and Fuel Cycle. So to make clear that, you
21 know, he's not the General Counsel.

22 But in any event, Scott Moore is certainly
23 right. That is still our position.

24 MR. MOORE: It did not pass the legal
25 threshold that it needed to go out for public comment,

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1 again, but that doesn't mean that it can't go out for
2 public comment again.

3 Now, in response to Charlie's point to
4 clarify, there are a couple of options. One is the
5 ACMUI could recommend to the staff that it should go
6 out for public comment again, and we'd ask that you
7 give us a basis for that if you pass a motion to do
8 so.

9 Another comment that the ACMUI could give
10 us, you could pass a motion that it be made available
11 to the public not necessarily for comment, but just
12 made available publicly, and there are mechanisms that
13 the staff could do that.

14 CHAIRMAN MALMUD: Excuse me. By the term
15 "made available," that means it will be made available
16 to the public to see prior to anyone in the NRC seeing
17 it? I mean, does that create an embarrassment for
18 anyone?

19 MR. MOORE: No, no. It won't be an
20 embarrassment.

21 CHAIRMAN MALMUD: I just want to make
22 sure.

23 Dr. Williamson.

24 MEMBER WILLIAMSON: Well, then, you know,
25 let me state my intention was not to materially try to

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1 delay the process of ultimate approval, but only to
2 aid this committee by sharing this with colleagues or
3 being able to share this, to be able to solicit
4 additional input on the details.

5 So given that, I would make the motion
6 that we make it available to the public and not
7 request a separate cycle of public commentary.

8 CHAIRMAN MALMUD: Mr. Lieto?

9 MEMBER LIETO: I was going to second that
10 until he said not make it available and not allow
11 public commentary. I think that's the reason you want
12 to do this, is so that they can get some input from
13 the other parties.

14 I mean, I don't disagree with that we
15 don't want another round of rulemaking and that whole
16 business, but you know, I think you need to see
17 this --

18 MEMBER WILLIAMSON: Well, sending it for
19 public commentary is a formal mechanism. It has to be
20 published in the Federal Register again. It would be
21 a substantial delay in their process of several
22 months. I am simply proposing to make it available to
23 the public immediately.

24 MEMBER LIETO: What's the value of making
25 it available if no one is going to have the ability to

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1 provide input to the staff to see if there are issues
2 that we may have not recognized that create
3 difficulties?

4 CHAIRMAN MALMUD: I understand your
5 question.

6 Dr. Suleiman.

7 MEMBER SULEIMAN: Right. We need to
8 follow some discipline in the process. If we want
9 this to be published and not get any comments, I agree
10 with Charlie Miller. There's no point in it. The
11 decision is made. We've been given the opportunity to
12 see it, but it's the NRC's decision.

13 That's why I was asking earlier for
14 clarification. If there was, for lack of a better
15 word, significant, substantive, whatever changes where
16 it has changed enough and that's the NRC's call, then
17 they would say, you know, "We have to go back and go
18 through the whole public comment period."

19 But it sounds like to me that we're beyond
20 that, and this was just a courtesy. Here's what the
21 final rule is going to be.

22 CHAIRMAN MALMUD: You've raised the
23 question which I was going to ask in a different
24 manner, and that is that we have physicists on our
25 committee. Dr. Vetter has seen it and has no

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1 objection to it. Dr. Williamson has no substantive
2 objection to it, though he says he has not reviewed
3 every last detail of it to his satisfaction, but he
4 has no objection to it. I don't see why the usual
5 process has to be invaded.

6 MEMBER WILLIAMSON: Can I state my
7 rationale, please?

8 CHAIRMAN MALMUD: Yes, you may.

9 MEMBER WILLIAMSON: My rationale would be
10 that there would be individuals I could personally
11 solicit feedback from on the details and be able to
12 give a more informed evaluation of this regulation as
13 a member of the ACMUI. That's maybe a weak rationale,
14 but that's, in fact, what I would do if it were made
15 available --

16 CHAIRMAN MALMUD: Thank you.

17 MEMBER WILLIAMSON: -- to those who are
18 interested in reading it.

19 At least I personally would solicit some
20 additional input from members.

21 MEMBER LIETO: But then you'd be providing
22 input into the working group.

23 MEMBER WILLIAMSON: That's correct. I
24 would, you know, attempt to do this. I think the time
25 frame of three, four days from now is very tight to do

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1 this, you know. To try to get a few more days would
2 be helpful.

3 CHAIRMAN MALMUD: Does anyone wish to make
4 a motion to that effect or shall we just --

5 MEMBER WILLIAMSON: I have made the
6 motion.

7 CHAIRMAN MALMUD: Trish?

8 DR. HOLAHAN: Yes, excuse me.. I'd like
9 to emphasize what Dr. Miller said. First of all, we'd
10 have to go to the Commission and ask if we'd have to
11 put out the draft rule language on the Web, but what
12 I understand is what you're saying is if we put it up
13 on the Web and you would solicit comments from
14 specific stakeholders and get back to us, and so you'd
15 need more time.

16 MEMBER LIETO: This is Ralph Lieto.

17 I would agree with what you just said,
18 Trish.

19 DR. HOLAHAN: Okay.

20 MEMBER LIETO: Now, how much time? Is two
21 weeks unreasonable or ten days or something like that?
22 I mean, I know we want to try to keep it short, but I
23 think what you're talking about in terms of basically
24 two business days is not really practical.

25 MEMBER WILLIAMSON: Yeah. So I think my

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1 motion would have to be amended to include enough time
2 to accommodate your process for querying the
3 Commission and then give people a few days to the
4 selected few people that perhaps I and other members
5 of the ACMUI would solicit to get input; we would need
6 a few days to --

7 DR. HOLAHAN: We would have to make it
8 available to all the public. You can't just go out to
9 a few.

10 MEMBER WILLIAMSON: Well, it would be
11 available to all the public, but you know, I am not
12 going to personally contact each member of the public
13 who reads this. I would contact a, you know, few
14 knowledgeable people, you know, and Dr. Vetter, could
15 detect errors in this.

16 MEMBER VETTER: I think what Dr.
17 Williamson has suggested does have value, but I also
18 think there's a huge risk there in going out and
19 soliciting input from a few selected individuals.
20 Someone out there will not be contacted and will be
21 very unhappy with the process.

22 CHAIRMAN MALMUD: Thank you, and there's
23 a member of the public that wishes to make a
24 statement.

25 DR. WHITE: Yes, I would just like to, in

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1 answer to Dr. Hiller's (phonetic) question, I think
2 the value is clearly the staff has taken guidance from
3 the ACMUI in this regard, and that if there's some way
4 for the regulated community to have consultation with
5 or voice an opinion to the ACMUI, I think that's an
6 appropriate method for perhaps effecting change in
7 this. I think it's not really a "do" loop issue. I
8 think it's more a limits issue. You know, the epsilon
9 and sigma issue.

10 We're getting very close to the final
11 product after many years of effort, and these last few
12 details would benefit from just one more look, and it
13 doesn't need to take more than a week or so. I mean,
14 I don't know exactly how much time, but we're really
15 not talking about extending another request for public
16 comments, but just rather one more set of eyeballs for
17 these final things which for physicists are very
18 important.

19 The grandfathering of AMPs is a vital
20 issue for us, and we don't know what the language
21 looks like.

22 CHAIRMAN MALMUD: Thank you. We've heard
23 your concern.

24 There is a motion on the floor. Has it
25 been seconded?

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1 MEMBER LIETO: I will second.

2 CHAIRMAN MALMUD: Mr. Lieto seconded it.
3 Any further discussion of the motion?

4 MEMBER SULEIMAN: What is the motion?

5 CHAIRMAN MALMUD: Would you repeat your
6 motion, Dr. Williamson?

7 MEMBER WILLIAMSON: The motion is to make
8 the predecisional rule publicly available so that
9 ACMUI members may be able to solicit additional input
10 in formulating written opinions for the staff.

11 MEMBER NAG: I would suggest that same
12 motion -- just leave out the last part of the
13 sentence. You don't need to hear why it has to be
14 made public.

15 MEMBER WILLIAMSON: All right. So I'll
16 rephrase. The motion is to make the predecisional
17 material publicly available and extend the deadline
18 for ACMUI input to give us five working days from the
19 date it is made publicly available to finalize
20 individual comments to the staff.

21 CHAIRMAN MALMUD: Dr. Suleiman.

22 MEMBER SULEIMAN: I think this modifies
23 the whole process. I think we should just go -- I
24 would not support.

25 CHAIRMAN MALMUD: You're not supportive of

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1 it.

2 MEMBER SULEIMAN: No.

3 CHAIRMAN MALMUD: Any other comments?

4 Call the question. All in favor.

5 (Show of hands.)

6 CHAIRMAN MALMUD: All opposed?

7 (Show of hands.)

8 CHAIRMAN MALMUD: The motion does not
9 pass.

10 May we move on to the next item if there
11 is another one under Part 35?

12 DR. BROSEUS: I've completed my
13 presentation.

14 CHAIRMAN MALMUD: You've completed your
15 presentation, Dr. Broseus?

16 DR. BROSEUS: Save one item, and that is
17 to thank you all for the extraordinary effort put into
18 this because everybody has put a lot of labor into
19 having the rule that comes out. Yes, pat yourselves
20 on the back. We are, too. This is a difficult rule,
21 and we're doing our best to make it good, and you guys
22 have done a lot in that direction. I really
23 appreciate this.

24 CHAIRMAN MALMUD: And the committee
25 appreciates your effort and the enormous input that

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1 we've had from you and your staff.

2 DR. BROSEUS: Well, I am at your disposal
3 if there are anymore questions.

4 CHAIRMAN MALMUD: We do have a full
5 agenda. Is it something that's urgent, Ralph?

6 MEMBER LIETO: Well, if we're not going to
7 be putting this out for a predecisional, then I think
8 we need to address these specific points then, and if
9 it takes a while, then I guess that's going to be the
10 case.

11 MEMBER WILLIAMSON: This is the last
12 moment. We need to take the time.

13 CHAIRMAN MALMUD: What would you like to
14 take a little time on?

15 MEMBER LIETO: Well, my next point that I
16 would like to address, I've got actually two. It
17 appears that in this predecisional documentation it
18 states that a person who was an RSO and then is no
19 longer an active listed RSO cannot be a preceptor. So
20 if our esteemed colleague, Dr. Vetter, leaves his
21 institution as an RSO and is no longer the listed RSO
22 on the license, he cannot be the preceptor for anybody
23 else's training and experience.

24 And so I would like you to address that
25 point first.

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1 DR. BROSEUS: Is that a question?

2 CHAIRMAN MALMUD: Is that a question to
3 Dr. Vetter?

4 MEMBER LIETO: No, it's a question to the
5 NRC staff.

6 DR. BROSEUS: We haven't changed the
7 definition of a preceptor except to add to it as
8 recommended by the ACMUI to say it could be a person
9 who is familiar with the training. In other words,
10 they don't have to direct the training. Okay? That's
11 in 35.2, is the definition.

12 So we haven't changed the definition
13 except to add to, as per your recommendation. Okay?

14 And the other areas where we talk about
15 the preceptor rule itself are basically unchanged. So
16 I'm not quite sure what the basis for the question
17 really is.

18 MEMBER LIETO: Well, it's on actually page
19 33. It says if an individual status as an RSO, ANP,
20 ANP or AU is dropped, revoked or removed from the
21 license or because of poor compliance with the NRC's
22 regulation, that person can no longer serve as a
23 preceptor. I mean that's what it states.

24 Now, I don't know if that was the intent,
25 but what it states is that --

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1 DR. BROSEUS: I'm not sure that we have
2 the same page number. Is this -- is there an issue
3 number associated with this? Because the --

4 MEMBER LIETO: Actually it's issue number
5 two on page 33 on what I have. It's your pagination.
6 So even an authorized user who may have been on a
7 license and maybe the Director of Training; so I think
8 there needs to be a clarification.

9 And I think this also gets to the issue of
10 authorized medical physicists and who can be a
11 preceptor for an authorized medical physicist. We've
12 got to, you know -- that would basically almost
13 eliminate a first pool of authorized medical
14 physicists.

15 DR. BROSEUS: I think as I read this, this
16 is in response to a comment from an agreement state
17 about who can and can't serve, and at the end we're
18 talking about if somebody is removed for cause that
19 that would be --

20 MEMBER LIETO: Well, it says "or" and it
21 doesn't --

22 DR. BROSEUS: Right, but we would have to
23 go back and, again, look at your comment and insure
24 that we haven't put something into the response that
25 is removing the ability to be a preceptor that's in

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1 conflict with the definition intended for --

2 MEMBER WILLIAMSON: Well, I guess this is
3 a good question. If the director of one's training
4 program retires and ceases to be an authorized user at
5 some future point in time, can that person serve as
6 the preceptor for a graduate of the program, presuming
7 they were under the assumption that they were an
8 authorized user, you know, at the time, in the time
9 frame that's relevant for documenting the applicant's
10 credentials.

11 That's the question.

12 DR. BROSEUS: My first stop is to read the
13 rule. Ron, do you want to add anything?

14 My first stop would be to read the rule
15 and see what it says.

16 MEMBER WILLIAMSON: Well, tell us. We are
17 asking you.

18 DR. BROSEUS: Yes.

19 MEMBER WILLIAMSON: I mean, that's
20 evading.

21 MEMBER LIETO: I think, you know, and I
22 know I'm sounding repetitive, it gets back to being
23 able to look at the rules that we're going to be, you
24 know, recommending and submitting changes for. You
25 know, if we're not going to -- I don't know if we need

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1 to go to a formal motion or not, but I think if we've
2 only got a few days to provide comments to the NRC
3 staff, you know, I think we need to be given the tools
4 to make, you know, valid comments and knowledgeable
5 comments to you and to see it in the whole context of
6 the preceptor definition, especially with the RSO and
7 especially with the authorized medical physicist
8 aspects because there has been a number of changes,
9 that I would like to see that, you know, within the
10 next day or so.

11 I mean, if I've only got basically to the
12 18th, then I'd like to see that, you know, by the end
13 of the day tomorrow.

14 MEMBER WILLIAMSON: I just would like to
15 have the answer to my question.

16 DR. BROSEUS: If I understood the question
17 correctly, could a person who was an authorized user
18 continue to serve as a preceptor.

19 MEMBER LIETO: Correct.

20 DR. BROSEUS: And I would have to look and
21 see what the rule says, but on the face of it, I would
22 say, no, they're not an authorized user. If a person
23 isn't named in the rule as a person who can serve as
24 a preceptor, then the answer to the question would be
25 no, but I also have to look at the definition, and if

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1 that person, for example, was in a training program,
2 during that training program, I'm not sure about this.

3 Ron?

4 DR. ZELAC: This is Dr. Zelac.

5 If one looks specifically, Ralph, at the
6 question of the radiation safety officer, the best
7 thing to do is to look back at the definition that
8 appears now in the rule for radiation safety officer,
9 and it reads that an individual who meets the
10 requirements in 3550(a), meaning Board certified, and
11 3559, recentness of training and experience, or is
12 identified as a radiation safety officer on a license.

13 So in Dr. Vetter's case, for example, if
14 he were to cease being the radiation safety officer at
15 Mayo Clinic, he would still qualify as radiation
16 safety officer on a quick read under the first
17 provision that I read, that he meets the requirements
18 in 3550(a) and 3559. At least for the next seven
19 years he would.

20 DR. BROSEUS: This is really not a new
21 question. This is an interpretation of the current
22 rule. So I think that answers the question.

23 Thank you.

24 MR. MOORE: And if I may address Dr.
25 Lieto's comment on the timing question, first of all,

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1 with regard to getting, you know, full information by
2 tomorrow, with regard to the red line strikeouts
3 version, the staff is preparing a red line strikeouts
4 version. One has been developed, but it's not QAed.

5 Going back to the comments from the
6 telecon, I think we said in response to Lynn's
7 recommendation that we thought it was a good idea and
8 we would certainly consider it.

9 The staff plans to do so for issuance of
10 the final rule. With regard to getting it out, we
11 want to make sure that we get the right thing out and
12 there are not errors in it before we issue it.

13 With regard to getting out a full rule, we
14 agree that that would be helpful. If the committee
15 needs additional time, that would be certainly
16 something we could consider, but as I had mentioned,
17 we would need to ask the Commission for that, and to
18 do that, you know, we would need you all to tell us
19 that you need additional time for that and give us a
20 basis for that, and you know, we would tell the
21 Commission that.

22 But absent that, we would have to work
23 under the schedule that we have now.

24 CHAIRMAN MALMUD: Dr. Williamson.

25 MEMBER WILLIAMSON: I think the other

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1 issue that was raised on the teleconference is the
2 issue of grandfathering for the authorized medical
3 physicist. Why that is of special concern is that the
4 authorized medical physicist as an entity within the
5 regulations hasn't existed until recently, and so
6 there is a concern about how the details of the
7 grandfathering would work in order to assure that
8 there are enough individuals who are grandfathered
9 into that status that there would be an appropriate
10 supply, an adequate supply of preceptors.

11 This is a confusing issue to me. As I
12 understand the concern, it's that in many agreement
13 state licenses there is no counterpart to the
14 authorized medical physicist or HDR physicist that's
15 named in the license, and so that there is a pool of
16 potential individuals fully competent HDR, gamma
17 stereotactic and Cobalt 60 teletherapy physicists who
18 are carrying out all of the duties named in the 600,
19 but simply because of the peculiarities, the
20 semantical differences effectively in the way licenses
21 are written in some agreement states versus in NRC
22 directly regulated states, there will be a group of
23 individuals who won't be grandfathered, and so there
24 is some concern, you know, how large this pool of
25 individuals will be, whether this was going to cause

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1 difficulties in the early implementation of the rule
2 to be able to get the individuals named on the
3 licenses, et cetera.

4 And so I think as I recall from the
5 teleconference this was sort of answered in the
6 negative as being, well, just tough luck. These
7 people won't count as AMPs and can't be preceptors.
8 And I was wondering if you had put some further
9 thought and have any idea on how this might be
10 resolved either in rule language or in the
11 implementation of the rule.

12 DR. BROSEUS: We in the working group gave
13 considerable attention to this issue, but I'm going to
14 defer to Ron and MSIB to see if he can address this a
15 little later. I might be able to.

16 CHAIRMAN MALMUD: Dr. Zelac?

17 DR. ZELAC: What the working group had
18 recognized was exactly the same issue that you've just
19 raised, and what the working group had hoped could
20 take place was a suggestion to be made available to
21 the general medical physics community as well as their
22 regulators, many of whom are in the agreement states,
23 to move ahead forthright before Subpart J is gone, to
24 in some way become named on a license, to become
25 listed on a license and thereby be eligible to serve

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1 as a preceptor for others seeking similar
2 authorization.

3 I know that there was reluctance on the
4 part of our Office of State and Tribal Programs to
5 convey this in that fashion, to make such a suggestion
6 through an all agreement states letter or some other
7 mechanism to the agreement states, but I think that
8 issue was probably at least one that I would have
9 expected would have been discussed at the recent OAS
10 meeting in some fashion so that there wouldn't be
11 people in such a gap in the future.

12 DR. BROSEUS: The reluctance, Ron, was in
13 putting a requirement in here that would be laid on
14 agreement states because we have to be very careful
15 about that.

16 DR. ZELAC: I wasn't speaking of a
17 requirement. I was speaking specifically of a
18 suggestion to be made, and I think there was --

19 DR. BROSEUS: -- SPB and others and the
20 state members of the working group are aware of this.

21 CHAIRMAN MALMUD: Thank you.

22 Mr. Bailey.

23 MEMBER BAILEY: I have to address that.
24 I mean, only one-fifth of the medical licensees are in
25 NRC territory. So you're going to have four-fifths of

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1 the facilities not having named medical physicists.
2 Quite frankly, this is the first time I've heard of
3 this potential problem, but I think we've probably got
4 wrapped around the axle on 10(e) for doctors, quite,
5 frankly.

6 I can tell you right off we in California
7 would object to it because it's an increase in work
8 load to go just to meet a new whim, to go through and
9 evaluate the medical physicists that are presently
10 operating on our licenses.

11 We do have a list of people that we
12 consider to be qualified as medical physicists, but to
13 go through and name them on a license would be a
14 tremendous work load, I think, on the states to do.
15 So I'm sure we would object to doing it.

16 DR. BROSEUS: But what I'm hearing though
17 is that the state recognizes that these people are
18 qualified and almost by implication that your state,
19 persons who are well qualified will likely be
20 authorized.

21 MEMBER BAILEY: I have to respond to that
22 that in most cases I would say we do not know who the
23 medical physicist is at a hospital. We know how the
24 RSO is. We know in most cases who the authorized
25 users are, but in many, many cases, we don't know who

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1 the medical physicist is or whether there is even a
2 resident medical physicist on the staff of that
3 hospital or whether or not they're contracting with
4 someone outside the hospital itself.

5 CHAIRMAN MALMUD: Dr. Williamson.

6 MEMBER WILLIAMSON: So what will your
7 state do then in this situation? Because a new
8 regulation will come around which says that you have
9 to have authorized medical physicists. One of the
10 criteria for being an authorized medical physicist is
11 that another authorized medical physicist attests to
12 the competence of the individual.

13 So what would be a solution to this in
14 your state? I'm curious to know.

15 CHAIRMAN MALMUD: The question is directed
16 to you, Mr. Bailey.

17 MEMBER BAILEY: Basically, what we are
18 doing right now is if this question comes up, and it
19 came up in the mammography field, is that we look for
20 Board certified people. Absent someone being Board
21 certified, then we have basically an underground
22 regulation that says, hey, you're going to get on the
23 list, and to do that, you have to have your training
24 and experience, your equipment, and your protocols
25 you're going to use.

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1 Now, I will go back and see what, if any,
2 plans we have made to add medical physicists to the
3 license, and I think we need to query all of the
4 agreement states. I'm not sure that all of the
5 agreement states -- in fact, I'm sure not all of the
6 agreement states are really aware of this provision.

7 MEMBER WILLIAMSON: I guess the other
8 question I would ask to the staff along the same lines
9 is, you know, my understanding of how we function as
10 a broad scope licensee, even as an NRC regulated state
11 is specific physicists and authorized users are not
12 actually mentioned on the license, but the license
13 gives the radiation safety committee the authority to
14 review the training credentials of candidates for
15 authorized user and authorized medical physicist.

16 And as an act of the radiation safety
17 committee, basically designate these individuals in
18 these roles. So would you consider individuals that
19 have been designated by the radiation safety committee
20 of a broad scope licensee in either an agreement
21 statement or in an NRC state to acceptable preceptors?

22 CHAIRMAN MALMUD: To whom is that question
23 addressed, Dr. Williamson?

24 MEMBER WILLIAMSON: This is addressed to,
25 I think, Dr. Broseus and Dr. Zelac, who seem to be

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1 fielding these questions.

2 DR. BROSEUS: Let me tell you what I'm
3 hearing, and we need to go back with. First, you have
4 identified the potential problem that a person cannot
5 serve as a preceptor who is not an authorized medical
6 physicist, but has never been authorized, and it's a
7 chicken and egg syndrome.

8 And so we have to look at have we
9 adequately provided for an avenue for people to serve
10 as preceptors to be precepting for an authorized --
11 attesting for a medical physicist. That's number one.

12 Number two is an issue that is already
13 there and dealt with routinely on broad licensees, and
14 that is basically the broad licensees have the same
15 responsibilities that license reviewers do. I
16 shouldn't say it that way, but they're bound by the
17 same rules. Okay?

18 Now, generally speaking, and I'd have to
19 look at this in detail, if an individual is named by
20 a broad licensee or a permittee, like in the VA, they
21 can serve in the same role as an authorized user,
22 authorized medical physicist or whatever. Please
23 correct me if I'm wrong, but I think that that's a
24 non-problem.

25 The problem we need to go back with to the

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1 working group is to make sure we have provided an
2 avenue appropriate for a person to attest for medical
3 physics.

4 MR. MOORE: Roger, if I may, in answer to
5 Dr. Williamson's question, I guess first I'd like to
6 say that the question that you raise, it's a problem
7 under the current rule as much as it's a problem under
8 the draft final rule, and so it's not a new problem
9 that you're raising. It's a problem with the rule
10 that's out there right now. The wording itself
11 doesn't change.

12 That said, you know, it's a valid
13 question. I can't speak for the legal interpretation,
14 but I think we would take a common sense approach, and
15 if a person is identified as a user under a broad
16 scope license or under a master material license and
17 that identification is made in writing somewhere, I
18 would think that we as a regulatory agency would
19 recognize that the same as if somebody was identified
20 on a license itself and accept that as a preceptor
21 identification.

22 And what you're really getting to is how
23 often do we challenge the credentials of a preceptor
24 and that's fairly rare.

25 MEMBER WILLIAMSON: Well, it's only rare

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1 because, in fact, the country is being governed by
2 Subpart J where this is a non-issue, and so, you know,
3 you say that, yes, it's in the current regulation, but
4 the reason we're all here discussing this today is
5 because we all know that the current regulation is
6 broken. That's why we're trying to fix it.

7 And so I think this is a -- I'm sorry if
8 I don't find your answer satisfying.

9 DR. BROSEUS: But let me repeat. I
10 understand that your issue is a person may never have
11 been named as an authorized medical physicist, and so
12 there's a potential problem. The definition requires
13 that a person be an authorized medical physicist to
14 serve as a preceptor, but no such party exists.
15 Bottom line.

16 MEMBER WILLIAMSON: That's my concern, is
17 how you're going to convert the existing user base.
18 For authorized users, I presume this is much less
19 significant a difficulty because that's a well
20 established entity within both state and federal
21 regulations. So it's sort of transparent to match.

22 CHAIRMAN MALMUD: We have presented you,
23 Dr. Broseus with that dilemma, which we hop you will
24 report back to us about at our next meeting.

25 MEMBER WILLIAMSON: So the fact that there

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1 aren't ready answers to his, you know, shakes my
2 confidence somewhat in, you know, giving an
3 unqualified endorsement to this rule..

4 CHAIRMAN MALMUD: Dr. Miller.

5 MR. MILLER: Something you just said was
6 troubling to me concerning reporting back at the next
7 meeting. I think Ralph and Jeff have offered a
8 concern in this area, and it sounds to me, if I
9 understand the concern that you raise, if we go
10 forward and promulgate the regulation as it's written,
11 it's going to be problematic.

12 So reporting back at the next meeting is
13 going to be an issue. I guess my question would be is
14 there some recommendation that the committee could
15 make to us to fix the problem.

16 MEMBER WILLIAMSON: Yes.

17 CHAIRMAN MALMUD: We will give Dr.
18 Williamson an opportunity as soon as we hear from Dr.
19 Howe.

20 MEMBER WILLIAMSON: I would recommend --
21 (Laughter.)

22 CHAIRMAN MALMUD: Dr. Williamson is
23 recommending we hear from Dr. Howe first.

24 DR. HOWE: I just wanted to make a comment
25 as to the fact that the NRC had this same predicament

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1 when we brought in the authorized medical physicist,
2 and one of the things that happened when we did that
3 was we already had -- and I don't know if the
4 agreement states do it -- we already had physicists
5 listed for teletherapy physicists, and because we line
6 itemed remote after-loaders, we had physicists listed
7 for authorization for HDR units and physicists listed
8 for authorization for gamma knife units, and those
9 physicists that were listed on licenses or recognized
10 by broad scopes as being physicists for HDR and
11 physicists for gamma knife were considered
12 grandfathered, and the teletherapy physicists were
13 certainly considered grandfathered.

14 So that gave us a small, but an existing
15 basis for having authorized medical physicist precept.

16 CHAIRMAN MALMUD: Thank you, Dr. Howe.

17 Dr. Williamson.

18 MEMBER WILLIAMSON: Well, I think this
19 sounds like I'm sure it was everybody's intention that
20 the rule work this way, but the language is stated in
21 such a specific way that it may not. So, you know, I
22 think my proposal would be that you amend the license
23 or the rule -- excuse me -- and change the
24 grandfathering procedure to basically mean just what
25 Dr. Howe said, that individuals who are now authorized

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1 to serve as physicists for high dose rate
2 brachytherapy, Cobalt 60 teletherapy and gamma
3 stereotactic by whatever mechanism in the agreement
4 states or in NRC states be grandfathered as authorized
5 medical physicists in those respective modalities and
6 avoid the language, the unduly restrictive language
7 listed on a license, you know, and come up with some
8 substitute language that captures the population.

9 Because my understanding would be even in
10 California, fuel cycle 86-4, which came out in 1992,
11 was an edict that basically said, created through
12 underground regulation or whatever you call it an
13 entity called HDR Physicists that had to be Board
14 certified, had to attend treatments.

15 And so I would presume the agreement
16 states, you know, essentially had some mechanism for
17 promulgating those rules. No?

18 CHAIRMAN MALMUD: You've made a
19 recommendation on discussion. Can you just make the
20 recommendation, a brief recommendation to the --

21 MEMBER WILLIAMSON: I will restate my
22 recommendation. My recommendation is that 3557 be
23 modified to read as follows: that physicists who have
24 been authorized to serve the function of authorized
25 medical physicists for high dose rate brachytherapy,

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1 gamma stereotactic radiosurgery and Cobalt 60
2 teletherapy be grandfathered to be allowed to serve
3 as authorized medical physicists for those respective
4 modalities.

5 CHAIRMAN MALMUD: Is there a second to
6 that motion? And then we'll open it for discussion.

7 MEMBER LIETO: Second.

8 CHAIRMAN MALMUD: It's been moved and
9 seconded, now open for discussion.

10 MEMBER BAILEY: Our biggest pool of
11 medical physicists are not in those areas. They
12 really are accelerator physicists, and I'm not sure
13 why I would exclude one of them from being named.

14 CHAIRMAN MALMUD: Dr. Williamson, do you
15 care to respond?

16 MEMBER WILLIAMSON: I'll try because I
17 think the intent of the new regulations is to require
18 the authorized medical physicist to have specific
19 experience, clinical experience essentially with the
20 modality in which they are allowed to precept in. So
21 that a physicist who has never supervised a high dose
22 rate brachytherapy procedure before and only does
23 external beam therapy would not be considered a
24 suitable preceptor, but someone who is currently --
25 and I'm sure California is full of high dose rate

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1 brachytherapy units -- would be, you know, a suitable
2 individual for serving as this preceptor.

3 CHAIRMAN MALMUD: Mr. Lieto?

4 MEMBER LIETO: I think Dr. Williamson
5 would maybe agree with this change to his motion and
6 it answered Mr. Bailey's concern if he replaced the
7 word "Cobalt 60" with "teletherapy," and that would,
8 I think, meet the intent of both groups.

9 MEMBER WILLIAMSON: Okay, yeah. Okay.

10 CHAIRMAN MALMUD: Are you willing to?

11 MEMBER WILLIAMSON: Oh, sure.

12 CHAIRMAN MALMUD: So your motion is
13 amended to replace Cobalt 60 with teletherapy. Does
14 the second remain intact?

15 MEMBER LIETO: So seconded.

16 CHAIRMAN MALMUD: All right. It has been
17 moved and seconded. Any further discussion of that
18 item?

19 Dr. Broseus.

20 DR. BROSEUS: I'd just like to clarify
21 because you brought up the point, and that is as
22 recommended by ACMUI for an authorized medical
23 physicist to qualify as an ANP, an individual has to
24 have training for the types of use which authorization
25 is sought, and that includes hands-on device

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1 operations.

2 And so I'm not sure if I hear your -- I'm
3 not sure if I'm clear about where your motion is, and
4 that is: would your motion allow all of those types
5 of medical physicists?

6 MEMBER WILLIAMSON: No. It would not be
7 --

8 DR. BROSEUS: Or would it be specific to
9 use?

10 MEMBER WILLIAMSON: It would be specific
11 to use. All I'm trying to do is suggest a more
12 general formulation of the grandfathering language
13 that, you know, gets around, you know, substitutes
14 listed on the license for some more general concept of
15 authorized currently by their license or licensee or
16 agency, whatever it is, to perform the functions
17 listed in 35.600. That's the concept, is that there
18 is a pool of working physicists within the agreement
19 state organization, within the agreement states that
20 one way or another have been authorized to perform the
21 required function sin 35.600, and those are the people
22 that logically need to be grandfathered, and we have
23 to alter the language.

24 CHAIRMAN MALMUD: Any further discussion
25 of the motion? Do you want to call the motion?

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1 MEMBER LIETO: I was just going to say the
2 bottom line, I think, here, Roger, is that in the
3 predecisional draft, it states that the NRC does not
4 believe that it is appropriate to grandfather medical
5 physicists to allow them to serve as AMPs, and what
6 we're saying is that that cannot be. We need this
7 initial pool of AMPs to be grandfathered, existing AMP
8 medical physicists to be grandfathered as AMPs, both
9 from the standpoint of continuing care and, two, to
10 serve as the pool for preceptors for shall we say the
11 second wave of AMPs?

12 CHAIRMAN MALMUD: Thank you.

13 Do you want to call the motion? All in
14 favor?

15 (Show of hands.)

16 CHAIRMAN MALMUD: Any opposed?

17 (No response.)

18 CHAIRMAN MALMUD: Any abstentions?

19 (No response.)

20 CHAIRMAN MALMUD: It carries unanimously.

21 Are there other items under this topic?

22 May we move on or shall we take a break
23 for lunch? How are you all feeling? Dr. Miller.

24 MR. MILLER: At the risk of having
25 everyone in this room shoot me --

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1 CHAIRMAN MALMUD: We're not armed.

2 MR. MILLER: -- I take it that our goal
3 from this meeting obviously our original intent was
4 not obtained. However, I'd like to be able to walk
5 out of this meeting if possible and tell me if it's
6 not possible with the knowledge that, with the
7 exception of the issues that have been raised and
8 voted upon, which we will take under advisement with
9 regard to change, that other aspects of the rule
10 are --

11 CHAIRMAN MALMUD: Acceptable?

12 MR. MILLER: -- acceptable and we can go
13 forward.

14 You know, what I'd like to be able to do
15 is to be able to say, you know, when we go forward
16 with the rule, "Here's the recommendations that ACMUI
17 made to us with regard to what you see before you,
18 Commission, and here's how we dealt with those."

19 And absent those specific items, because
20 the Commission will ask us this, is ACMUI okay with
21 the rule as it's being proposed?

22 CHAIRMAN MALMUD: My feeling is that the
23 answer to your question is affirmative, but let me ask
24 the members of the committee.

25 With the exception of those items which

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1 we've brought to the attention of staff, do we approve
2 of that which we've reviewed to move forward?

3 Sally?

4 MS. SCHWARZ: I would like specifically to
5 state rather than just generally; I would like to
6 state for nuclear pharmacy since we really haven't
7 mentioned this at all in the discussion. I mean, it's
8 really the only specialty that's not been discussed;
9 that we do agree with the regulations that are written
10 for the training and experience for nuclear pharmacy.
11 We have no problems with it as it is written.

12 CHAIRMAN MALMUD: Thank you.

13 Shall we entertain a motion to move
14 forward with all of the items except those which have
15 been brought to the attention of staff?

16 MEMBER EGGLI: So moved.

17 CHAIRMAN MALMUD: Dr. Eggli. A second to
18 that?

19 MS. SCHWARZ: Second.

20 CHAIRMAN MALMUD: Ms. Schwarz.

21 All in favor?

22 (Show of hands.)

23 CHAIRMAN MALMUD: Any opposed?

24 (No response.)

25 CHAIRMAN MALMUD: Any abstentions?

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1 (No response.)

2 CHAIRMAN MALMUD: It carries unanimously.

3 You have achieved your goal.

4 MR. MILLER: Thank you.

5 (Laughter.)

6 CHAIRMAN MALMUD: Now, is there a reward
7 for that?

8 MR. MILLER: Let's go to lunch.

9 CHAIRMAN MALMUD: We'll reconvene at one
10 o'clock promptly.

11 (Whereupon, at 12:12 p.m., the meeting was
12 recessed for lunch, to reconvene at 1:00 p.m., the
13 same day.)

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AFTERNOON SESSION

(1:03 p.m.)

CHAIRMAN MALMUD: We are now back for the afternoon session, which begins with the second half of the morning session, and the item on the agenda now will be introduced by -- I lost my place.

PARTICIPANT: This is the proposed change on the AO criteria.

CHAIRMAN MALMUD: And this will A. Jones of the NRC.

PARTICIPANT: Andrea Jones.

MS. JONES: Yes.

CHAIRMAN MALMUD: Andrea Jones. I'm sorry. Is it Dr. or Ms. Jones or Ms. Jones?

MS. JONES: Ms.

CHAIRMAN MALMUD: Ms. Jones. Ms. Jones, and what is your role with the NRC so we may introduced you properly?

MS. JONES: Health physicist.

CHAIRMAN MALMUD: This is Andrea Jones, health physicist with the NRC, and the project is entitled "Proposed Changes to AO Criteria."

Thank you.

MS. JONES: Okay. Thank you.

Today I'm going to present new language

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1 that, if approved by the Commission, will change the
2 way the NRC classifies and reports to Congress medical
3 events that we call abnormal occurrences.

4 Okay. What is an AO? The NRC defines an
5 abnormal occurrence as an unscheduled incident or
6 event determined to be significant from the standpoint
7 of public health or safety.

8 An AO can occur at a nuclear power plant,
9 a fuel facility, a radiography fill site, but in the
10 majority of the cases that we get reported to us, they
11 occur at hospitals or medical facilities.

12 Okay. Why should we revise the AO
13 criteria? To appropriately classify and report to
14 Congress only those events that the Commission
15 considers to have safety and security significance; to
16 reduce potential misunderstanding by the public of
17 actual health or safety significance from medical
18 event occurrences; and to acknowledge the introduction
19 of evolving therapeutic treatment procedures
20 delivering high radiation doses to portions of an
21 organ or tissue.

22 Let me give you just a couple of examples
23 to support a revision of the AO criteria. In 2003,
24 one of the cases that we included in the AO report
25 involved an event where a patient received four

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1 millicuries of Thallium 201 instead of the prescribed
2 dose of four millicuries of Iodine 131.

3 What's the safety significance involved in
4 this case? Well, the oncologist evaluating the case
5 reported that no adverse health effects would occur.

6 Another case. During an intervascular
7 brachytherapy treatment procedure, 2,300 rads was
8 given to an area approximately one and a half inches
9 away from the intended prescribed treatment site. If
10 a member of the public were to read this write-up,
11 they may think a high dose of 2,300 rads is really,
12 really a bad thing, but the doctor evaluating the case
13 reported that the threshold delivered to this artery
14 was well below the threshold where adverse effect
15 would occur.

16 Okay. This slide just gives the current
17 wording for medical licensees. A medical event will
18 be considered an AO if it results in a dose that is
19 equal or greater than 100 rads to the bone marrow,
20 lens of the eye of the gonads, or equal to or greater
21 than 1,000 rads to any other organ.

22 And a dose that is at least 50 percent
23 greater than that prescribed or the wrong
24 radiopharmaceutical or is delivered to the wrong
25 treatment site by the wrong treatment mode or wrong

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1 route of administration. That's the current wording.

2 The proposed new language. I'm not going
3 to read all of the different sections, but in summary,
4 what we did was -- and when I say "we," meaning the AO
5 working group -- we would add a new section which
6 would be recognized as Section A, adding the phrase
7 "unintended permanent functional damage by a
8 physician."

9 The term "tissue" would also be added to
10 "organ" to aid in classifying those areas where dose
11 was delivered to an area that's not called and
12 ordered.

13 B. The second change would be to increase
14 the dose threshold for the gonads from 100 rads to 250
15 rads. The term "tissue" is also added.

16 MEMBER NAG: Excuse me. Do you have this
17 in the handout? I'm trying to look for the handout.
18 Under what section?

19 MR. ESSIG: It's called "Proposed AO
20 Change."

21 MEMBER NAG: No handout?

22 MEMBER SULEIMAN: We have lots of no
23 copies actually.

24 MR. ESSIG: Do you have one?

25 CHAIRMAN MALMUD: I have one. He has one.

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1 A select member has one.

2 MS. JONES: I'm sorry. I thought that --

3 CHAIRMAN MALMUD: I have one because I
4 have the distinct advantage of having left my book at
5 home and received the book as I arrived here. So I
6 didn't realize I had an advantage until now.

7 MR. MILLER: Trish, are there copies
8 there?

9 DR. HOLAHAN: Yes.

10 MR. MILLER: Trish will circulate copies.
11 We have an instant solution to this problem.

12 CHAIRMAN MALMUD: And may I ask a question
13 while we're waiting for the copies to be distributed?

14 MS. JONES: Yes.

15 CHAIRMAN MALMUD: The wording that you
16 have indicated has already been added in the second
17 slide on page 2; is that right, where you said that
18 the word "tissue" was added to "organ"?

19 MS. JONES: Yes.

20 CHAIRMAN MALMUD: Under B(3).

21 MS. JONES: Yes.

22 CHAIRMAN MALMUD: Very good. I have been
23 following you.

24 MS. JONES: Okay. That's your question?

25 Okay.

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1 MEMBER SULEIMAN: Why are you using
2 absorbed dose and not dose equivalent?

3 MS. JONES: That's the way the current
4 criteria is classified, is stated. That's the current
5 terminology that we use.

6 MEMBER SULEIMAN: So if it's an alpha or
7 a beta source?

8 MEMBER NAG: Now, the word "medical event"
9 and "abnormal occurrence" are two different entities
10 or are they going to be used interchangeably?

11 MS. JONES: No. A medical event is the
12 new wording for the previous term "medical
13 administration." And "abnormal occurrence" is a
14 different thing. It's at a higher threshold.

15 MEMBER SULEIMAN: Can I ask my question
16 again? I'm questioning why you're not using dose
17 equivalent rather than absorbed dose. Why not
18 sieverts or REM?

19 If you're using an alpha or beta course
20 technically the dose would be a factor ten times less
21 when, in fact, the dose equivalent would be higher.

22 MS. JONES: Okay.

23 MR. ESSIG: We're talking about acute
24 events here, I think, in which case absorbed dose is
25 probably more accurate.

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1 MEMBER SULEIMAN: No. Let's say it's an
2 alpha source. It's in contact or beta, and so you
3 know, if you're delivering 1,000 rads beta, it's maybe
4 -- a wrong example. Let's say it is an alpha emitter.

5 MR. ESSIG: For a medical event?

6 MEMBER SULEIMAN: Well, I'm trying, but
7 the dose would be ten times higher. In other words,
8 1,000 rads of an alpha source would be 10,000 rem, and
9 so the actual equivalent would be ten times higher.
10 So there's a risk that would be greater.

11 Nominally for gamma or X-ray, they're
12 equivalent, but in those situations like a
13 brachytherapy, don't you take that into consideration
14 when you do your dose calculations?

15 MEMBER SULEIMAN: Do we have any alpha --

16 PARTICIPANTS: No.

17 MR. ESSIG: Betas are -- I mean, most of
18 the time they're going to be equivalent, but I'm
19 thinking of the situation where you have a
20 contribution from some --

21 MEMBER SULEIMAN: It would only be alphas.
22 The quality factor for betas is one.

23 MEMBER NAG: If I may as, (a), I guess
24 it's quite clear the result is unintended permanent
25 functional damage. The first thing is under B, the

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1 problems which are created by radioactive implants
2 that are closed to the eye because many times the eye
3 just by having the sources a few millimeters away
4 could increase the dose to the lens just quickly. A
5 radioactive implant for parietal melanomas in the eye,
6 that very easily can give, you know, more than that
7 dose to the lens of the eye.

8 Secondly, for the gonad, if you are having
9 an implant in the upper prostate, a gonad just by
10 having the implant a few millimeters one way or the
11 other can easily give a dose greater than what you are
12 saying the gonads show.

13 We have to see how we are going to word
14 this.

15 MEMBER EGGLI: Subir, this isn't "and"
16 condition. You must meet A first before you even
17 begin to apply B. This is an "and" condition so that
18 the threshold is unintended damage.

19 DR. HOLAHAN: And also it has to meet the
20 criteria for medical event.

21 MEMBER NAG: Okay, but I think A itself,
22 if you are having a permanent damage even if it did
23 not have any of the B, it would be a problem.

24 MEMBER VETTER: But if you prescribed
25 this, then it's not a medical event. If it all was

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1 administered in accordance with your prescription,
2 then it doesn't matter whether the eye got 100 rads or
3 1,000 rads. If that was your prescription, it's not
4 a medical event.

5 MEMBER WILLIAMSON: What if the GYN
6 patient had a fistula, for example? That happens,
7 say, two percent of the time. It's a complication,
8 you know, at a frequency level with a properly
9 administered treatment you would accept. You don't
10 want this to count.

11 MEMBER VETTER: These abnormal
12 occurrences, first of all, it's a medical event which
13 means didn't go the way you planned, and it's a high
14 level medical event.

15 MS. JONES: Right.

16 MEMBER NAG: Okay.

17 MR. ESSIG: And correct me if I'm wrong,
18 but if I can make another clarification here, I
19 believe that the B(1) is the same as is currently.
20 Even though it's proposed wording, B(1), the 100 rads
21 to major portion of bone marrow lens to the eye is the
22 same as it now.

23 MS. JONES: Right.

24 MR. ESSIG: The only thing that was
25 changed is that the gonads had previously been

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1 included under that 100 rad statement.

2 MS. JONES: Correct.

3 MR. ESSIG: We have now moved them to the
4 250 rad, and so it's --

5 MEMBER NAG: My misunderstanding was the
6 end because without the end, if it was either A or B,
7 then it would have been a problem.

8 CHAIRMAN MALMUD: Dr. Miller.

9 MR. MILLER: Quickly, I think what Andrea
10 is trying to do here is walk the committee through
11 some proposed changes to the O criteria, and if I
12 could ask for your patience, if she could walk through
13 all of the criteria, then I think what we would like
14 to do is to get your views on the new proposed
15 criteria that the staff has developed, but I think it
16 would be beneficial to hear the whole presentation
17 because I think when we keep jumping in in the middle,
18 it kind of discombobulates the --

19 CHAIRMAN MALMUD: Thank you.

20 Now that everyone has a copy of the slide,
21 would you please continue?

22 MS. JONES: Okay. The proposed new
23 language which is denoted in bold with a new element
24 recognized as Section A, so NRC will consider a
25 misadministration a medical event that results in

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1 unintended permanent functional damage to any organ or
2 tissue as determined by a physician and which results
3 in a dose that is equal to or greater than 100 rads to
4 a major portion of the bone marrow or the lens of the
5 eye or equal to or greater than 250 rads to the gonads
6 or equal to or greater than 1,000 rads to any other --
7 and I left the T out. I'm sorry -- to any other organ
8 or tissue.

9 And there's a C: and represents either a
10 dose or a dosage that is 50 percent greater than that
11 prescribed in the written directive or a dose or a
12 dosage administered in the absence of a written
13 directive or a written directive was needed, but the
14 dose was given in mistake. It wasn't an intended
15 dosage.

16 And also we add the term "unsealed by
17 product material" to three.

18 So really the proposed new wording, the
19 major things that we're doing is we're adding A. The
20 event has to result in some type of unintended
21 permanent functional damage to an organ, and we add
22 the word "tissue" because previously sometimes we get
23 cases where there's not -- the area exposed isn't
24 defined as an organ.

25 So you have to get A, first of all, in

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1 order to even begin to meet the criteria for being
2 classified as an AO. So B, what's the change in B,
3 which was the previous A? We raised the dose to the
4 gonads to 250 rads, and we added the word "tissue" for
5 the same reasons that we added it in A. Okay?

6 C, what we really did here, we tried to
7 capture those events that were given in error where
8 the doctor, because of the quantities or the
9 treatment, the doctor didn't even prepare a written
10 directive because the facilities' procedures didn't
11 require one. But there was permanent functional
12 damage and the dose threshold was exceeded, and it
13 follows the regular criteria.

14 MEMBER WILLIAMSON: Just a question of
15 clarification. For any of these, A, B, or C, to be
16 invoked, it already has to be a medical event per the
17 definition in Part 35. So we're starting out with the
18 assumption --

19 MS. JONES: Yes.

20 MEMBER WILLIAMSON: -- that this already
21 meets the criteria.

22 MS. JONES: It reached the medical event.

23 MEMBER WILLIAMSON: Okay.

24 MEMBER LIETO: So is C just a repeat or
25 what the definition is of a medical event?

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1 MS. JONES: No, C adds. It adds a new
2 "or" where there was -- you know, if you were -- where
3 there was an administration given and a written
4 directive wasn't prepared. So maybe the technologist
5 didn't know that she was supposed to give five
6 microcuries and she gave 500 millicuries. She didn't
7 -- I mean, there wasn't a written directive prepared.
8 So she didn't have the prescriptive directions in
9 front of her.

10 MS. McINTOSH: Pardon me. May I make a
11 comment right here? I'm on the working group with
12 Andrea to propose these changes.

13 For that language right there that's
14 highlighted, the purpose of that language is to
15 capture events whereby the dose administered was at a
16 level where a written directive was required, but
17 because the intended dose didn't require a written
18 directive, one was not prepared.

19 So stated differently, the doctor may have
20 intended to give the patient a diagnostic level dose,
21 but what wound up being administered was a therapeutic
22 level dose.

23 Well, in that case, a written directive
24 would not have been prepared because what was intended
25 was a dose that didn't require a written directive.

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1 So we want to capture events whereby the dose that was
2 administered, there should have been a written
3 directive prepared, and currently we're not capturing
4 those events because of the technicality that we don't
5 have that language in there. Yet a mistake, a
6 significant mistake was made.

7 So that's the purpose of adding that
8 proposed language there.

9 My name is Angela McIntosh, for the
10 record.

11 CHAIRMAN MALMUD: Thank you, Angela.

12 May we continue with your --

13 MS. MCINTOSH: Dr. Malmud, I believe Dr.
14 Howe.

15 CHAIRMAN MALMUD: Oh, all right. Because
16 we were going to -- okay, all right.

17 MS. SCHWARZ: This pertains to the
18 statements, Dr. Howe. I think in this case the
19 medical event that's at the top of the slide is not
20 the definition of a medical event that's in Part 35.
21 It is just the plain language medical event. It's
22 really an event in a medical use licensee's site
23 because of this additional part where we've had people
24 receive therapeutic doses when they were only supposed
25 to get diagnostic, and we want to capture those that

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1 have permanent functional damage.

2 And OGC has interpreted the reporting
3 requirements in Part 35 not to capture the case in
4 which there wasn't a written directive because one was
5 not intended, to start out with, and a therapeutic
6 dose is given.

7 So this is to help capture those.

8 CHAIRMAN MALMUD: Thank you.

9 Dr. Vetter.

10 MEMBER VETTER: Just quickly, if these
11 don't meet the definition of a medical event as
12 described in Part 35, they shouldn't be called medical
13 events.

14 MEMBER WILLIAMSON: Here, here.

15 MEMBER VETTER: We should use some other
16 term.

17 MS. JONES: Well, we call them abnormal
18 occurrences.

19 MEMBER VETTER: No, I mean in the
20 definition of this particular abnormal occurrence
21 we're seeing, first of all, these are medical events.
22 If these do not meet the definition of medical event
23 as per Part 35, they should not be called medical
24 events.

25 MS. JONES: Okay.

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1 MEMBER WILLIAMSON: It should say "an
2 administration of byproduct material that."

3 MS. JONES: I understand.

4 MEMBER WILLIAMSON: Good comment.

5 MS. JONES: Yeah.

6 CHAIRMAN MALMUD: Please go on.

7 MS. JONES: Okay. In conclusion, if
8 approved by the Commission, the revised medical
9 criterion will insure that -- and I'm just going to
10 say "medical events" for the purpose of the slides
11 already prepared -- insure that the medical events
12 reported to Congress have resulted in permanent
13 functional damage to a specified target organ or
14 surrounding tissue as determined by a physician; will
15 capture the current recommendations of ICRP 60;
16 include medical events where the dose was administered
17 in error and a written directive was not required for
18 the intended administration; and include unsealed
19 byproduct material commensurate with Part 35.

20 So I'm open to any questions or comments
21 that you may have right now. However, I am
22 requesting, you know, written comments to be submitted
23 to Angela by the end of this month.

24 CHAIRMAN MALMUD: Thank you, Ms. Jones.

25 MS. JONES: Thank you.

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1 CHAIRMAN MALMUD: Are there any questions
2 or comments for Ms. Jones?

3 MEMBER NAG: Yes.

4 CHAIRMAN MALMUD: Dr. Nag.

5 MEMBER NAG: Now that I'm practicing all
6 of the "ands" and "ors" and so on, if you have a place
7 that this is no longer a medical event, you know, even
8 just the administration of a routine radioactive
9 material, you have now an unintended functional damage
10 and at the same time there was, for example, if this
11 was an implant in the eye, the lens would
12 automatically or most likely have received more than
13 100 Gray; almost any event that is having some
14 unintended functional damage in the eye will
15 automatically be in there.

16 MS. JONES: Oh.

17 MEMBER NAG: Yes.

18 MEMBER WILLIAMSON: Not if you intended to
19 damage the eye. If you did a treatment, say, of the
20 organ of the right eye and you accepted knowingly and
21 consented the patient and told them, you know, "Your
22 lens is going to get this dose and you're going to
23 have to have a lens transplant most likely," I think
24 that Phrase A because of the word "unintended" in
25 there would exclude this.

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1 Now, if you treated the wrong eye by
2 mistake, if the therapist made a mistake and treated
3 the wrong eye, and that lens got a dose of 2.5 Gray
4 and the patient had a cataract or some other damage,
5 then I think it would be an abnormal occurrence,
6 right?

7 MS. JONES: That's exactly right. This is
8 not intended to capture therapy. This is intended to
9 capture mistakes, and that's the reason why the word
10 "unintended" has been included. Something happened
11 that was not intended. So damage occurred to the
12 patient.

13 MEMBER NAG: And in that I think it may be
14 a good idea to have at the beginning that it had to be
15 a medical event although, you know, you are saying
16 that doesn't really mean medical event. Perhaps it
17 would be better if the entry would be that it had to
18 be a medical event in the first place.

19 MEMBER WILLIAMSON: But then they couldn't
20 capture all of the events they want to because if one
21 gives a diagnostic dose of radionuclide and, you know,
22 makes a mistake and gives 100 times too much
23 activity --

24 MEMBER NAG: That itself would be a
25 medical event.

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1 MEMBER WILLIAMSON: No, it is not. They
2 just told us that the definition of medical event
3 fails to capture that. So that's why they need to put
4 some more neutral language like "an administration of
5 byproduct material that."

6 MEMBER NAG: Yeah, you can put that.
7 Administration of the byproduct material that forces
8 a medical event, number one, and results in permanent
9 damage. That I think will solve that problem.

10 MEMBER WILLIAMSON: It will exclude, you
11 know, the bullet on her last slide insured -- where is
12 it? "Include medical events where the dose was
13 administered in error and a written directive was not
14 required," because the medical event definition in
15 Part 35 does not apply to cases where a written
16 directive was not required. Am I right?

17 MEMBER VETTER: No, you can still have
18 medical events.

19 MEMBER WILLIAMSON: You can have a medical
20 event where --

21 MS. JONES: Yeah.

22 MEMBER VETTER: If there's 50 rads to an
23 organ or more than five rads to the whole body and
24 it's more than --

25 MEMBER WILLIAMSON: I thought someone just

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1 -- I thought that Dr. Howe just said that the Office
2 of General Counsel had ruled that a misadministration
3 of a diagnostic dose that caused injury could not be
4 a medical event per Part 35. Is that not correct?

5 DR. ZELAC: Dr. Malmud.

6 CHAIRMAN MALMUD: Dr. Zelac.

7 DR. ZELAC: What was excluded from her
8 statement apparently is the condition relating to dose
9 that results from this. If you, in fact, administered
10 a dosage that exceeded on a percentage basis or was
11 outside of the range that was intended, that by itself
12 would not qualify as a medical event if we're talking
13 about a diagnostic dosage.

14 However, if the variation from the
15 intended dosage was sufficiently great that the
16 resultant dose to an organ exceeded the 50 rad limit,
17 then, in fact, it becomes a medical event.

18 So it's two conditions that are required.

19 MEMBER WILLIAMSON: All right. Then maybe
20 Dr. Nag's point is a good point, that it seems
21 unlikely you're -- what kind of a major complication
22 are you going to have without the diagnostic
23 administration satisfying the medical event criteria
24 in Part 35?

25 MS. JONES: Probably none.

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1 DR. HOWE: Dr. Malmud, may I make a
2 comment?

3 CHAIRMAN MALMUD: Please, Dr. Howe.

4 DR. HOWE: We've actually had people that
5 have given the wrong administration of the therapy,
6 but they haven't had a written directive either, and
7 this would capture those events also.

8 MEMBER NAG: That would automatically be
9 a medical event.

10 DR. HOWE: No, it would not because our
11 Office of the General Counsel reviewed these cases
12 with us, and they said, no, the prescribed does didn't
13 exist. So it can't be greater than the prescribed
14 does because there was no written directive.

15 And it's a problem we need to come back
16 and probably look at the rule language for again, but
17 that's what this is trying to capture, is the fact
18 that there are a few cases, and we've tried to set the
19 bar very high -- in other words, there's permanent
20 functional organ or tissue damage -- that will
21 capture these cases for which for one reason or
22 another there was no written directive, and so it
23 doesn't meet the criteria for a medical event, but it
24 certainly is a serious occurrence.

25 MEMBER NAG: Life threatening. If you

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1 don't have a medical directive, that automatically
2 becomes a medical event. A medical event is an
3 occurrence where a written directive is not there,
4 when a written directive is required.

5 DR. HOWE: Dr. Nag, there's clearly a
6 violation of the regulations where to deliver a
7 therapeutic dose you should have had a written
8 directive. However, our Office of the General Counsel
9 has determined that when you go to the definition of
10 a medical event, it has to be a dose or dosage that
11 differs from the prescribed, and the prescribed is
12 that which is written in the written directive.

13 So if there is nothing written in the
14 written directive, then you don't have a prescribed
15 and you don't have a recording requirement because you
16 didn't have a medical event.

17 You can have a violation of the
18 regulations, but those cases would not be captured for
19 the abnormal occurrence in severe incidences because
20 they technically didn't meet medical event.

21 CHAIRMAN MALMUD: Dr. Eggli.

22 MEMBER EGGLI: Now, it strikes me that if
23 you don't have a written directive that you have to
24 have a standard dose by policy or procedure, and
25 wouldn't that be covered if you exceeded your standard

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1 policy or procedure dose?

2 DR. HOWE: In the cases that we've had,
3 no, there hasn't been a standard.

4 MEMBER EGGLI: Because you can't just give
5 anything for a diagnostic study. I mean either you
6 have to have a prescribed dose or you have to have a
7 policy that says for a bone scan we give 20
8 millicuries. I mean, you can't just willy-nilly give
9 100 millicuries and say that's okay.

10 DR. HOWE: This case also captures those
11 therapeutic procedures that are given without a
12 written directive.

13 MEMBER NAG: I know that the therapeutic
14 procedure for which there is no written directive
15 required. Could you tell me -- I'll give you an
16 example. All the implants I do require a --

17 DR. HOWE: Dr. Nag, the point isn't
18 whether you were supposed to have a written directive.
19 The point is there wasn't one. You were supposed to
20 have it, but it wasn't there.

21 MEMBER NAG: Yeah, but the definition of
22 medical event includes having a procedure where a
23 medical directive is not there. That automatically
24 becomes --

25 MEMBER WILLIAMSON: That's what they're

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1 telling you. That's not true.

2 MEMBER NAG: But there is. Why wouldn't
3 you include that?

4 DR. HOWE: That's our problem. It's not
5 there, Dr. Nag.

6 CHAIRMAN MALMUD: May I try and bring some
7 clarity to this? The circumstance that you're
8 describing, Dr. Howe, is one in which the physician
9 should have written a directive, did not do so. The
10 wrong dose was given. Since the current definition of
11 a medical event includes not abiding by the written
12 directive, it's not currently considered a medical
13 event because there was no breach of the written
14 directive which didn't exist.

15 DR. HOWE: That's correct.

16 CHAIRMAN MALMUD: All right. I understand
17 the problem. This does address that problem, does it
18 not?

19 DR. HOWE: Yes, it does.

20 CHAIRMAN MALMUD: Is there anyone who
21 feels that this does not address that problem? Dr.
22 Lieto.

23 MEMBER LIETO: I don't think it fixes it
24 because what you should do is change the definition of
25 the medical event to require a written directive, and

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1 that doesn't seem to be in here.

2 CHAIRMAN MALMUD: Was that given
3 consideration to changing the definition of a medical
4 event?

5 DR. HOWE: We currently have a user need
6 memo that we're in the process of finalizing going to
7 rulemaking that would change the rule text, but in the
8 meantime we would not have these severe events
9 reported when they are a severe event and they should
10 be reported under the abnormal occurrence.

11 So it's going to take us years to get rule
12 language changed, and the priority for going in and
13 opening Part 35, I believe, at this particular point
14 is very low.

15 CHAIRMAN MALMUD: All right. So now we
16 understand that the presentation by Ms. Jones is for
17 a specific instance which is not covered by the
18 current regulations adequately and that this would
19 cover it until the definition of a medical event can
20 be redefined. Is that a fair statement?

21 DR. HOWE: I believe that's clear.

22 MR. MILLER: Almost.

23 CHAIRMAN MALMUD: Almost. What did I
24 leave out?

25 MR. MILLER: I think the distinction that

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1 you have to make is the purpose for which it's used.
2 What we're offering here is we have a definition
3 currently of abnormal occurrence, you know. We're
4 focusing on the medical abnormal occurrence at this
5 point in time.

6 CHAIRMAN MALMUD: Yes.

7 MR. MILLER: We have a requirement to
8 report to Congress the number of abnormal occurrences
9 every year and what they are. What we're proposing to
10 do here is to change the definition of abnormal
11 occurrence as it relates to the medical area so that
12 what we report to Congress truly captures all that we
13 would intend to report and fix the problem for the
14 definition of abnormal occurrence.

15 It doesn't fix the problem at this point
16 in time of the definition of a medical event, and I
17 think Dr. Williamson has offered a way around that for
18 the purposes of the definition of abnormal occurrences
19 as to, you know, not call it a medical event. I
20 think you used the term "administration of byproduct
21 material." Dr. Vetter identified the fact that you
22 couldn't call it a medical event if it didn't meet the
23 strict definition.

24 So the distinction is it's for different
25 purposes. You know, it's not to replace the

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1 definition of medical event.

2 CHAIRMAN MALMUD: We understand.

3 MR. MILLER: It's to fix the abnormal
4 occurrence definition to more accurately report to
5 Congress those things that are really of concern to us
6 that meet the threshold.

7 CHAIRMAN MALMUD: Pretty straightforward.

8 Mr. Lieto.

9 MEMBER LIETO: Well, I'm going to take the
10 devil's advocate side here. I have an event that does
11 not have to be reported. In other words, I give ten
12 millicuries to a patient of 131 that was only supposed
13 to get 100 mics. I don't write a written directive.

14 I don't have to report it --

15 MS. JONES: Right.

16 MEMBER LIETO: -- according to this
17 because it doesn't meet a medical event.

18 MS. JONES: Right.

19 MEMBER LIETO: So how do you capture
20 something that doesn't have to be reported?

21 MEMBER VETTER: Excuse me. You said
22 you're going to give ten millicuries instead of --

23 MEMBER LIETO: No, I gave ten millicuries
24 and I was supposed to give 100 mics.

25 MEMBER VETTER: That is a medical event

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1 because ten millicuries of I-131 to the thyroid is not
2 insignificant.

3 MEMBER LIETO: No, I didn't write the
4 written directive.

5 MEMBER WILLIAMSON: But it gives a dose of
6 more than 50 centigrade to some organ, right?

7 MS. JONES: Well, it would have to result
8 under the new wording.

9 MEMBER LIETO: See, what I'm saying is
10 that you need to change -- what we're doing is we're
11 putting a Bandaid in the wrong spot. Okay? We're not
12 fixing what needs to be fixed because if I don't have
13 to report it because I didn't have a written
14 directive, what's --

15 DR. HOWE: This is Dr. Howe.

16 Just because you don't have to report it
17 doesn't mean that NRC may not become aware of it
18 because it is a violation of the regulations and we
19 may become aware of it during inspection or at some
20 other point at which the information comes forward.
21 So it's a violation of the regulations and is a
22 regulatory concern.

23 But you're right. It's not reportable
24 under the medical event reporting requirements.

25 CHAIRMAN MALMUD: Dr. Suleiman.

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1 MEMBER SULEIMAN: What if you give a 50
2 rad dose without a written directive and that's what
3 you intended? So you deliver the dose you intended,
4 but there was no written directive. So what would
5 that be?

6 MS. JONES: If there was no permanent
7 functional damage, then it wouldn't be an AO.

8 CHAIRMAN MALMUD: It wouldn't be
9 reportable, but it would still be something which the
10 radiation safety officer --

11 MS. JONES: Yes.

12 CHAIRMAN MALMUD: -- within the
13 institution would monitor and point out was an error.

14 MS. JONES: Right.

15 MEMBER WILLIAMSON: And if they found it
16 during an inspection, you could be cited for a
17 violation.

18 MS. JONES: Right.

19 PARTICIPANT: I also understand the legal
20 argument in that you have never specifically
21 prescribed the dose, how can you know that you are
22 exceeding it by a certain quantity since there's no
23 reference value to compare it against.

24 So that's dangerous, but I can sometimes
25 understand their perspective.

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1 MEMBER LIETO: I mean, I see what Andrea
2 and Angela and the group is trying to do, but you
3 know, I guess why can't you just -- I mean, we all
4 recognize that this just simply needs to have that one
5 line item in the definition of a medical event.

6 You're doing all of these changes to Part
7 35 right now. Why don't you just slip it in there?

8 (Laughter.)

9 MEMBER LIETO: It's not a significant
10 change.

11 CHAIRMAN MALMUD: Well, I think
12 experience, which Dr. Howe has reinforced by reminding
13 us, indicates that it would take a long time to get
14 that done, and here is a potential solution to a
15 current problem which Andrea Jones has given us a
16 solution to.

17 MR. MILLER: I think, again, what Ralph
18 has offered is exactly on target with regard to a
19 problem that we have to separate into two separate
20 issues here because the definition of medical event
21 needed to be changed, and I think we agree that it
22 should be, and that will go through its due course in
23 order to get changed.

24 What we're trying to focus on here is
25 getting current and accurate wording for what an

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1 abnormal occurrence should be so that the annual
2 reporting of that to Congress reflects our current
3 thinking on what an abnormal occurred should be,
4 regardless of whether or not it's reportable to the
5 NRC.

6 As we've pointed out, we may learn a
7 matter by some other means even though it might not be
8 reported.

9 CHAIRMAN MALMUD: Ralph, you wanted to say
10 something?

11 MEMBER LIETO: Well, I was just going to
12 say in the last occurrence report, I mean, you still
13 have captured those events and reported them. I mean,
14 it's not like this definition is not prevented the NRC
15 from capturing these events and reporting them to
16 Congress in line with this new proposed definition,
17 and I don't have an objection there.

18 I guess, you know, the issues of getting
19 the real problem fixed, which as Charlie pointed out
20 is a separate issue.

21 CHAIRMAN MALMUD: Mr. Essig was next, I
22 believe.

23 MR. ESSIG: Just to quickly add on, I
24 don't know that we've clarified or made the point yet
25 that the language you're looking at here is not for a

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1 rule. It's for management directive, which is an
2 internal NRC document. So a rulemaking would be a
3 totally separate issue. This is just language and
4 management directive which is much easier to change.

5 CHAIRMAN MALMUD: Thank you.

6 Dr. Holahan.

7 DR. HOLAHAN: Yes. The other thing, and
8 I haven't talked to the working group yet, but the
9 criteria for AOs also includes for our licensees human
10 expose to radiation from licensed material. If the
11 committee believes it's important to keep it to
12 medical events, maybe we could put it in that
13 criteria, the things that are not technically a
14 medical event.

15 CHAIRMAN MALMUD: Thank you.

16 Dr. Essig.

17 MR. ESSIG: I think that this is good,
18 particularly with the addition of Part A and the
19 changing of the threshold to resulting in functional
20 damage. I think this is real good, and I think we
21 should endorse it.

22 You know, some of the wording may be
23 convoluted. We may be trying to fix a problem
24 incompletely fixed, but I think just the addition of
25 Part A itself justifies our endorsing it.

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

3 MEMBER WILLIAMSON: Second.

4 CHAIRMAN MALMUD: Any further discussion?
5 (No response.)

6 CHAIRMAN MALMUD: All in favor?
7 (Chorus of ayes.)

8 CHAIRMAN MALMUD: Any negatives?
9 (No response.)

10 CHAIRMAN MALMUD: Any abstentions?
11 (No response.)

12 CHAIRMAN MALMUD: You have carried it
13 unanimously. Thank you.

14 MS. JONES: Thank you.

15 CHAIRMAN MALMUD: The next item on the
16 agenda, national source tracking.

17 MR. ESSIG: We were pulling that off the
18 agenda because of time.

19 CHAIRMAN MALMUD: And then we're going to
20 go to the ICRP recommendations.

21 MR. ESSIG: Yes, and I wanted to make a
22 word or two of introduction.

23 CHAIRMAN MALMUD: Mr. Essig is going to
24 introduce Dr. Vetter and the issue that is before us,
25 and there is a handout which you all should have, and

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1 we're passing around something else relevant to this
2 discussion.

3 MR. ESSIG: And while that's being passed
4 around, I should --

5 CHAIRMAN MALMUD: So there are two
6 handouts to this; is that correct?

7 MR. ESSIG: No, not this one. It's in
8 your packet.

9 CHAIRMAN MALMUD: It's in the book.

10 MR. ESSIG: Or it was given to you.

11 CHAIRMAN MALMUD: Or it was given to you,
12 one of the two.

13 MR. ESSIG: I should just add that I
14 really wasn't going to introduce Dr. Vetter since he
15 needs no introduction. I was just going to introduce
16 the topic.

17 The topic is next week you have one of
18 your handouts, notes that the Advisory Committee on
19 Nuclear Waste will be meeting, and they have a working
20 group which will be reporting to them on Tuesday, the
21 19th regarding their comments on the proposed ICRP
22 2005 recommendations.

23 They've pulled together a large number of
24 speakers, some NRC people, an NIH expert on biological
25 aspects of radiation protection, and Dr. Keith

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1 Eckerman from Oak Ridge National Laboratory, a number
2 of very well known people in the community.

3 And you will notice on the agenda, page 2,
4 at two o'clock your own Edgar Bailey, representing
5 CRCPD, will be presenting, and then followed by him
6 will be Dr. Vetter.

7 And the purpose of today was for Dr.
8 Vetter to give an overview of the recommendations and
9 some of his insights, and then entertain any comments
10 from the committee that he should carry to the meeting
11 next Tuesday representing really, although it says
12 Mayo Clinic, he's really representing the ACMUI. That
13 was asked for. They wanted a representative of the
14 ACMUI.

15 So I believe we'll be asking you to
16 empower Dr. Vetter to carry forward any comments that
17 you may have or if you have no comments, to accept the
18 comments that he has prepared.

19 CHAIRMAN MALMUD: Thank you, Mr. Essig.

20 Dr. Vetter.

21 MEMBER VETTER: Thank you.

22 I'm going to forego the formal slides
23 projecting them on the screen. We'll just take a look
24 at the handout because most of this I'll skip through
25 rather quickly.

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1 ICRP's fundamental aim hasn't changed much
2 or basically not at all. The intended use might be
3 worth emphasizing that their intention is to influence
4 regulatory agencies, management bodies, and so forth.
5 Oh, by the way, these slides, potential impact of ICRP
6 2005, they were provided for you. Okay. You have
7 them.

8 So the intended use, ICRP intends for
9 their recommendations to influence regulatory
10 agencies. They're not in large measure directing
11 these at us as individual practitioners, but there are
12 certain aspects of it that do affect us individually.

13 They do define safety culture. They have
14 some principles of protection which there are a couple
15 of things that are worth mentioning. One of them is
16 that they now more clearly spell out a restriction on
17 dose from certain activities, and they call this a
18 constraint.

19 And I must say, if you have the same
20 reactions I do, you have to read through some of this
21 several times before you really begin to understand
22 what they mean by "constraint," but I'll try to point
23 that out to you as we go.

24 So they do have some restrictions on dose
25 called a constraint. This is not a dose limit for an

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1 individual, but it's a constraint, dose constraint on
2 particular activities. They want us to understand
3 that their position is that achieving a constraint is
4 an obligation. So it almost becomes a limit, a dose
5 limit or it does become a regulatory limit of sorts.

6 And they also make it very clear that if
7 a program does not maintain a constraint, then it is
8 failing. The program is failing in that regard.

9 The scope of the recommendations, they do
10 clearly define what they mean by various sources. A
11 source is a cause of an exposure, not a particular
12 radiation source.

13 I'm not going to read through most of
14 these. Practice judgment. Judgment it's worth
15 pointing out, I think. They're saying that the
16 responsibility for justification falls on governments
17 or government agencies, except for medical.

18 In other words, if the public is going to
19 be exposed to a source of radiation through some
20 proved activity, that is up to the government to
21 justify that. For medical it's different. For
22 medical they're saying that justification has more to
23 do with not causing harm to patients, doing more good
24 to patients than harm. They're saying that the
25 practice must be justified, and the justification lies

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1 more with the profession than the government.

2 So justification for implementation of
3 computerized tomography, for example, or PET or a new
4 byproduct material, introduction of a new source of
5 radiation to a practice must be justified by the
6 profession, but justification of the procedure, so
7 applying that to a particular patient or in a practice
8 must be justified by the practitioners.

9 Classes of exposure, the classified
10 exposure by various groups of people and how they can
11 be exposed. Occupational, pretty straightforward,
12 occurs at work principally as the result of work, that
13 being the responsibility of management. Medical,
14 exposure of persons as part of their diagnosis or
15 treatment, and there are no constraints for that
16 particular class of exposure. There they clearly
17 point out and emphasize that those exposures must be
18 justified.

19 And then finally, public, all other
20 exposures. That's a class of exposure.

21 Now to the point of dose constraints.
22 Just the definition or the purpose of a dose
23 constraint. A dose constraint is to provide
24 protection for the, underscore, most exposed
25 individual; so the individual who would get the

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1 highest dose within a class of exposure. That would
2 be occupational, medical or the public, whichever
3 individual gets the highest dose within one of those
4 classes, from a single source.

5 Now, it falls out of the purview of the
6 NRC, but I will mention because some of you in this
7 room would be very familiar with this issue. There is
8 a very contentious issue in the radiation protection
9 community right now that falls right square in this
10 ballpark, and that is the design of diagnostic X-ray
11 facilities to prevent the public from receiving a
12 certain dose, and the NCRP has recently approved a
13 report that will allow a hospital to design a shield
14 that could result in the highest dose to an individual
15 member of the public of 100 millirem.

16 Now, that is the public limit, 100
17 millirem. Most states have adopted that, but the NCRP
18 also has buried in one of its recommendations, we
19 don't call it a constraint in this country, but it's
20 sort of a sublimit; that if a member of the public
21 could be exposed to more than one source of radiation,
22 then each of those sources should be a fraction of
23 that 100 millirem limit.

24 And so now the argument is, well, members
25 of the public who sit in a waiting room, if they could

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1 receive 100 millirem at this hospital, what if they're
2 living over here and they're receiving 25 millirem
3 from this source of air from a reactor or whatever it
4 might be? I know they don't get that much, but it's
5 a philosophical issue.

6 So this is a big deal. This constraint
7 thing is a big deal, and I think we need to just be
8 aware of that.

9 So relative to our own activities as it
10 applies to public exposure, we need to keep in mind
11 that a constraint means that the individual member of
12 the public could be exposed. If the member of the
13 public could be exposed to more than one source of
14 radiation, then each of those sources can't expose the
15 member of the public to the limit. The limit is a
16 combination of all those sources, and each one of them
17 must be constrained. That's the recommendation.

18 And that's where it gets confusing,
19 because in the next table you'll see that the dose
20 constraint, the maximum value of the dose constraint
21 is the value listed. So, for example, for societal
22 benefit, that would be a member of the public,
23 societal benefit meaning people are not being
24 informed; they're not being trained; there's no
25 individual assessment as to what their exposure is.

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1 The constraint is one millisievert or 100 millirem.
2 That's the maximum constraint.

3 The next table shows you the limit, and
4 you'll see the limit for a member of the public is
5 also one millisievert or 100 millirem. That's the
6 limit. So if the member of the public is being
7 exposed to more than one source of radiation, then
8 each of those must be constrained so that the member
9 of the public doesn't get 100 millirem.

10 Do you see what I'm saying?

11 And that will be problematic in terms of
12 agreeing philosophically with that. It really comes
13 down to a very difficult problem on application. Does
14 that mean that every hospital has to assure that a
15 member of the public doesn't get one-tenth if they
16 could go to ten different hospitals? I mean, where do
17 you draw the line here?

18 This is going to require some significant
19 discussion.

20 Now, just to point out again, as Tom
21 mentioned, the purpose of my presentation here is to
22 take your views to next week's meeting. So I don't
23 know that we want to spend a whole lot of time
24 discussing this because this is simply a
25 recommendation at this point, but if you perceive that

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1 this could be a significant problem, I want to take
2 that to next week's meeting.

3 Dr. Miller, did you have a question?

4 MR. MILLER: I have a question out of
5 ignorance. Would by that definition X-rays be
6 included?

7 MEMBER VETTER: These recommendations
8 apply to everyone.

9 MR. MILLER: So if someone went to get a
10 dental X-ray or a medical X-ray --

11 MEMBER VETTER: Oh, I'm sorry. They don't
12 apply to the procedure itself, to the patient's dose.
13 They apply to the visitor waiting for the patient, the
14 visitor in the waiting room.

15 MR. MILLER: Okay. So if you were the
16 patient you wouldn't have --

17 MEMBER VETTER: There's no constraint on
18 patient dose.

19 MR. MILLER: Okay.

20 MEMBER VETTER: An there's no limit on
21 patient dose.

22 MR. MILLER: Okay.

23 MEMBER VETTER: This is a member of the
24 public who would be waiting for the patient in the
25 waiting room.

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1 MR. MILLER: I understand, but if they by
2 some means were to get some dose from that source,
3 that would be counted?

4 MEMBER VETTER: If who? Oh, you mean the
5 patient while they were in the waiting room?

6 MR. MILLER: Yeah, if I was in the waiting
7 room.

8 MEMBER VETTER: Absolutely, yes.

9 MR. MILLER: Not that it's practical, I
10 mean, but if by some means they did.

11 MEMBER VETTER: Right. Anyone sitting in
12 the waiting room basically.

13 MR. MILLER: I guess from -- I'm sorry I'm
14 interrupting.

15 MEMBER VETTER: No, that's okay.

16 MR. MILLER: But the thought that I have
17 is how are you going to accumulate this. How are you
18 going to account for this? People are going to have
19 to walk around with dosimetry on?

20 MEMBER VETTER: No, I think --

21 MR. MILLER: From a practical perspective,
22 how would you accumulate the fact that you have
23 exceeded the hundred by all of those means?

24 MEMBER VETTER: No, that's a very good
25 question, a very good question, and the medical

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1 community, medical physics community is almost in an
2 uproar over this because you can't. You can't
3 possibly measure. You have to calculate it, and so
4 the constraint is something that has to be -- it's
5 almost an artificial thing. You have to design your
6 facility so that the maximally exposed individual
7 would not get more than the constraint.

8 MR. MILLER: The radiation safety
9 community has been practicing this for decades. It's
10 just that now they're trying to come up with some
11 guidance and come up with some new numbers, but the
12 fact is we're dealing with some very, very low
13 numbers, and so it's not a completely new practice.
14 It's just that the numbers are going to be downsized
15 somewhat, and that's caused the anxiety.

16 MEMBER VETTER: Well, what's really
17 different about it is there's very little data to
18 support -- well, the data that has been collected
19 suggests that anyone sitting in a waiting room is
20 going to get almost an immeasurable dose, but when the
21 waiting room is designed, when you determine the
22 thickness of the shield on the wall, what criteria do
23 you use for that?

24 One of them is what's the permissible dose
25 to that person sitting in the waiting room, and

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1 historically the medical physics community has used
2 the public dose limit as the maximum dose to any
3 person sitting in the waiting room.

4 The constraint would suggest that you must
5 use a lower number because that member of the public
6 might be exposed to more than one source of radiation.
7 In other words, they might go to Hopkins and then
8 they go to Georgetown and so forth. So each one of
9 them would need to design their facility so that the
10 member of the public would receive some fraction of
11 the maximum permissible dose, not the maximum
12 permissible dose.

13 MEMBER WILLIAMSON: I think there can be
14 -- I'm sorry.

15 MR. MILLER: I'm sorry. I didn't mean to
16 interrupt you.

17 CHAIRMAN MALMUD: That's the purpose of
18 this.

19 MEMBER WILLIAMSON: Yeah. Well, I think
20 an analogy can be made between this and prostate
21 brachytherapy. In prostate brachytherapy, if you
22 placed the regulatory limit at something, a minimum or
23 maximum dose, that's a single point. The result will
24 be notoriously unreliable and of no clinical
25 significance.

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1 So I think the problem with the system is
2 the fact that it doesn't deal with a stochastic model
3 of the patient population, but tries to base the whole
4 idea on the concept that no single individual
5 exceeding the maximum dose with 100 percent
6 probability, which is, you know, a clogged procedure.

7 So I think that the fundamental suggestion
8 one could make to inform this process better is to go
9 to some sort of a probability based model where the
10 likelihood of individuals being in three successive
11 waiting rooms at Hopkins, Mass. General Hospital,
12 wherever, is taken into account.

13 CHAIRMAN MALMUD: Dr. Miller.

14 MR. MILLER: Dr. Vetter, I'm sorry if I
15 missed the innuendo, but this would be for more than
16 just medical; is that correct, as you're defining it?

17 MEMBER VETTER: Yes, right. The ICFP 2005
18 applies to -- when they say the dose to the public, it
19 could be from any source.

20 MR. MILLER: So if I were a member of the
21 public who was visiting a nuclear power plant, then
22 the dose I received for that would have to be added to
23 this by that. Okay?

24 If I had some business and I happened to
25 be adjacent to an industrial radiography facility,

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1 that would have to be added.

2 MEMBER VETTER: Yes, all of those are
3 added.

4 MR. MILLER: I think that that begins to
5 show the difficulty.

6 MEMBER VETTER: Well, the point they would
7 make, Dr. Miller, the point they would make is it
8 isn't right to expose that person to 100 millirem per
9 year in each case. That's the point that ICRP would
10 make.

11 MR. MILLER: Is it only from regulated
12 activities as opposed to natural sources of radiation
13 or is that --

14 MEMBER EGGLI: What if I live in a brick
15 house?

16 MEMBER VETTER: Cosmic are excluded.
17 Radon is not.

18 MEMBER EGGLI: So what about natural
19 radiation in brick?

20 PARTICIPANT: That's background. So
21 that's excluded.

22 MR. MILLER: Radon is not.

23 MEMBER VETTER: No, that would be --

24 MEMBER EGGLI: A brick house is going to
25 give me --

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1 MEMBER VETTER: That does not --

2 MEMBER EGGLI: -- in a year.

3 MEMBER VETTER: They don't specifically
4 address brick. What they do is they address any
5 activity that could increase your dose, and so they
6 would probably say the brick should be included.

7 MR. MILLER: How about a flight, if I took
8 an airplane?

9 MEMBER VETTER: A flight would be
10 included, yeah, anything that -- what they're saying
11 is their recommendations apply to anything, any new
12 exposure or anything where you manipulate something
13 and increase the dose. The example they use in that
14 regard is radon.

15 DR. HOLAHAN: I'm going to ask Vince
16 Holahan to speak to that because he's shaking his
17 head.

18 DR. VINE HOLAHAN: Yes, good afternoon.
19 Vice Holahan. I'm from Research.

20 The key point here is controllable
21 sources. If it's not a controllable source, it
22 doesn't come under the jurisdiction of the scope of
23 these recommendations. A case in point, Dr. Miller
24 had mentioned an airplane flight. That's not
25 considered by definition a controllable source.

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1 You'll also find that when we talk about
2 radon, it generally tends to be the industrial
3 applications, and they say if you fall below a certain
4 level and they articulated what the maximum level
5 should be, then that's considered now a
6 noncontrollable source. So they've got some breaks in
7 there.

8 MS. SCHWARZ: I have a question. Have
9 they made any recommendations of how many sources in
10 a year, I mean, or that there should be a limit to
11 each occurrence?

12 MEMBER VETTER: No. My understanding is
13 they are recommending to governments that each source
14 of radiation, controllable source of radiation, should
15 have a constraint, and the maximum constraint is one
16 millisievert per year for a member of the public, 20
17 for occupational and so forth.

18 So each government would have to decide on
19 how many constraints would be appropriate.

20 CHAIRMAN MALMUD: Thank you.

21 Please go on.

22 MEMBER VETTER: Did Ralph -- do you?

23 MEMBER LIETO: No, I was going to wait
24 until you finished.

25 MEMBER VETTER: Okay. That's constraints.

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1 Now, relative to dose limits, the
2 occupational limit, they are simply reemphasizing
3 that, 20 millisieverts per year or that's two rem,
4 averaged over five years with a maximum of 50
5 millisieverts or five rem in any one year. I don't
6 believe that's different, but they're simply
7 reemphasizing that.

8 Now, relative to medical, I know Vince
9 Holahan has taken a look at some doses from other
10 sources where the NRC is able to track those doses,
11 but relative to occupational doses in medicine, we
12 have --

13 MEMBER VAN DECKER: No national database
14 to track those.

15 MEMBER VETTER: People don't do a whole
16 lot of publishing on what the doses are within their
17 facility, except to say that our doses in cardiology
18 were such-and-so, and we took the following action,
19 and so now they're such-and-so. So they're lower. So
20 this action was a good thing to do.

21 So they're very specific relative to
22 cardiac lab dose or nuclear medicine personnel in the
23 hot lab, that sort of thing.

24 We don't have a good idea of what average
25 doses are in medicine, what maximum doses are in

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1 medicine. I took a look at my own facility, and we
2 would be able to live with this. The only people that
3 get badge doses that exceed five rem in any one year
4 are people such as interventional cardiologists who
5 are wearing an apron, and when you factor in the
6 apron, the effective dose is a couple hundred millirem
7 a year.

8 In nuclear medicine, our technologists,
9 the highest doses they get are a few hundred millirem
10 per year. The imaging techs would get less than that.
11 Those that work in the hot lab would be a few hundred
12 millirem a year.

13 Their hand doses can get pretty high if
14 you don't watch them, but nothing that -- so this is
15 just looking at one facility, but I don't have a good
16 handle on average doses -- I don't mean average
17 dose -- on a distribution of doses among workers in
18 medical facilities in this country, and I don't know
19 if anybody does.

20 MEMBER VAN DECKER: Well, there have been
21 some published studies, occupational for RTs,
22 radiological technologists, and whatever, and the
23 results are relatively --

24 MEMBER VETTER: They're all within these
25 limits.

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1 MEMBER VAN DECKER: Yeah, yeah.

2 CHAIRMAN MALMUD: Ralph?

3 MEMBER LIETO: I was just going to make
4 the comment that medical exposures probably provide
5 the largest group of individuals that are exposed
6 ionizing radiation, but there's no requirement or any
7 resource that keeps any type of a national either
8 database or even just like the NRC requires, I think,
9 for a fuel cycle and nuclear power and waste and so
10 forth. They have to provide these -- what do you call
11 it? -- not necessarily the individual exposures, but
12 --

13 DR. HOLAHAN: Yes, but it's a rare
14 database and they have to provide statistical data.

15 MEMBER LIETO: Right. I mean, there's
16 nothing like that for medical. So, you know, there's
17 really no central location that that's kept so we
18 really don't have a good handle onto what that
19 actually is when you start to look at, you know, the
20 fluoroscopy exposures and so forth.

21 MEMBER VETTER: So based on the feedback
22 or our knowledge in this room, we should be able to
23 live with this occupational limit of 20 millisieverts
24 per year averaged over five years.

25 DR. HOLAHAN: I have a question to that.

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1 Are you sure that the interventional cardiologist can
2 live with that? Because we were under the impression
3 that they had troubles meeting the five rem.

4 MEMBER EGGLI: Yeah, they do. So do
5 conventional radiologists.

6 MEMBER VETTER: To the bad, you mean.

7 MEMBER EGGLI: No, adjusted dose. There
8 are a lot of procedures that are very high.

9 CHAIRMAN MALMUD: Dr. Van Decker, the
10 question is are you familiar at all with the exposures
11 of interventional cardiologists, your colleagues, with
12 respect to annual dose?

13 MEMBER VAN DECKER: I would preface it by
14 saying I'm not an interventionalist myself, but having
15 been on enough radiation safety committees, I would
16 say that most of them to badge break this number but
17 on calculated effect of doses usually are much less,
18 and so don't break the limits at that point.

19 CHAIRMAN MALMUD: Thank you.

20 I think we had some additional comments.
21 Dr. Suleiman.

22 MEMBER SULEIMAN: Yes and no because I'm
23 going back and forth with the medical exposure and
24 the --

25 CHAIRMAN MALMUD: Oh, I'm sorry. I

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1 thought you had your hand up.

2 MEMBER SULEIMAN: And I didn't. I was
3 vacillating between whether I should say something or
4 not, but the effective dose with the whole body dose
5 and the organ doses there when you're dealing with the
6 specific organ doses, you're introducing a factor of
7 ten or so greater safety, you know, but I don't think
8 this is -- as I said earlier, I think we can live with
9 these numbers. I think it's just more of what we've
10 been doing in the past.

11 The two rem per year, I think you can
12 allow five rem in a given year. They just don't want
13 you to exceed an average of two rem over a ten-year
14 period of time.

15 So it's an effort to sort of impose more
16 constraint, but it's not, like you said, a limit. So
17 the interventionalist, I agree that you hear stories
18 about them approaching the limits, but you also hear
19 about some stories where good radiation safety
20 practice can get those doses lower.

21 So aside from the academic debate about
22 how you calculate the doses and what it's doing, I
23 think those numbers are pretty realistic.

24 MEMBER VETTER: So it may be fair to say
25 that anecdotally these numbers are realistic, but we

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1 really don't know whether or not or what the impact
2 this would have on individual practices.

3 CHAIRMAN MALMUD: Dr. Williamson.

4 MEMBER WILLIAMSON: Well, I guess there's
5 two other categories of workers. I'd ask the question
6 whether this means we're going to leave the two rem
7 limit, and that would be cyclotron workers, especially
8 from positron emitting radionuclides where it's high
9 energy and aprons aren't going to make any difference,
10 and I think the other group where there may be some
11 concern might be source handlers and manufacturers
12 where I hear anecdotally workers do get pushed.

13 DR. HOLAHAN: Manufacturers and
14 distributors are already required to input into the
15 REARS (phonetic) database, and I don't know.

16 PARTICIPANT: I don't know what those
17 doses are.

18 DR. HOLAHAN: But I think they're below
19 the limits, but I don't know if they're below two rem.

20 CHAIRMAN MALMUD: Thank you.

21 MS. SCHWARZ: I would say for PET workers,
22 not even the cyclotron operators, I mean, for the
23 technologists, that would run about 200 millirem a
24 month. So over a year, 200 millirem a month. I mean,
25 that's not all workers, and probably if you look at

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1 averages you'll be all right, but individual workers
2 may have some problems.

3 MEMBER LIETO: I was just going to say
4 that I think the two rem is going to create some
5 difficulties, and I think people need to recognize
6 that, you know, basically that's the dose. Even
7 though it's constraint on one page, it's a limit on
8 the other, and Dick's presentation here, and I think
9 that it gets to the question what is wrong now with
10 the current limits.

11 You know, we are for the most part living
12 below the five rem and probably very close to below
13 the two rem for even our worst case situations. What
14 is the necessity; what is the driving force for
15 ratcheting these down even further? Okay? Because
16 it's just going to, I think, require I think the
17 economic factors and so forth.

18 People are going to say, well, the limit
19 is two rem. You know, if I'm going to implement
20 ALARA, does that mean now the new ALARA levels should
21 be 200 millirem?

22 You know, I just think this is really,
23 really not a good thing.

24 DR. HOLAHAN: And I just want to note that
25 this was the same thing that was in ICRP 60 that we

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1 didn't adopt.

2 CHAIRMAN MALMUD: Dr. Eggli.

3 MEMBER EGGLI: Also, what is this going to
4 do to the cost of construction of medical facilities
5 when you have to increase the shielding to meet these
6 new guidelines? Right now we have a new CT scan, and
7 we're not going to install because the cost of adding
8 the shielding to the space where we want to install it
9 is equal to the price of the instrument. So it's not
10 going to happen.

11 I mean, this could have problems as you
12 ratchet down the public exposures. The cost of
13 shielding medical devices is going to make a
14 significant impact on the cost of health care.

15 MR. BAKER: I think that's a good point.
16 In their recommendations ICRP does not address quality
17 of life or any of those issues. They don't try to
18 quantify benefit in any way. There's simply their
19 mission. They have blinders on, and their idea is to
20 try to keep doses as low as possible, you know,
21 justify and so forth.

22 I think they tried to be reasonable, but
23 they're very firm believers in the linear, no
24 threshold dose response curve, and they're driving the
25 doses down, and they don't look at these other side

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1 issues.

2 MS. SCHWARZ: And another issue: have
3 they quantified any risks? I mean, is there reason
4 because they have determined the risks from ionizing
5 radiation?

6 MEMBER VETTER: Well, they've indicated
7 that they have examined the biological literature and
8 so forth, and first of all, these numbers, as Trish
9 mentioned, the two rem average over five years, that's
10 not a change. They're simply underscoring.

11 MS. SCHWARZ: No, I understand.

12 MEMBER VETTER: Yeah.

13 MS. SCHWARZ: I understand.

14 MEMBER VETTER: No, they believe that
15 that's what they have selected as an acceptable risk.

16 CHAIRMAN MALMUD: Dr. Williamson.

17 MEMBER WILLIAMSON: Yeah, I think
18 especially given that this two rem has been instituted
19 in their literature for some time, the area of most
20 concern would be paring back the 100 MR limit for
21 members of the general public, and I think that this
22 is an opportunity to try to -- how shall I say it? --
23 at least delay their program to ratchet down dose
24 limits in an ever more irrational way to zero, no
25 matter what the cost to anybody.

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1 So I'm wondering what your opinion would
2 be, Dick, about what would be sort of tactically the
3 most appropriate and -- how could I say? -- useful
4 objections to bring up at this event that would make
5 sense to them and resonate, would actually have some
6 impact in modifying this, slowing down the approval of
7 this effective lower limit for the members of the
8 general public.

9 MEMBER VETTER: Well, this isn't new
10 either. They've had a constraint for members of the
11 public prior. So this isn't new either.

12 I think it might be a little different.
13 Do you know, Vince? It's .3 millisieverts per year.
14 What was the old one?

15 DR. VINCE HOLAHAN: Well, right now we
16 already have constraints. We use constraints in our
17 rulemaking, and an example of that is the
18 decommissioning rule, and we're fighting with EPA as
19 a constraint for decommissioning. The unrestricted
20 release of those sizes should be 15 millirem or 25
21 millirem.

22 We have water standards that are four
23 millirem. So these are already being used in this
24 country, and we essentially call them constraints. So
25 this is not a new issue.

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1 One issue I would like to raise is there's
2 another class of worker you've got to consider, and
3 this is one of the few changes they have in their
4 limits, even though they say there are no changes in
5 the limits. That's to the fetus. The fetal exposure
6 would not be 100 millirem.

7 So my question would be: what is the
8 impact on the declared pregnant worker?

9 MEMBER VETTER: Yeah, that's in one of my
10 later slides, but we can talk about it now.

11 DR. VINCE HOLAHAN: And right now in the
12 United States, the fetal exposure for the declared
13 pregnant worker is 500 millirem during the remainder
14 of the course of the pregnancy.

15 Part 60, ICRP 60, which was published in
16 1991, is 200 millirem to the surface of the abdomen.
17 Now these recommendations would say 100 millirem, and
18 I would ask what impact would this have on some of
19 your declared workers that might be, in particular,
20 medicine and things like that.

21 CHAIRMAN MALMUD: Ralph.

22 MEMBER LIETO: I'll tell you right now
23 they wouldn't be able to work. All right? Period.
24 Because I have to assure that, and for me to say that
25 a nurse, nuke med tech or whatever, I have not ever

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1 had anybody in the decades that I've been responsible
2 for this had a pregnant worker exceed 500, but I've
3 had a few over 100. Okay?

4 Now, the fact that I know that it can
5 occur means, one, that they would not be able to
6 declare pregnancies, okay, if they wanted to continue
7 on working, is basically what it gets to because if we
8 have to meet this 100 millirem, you can't have
9 declared pregnancies because they're going to be
10 mutually exclusive in the training or practice of
11 using ionizing radiation.

12 And I think it's catastrophic.

13 CHAIRMAN MALMUD: Dr. Eggli.

14 MEMBER EGGLI: I think along that line I
15 agree with Ralph on a far broader basis. I think an
16 interventional physician who is getting exposed to
17 somewhere near the limit is going to be inclined to
18 take their badge off and put it in a drawer and going
19 to continue to work because if you damage my
20 livelihood and tell me I can't work for the next five
21 years because I've hit my limit, that ain't going to
22 fly.

23 So I think that you have to look at what's
24 the benefit, you know. I understand that if you
25 believe in the linear nonthreshold model, then you can

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1 calculate a mathematical benefit, but you have to look
2 at the cost of that benefit, and the cost of that
3 benefit, I think, as we ratchet these things down to
4 ever lower levels becomes economically for society as
5 a whole and for individuals within that society
6 becomes prohibitive.

7 CHAIRMAN MALMUD: Thank you.

8 Another comment? Let's see. Dr. Suleiman
9 and then Dr. Lieto.

10 MEMBER SULEIMAN: At FDA actually we're
11 dealing with some ethical issues regarding young
12 pediatric, the fetus, and the radiation risks, I've
13 had that responsibility lately, but there's a whole
14 other issue that has an element of what's probably
15 driving this very thing. So my perspective on this is
16 that I think I can live with the two rem, five rem
17 because I think in reality it's obtainable.

18 But I am concerned when you're getting
19 down to what we would consider background levels, when
20 you're talking about a millisievert and you're going
21 to pick up three during the course of a year and
22 you're further restraining or constraining the fetus
23 at an almost ridiculously low level for an
24 occupational worker, I think that's probably if you're
25 going to argue pick your battles, that's probably

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1 where you ought to focus on it rather than the
2 occupational limits.

3 CHAIRMAN MALMUD: Thank you.

4 Ralph.

5 MEMBER LIETO: Well, I was going to just
6 say like Orhan had said that we're looking at
7 fractions of background that they want to have these
8 limits put at, which really makes it very difficult to
9 understand the credibility for this, other than
10 simply lower is better, and I wanted to go back to a
11 point that I think Dr. Miller might have asked about
12 with the shielding.

13 We've run into this already on the
14 diagnostic X-ray side in my state, and what you have
15 to also look at is not only future facilities,
16 existing facilities that have already been designed in
17 existence, especially in urban areas.

18 What you're now saying is that I think
19 they're using a constraint of one-third in the ICRP.
20 Putting the exact same machine in there with the exact
21 same work load, everything else identical, you now
22 have to put three times the shielding in to meet this
23 constraint level. Okay? Just simply because they
24 want to lower it to these newer values, and I think
25 that what it basically is going to prevent, renovation

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1 and reuse of existing therapy rooms. It will prevent
2 facilities in urban areas from expanding because
3 there's no place to go to. Okay? They have to
4 basically use those areas that currently exist.

5 And, again, it gets to this what is the
6 benefit that we are trying to achieve, and I just see
7 it as being a blank answer as far as what the benefit
8 is.

9 CHAIRMAN MALMUD: Thank you.

10 Dr. Eggli.

11 MEMBER EGGLI: And to speak to the benefit
12 question, if you look at the incidences of cancers in
13 occupational workers, they're, in fact, lower than the
14 general population. So what are we trying to achieve
15 here?

16 I think that we have achieved with
17 radiation safety for both the public and for
18 occupational workers, we've achieved a very high
19 standard already. What better can we do than making
20 occupational workers have a lower incidence of cancer
21 than the general population? What are we trying to
22 get to?

23 MEMBER VETTER: If you use that argument,
24 they'll throw the healthy worker effect at you.
25 You're looking at a subpopulation whose health is

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1 better than the general public.

2 MS. SCHWARZ: I would like to make a
3 comment about the pregnant female.

4 CHAIRMAN MALMUD: Dr. Schwarz.

5 MS. SCHWARZ: I'm concerned about just to
6 add to the already stated facts. I think it's
7 definitely going to be problematic in that if a woman
8 does declare pregnancy, essentially will have to be
9 taken out of the work area, I mean, and not be allowed
10 to work. So this will essentially, though maybe not
11 on paper, could discourage women from being hired.

12 I mean, there could be an element that
13 could affect that, I'm sure.

14 MEMBER VETTER: Just in that regard
15 there's the Johnston Controls case which prohibits us
16 from doing that.

17 CHAIRMAN MALMUD: Prohibits who from doing
18 that?

19 MEMBER VETTER: It would prohibit us from
20 doing something that would affect the welfare of that
21 pregnant worker. In other words, we could transfer
22 her to another job temporarily that gave her the same
23 amount of money and so forth, but we can't do anything
24 to discriminate. We must protect that person so that
25 that person has the same opportunity as a male who

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1 can't get pregnant.

2 So, I mean, the Supreme Court did that
3 one. We can't discriminate. We can't not hire a
4 pregnant woman because she's pregnant.

5 MS. SCHWARZ: No, I understand that, but
6 what I am saying --

7 MEMBER VETTER: Or prevent her from doing
8 nuclear medicine or whatever.

9 MS. SCHWARZ: You could discourage her
10 from being hired in general, not in writing, not in
11 terms of policy.

12 MEMBER VETTER: Right.

13 MS. SCHWARZ: But in terms of the mental
14 review of management.

15 MEMBER VETTER: I see what you're saying.

16 MS. SCHWARZ: Understanding that if
17 they're dealing with a young female population, that
18 it could discourage them from being the choice between
19 two equal candidates.

20 CHAIRMAN MALMUD: That's a valid
21 observation.

22 We do have a comment from the public which
23 I'd like to entertain now if the committee will
24 permit.

25 DR. WHITE: Gerald White. I'm here for

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1 the AAPM, but speaking just personally.

2 I can't help but hang crepe on many of
3 these issues about experiences of community hospitals.
4 One issue about pregnant women that hasn't really been
5 stated explicitly is that of pregnant radiologists and
6 pregnant cardiologists.

7 If in my community hospital I go to a
8 pregnant cardiologist and say, "You cannot do your
9 patients in our hospital because we can't keep you
10 below 100 MR," that woman and all of her patients will
11 be at the hospital across town before you know it.

12 The pressures to ignore that rule or to
13 find some way around that rule will be enormous. In
14 order to encourage respect for the science of
15 radiation protection, the rules have to be reasonable
16 and enforceable, and if they're not, not to pick on
17 physicians, but physicians will be the first ones to
18 find a way around them and the hardest to control.

19 And these are the people in the hospital
20 we look to for leadership, for sensibility, and we're
21 going to lose that. It's going to be a net
22 degradation in the radiation protection program in
23 hospitals.

24 CHAIRMAN MALMUD: Thank you.

25 Would you like to go on, Dr. Vetter?

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1 MEMBER VETTER: Sure. Okay. Anything
2 more on dose limits?

3 CHAIRMAN MALMUD: No.

4 MEMBER VETTER: For physicists, the
5 weighting factors for certain types of radiation will
6 change a little, but I don't think that has a major
7 impact on any of us. For protons, it goes from five
8 to two, the weighting factor, and for neutrons, it's
9 roughly the same. It's just they determine the
10 weighting factor a little bit differently.

11 The tissue weighting factor has changed
12 somewhat. I don't perceive that that would have much
13 of an effect on how we calculate occupational dose.
14 In fact, most of our doses are simply measured with
15 badge. We don't have many up ticks or intakes. So
16 we're not very often calculating internal dose.

17 If we do, ICRP would say we calculated a
18 little bit differently the effective dose from prior
19 because some of the tissues have been changed a little
20 bit. I don't think it's significant enough to go into.

21 Do you want to flip to the last page, page
22 4? Application of dose constraints. This is where I
23 perceive we've already talked about this. I perceive
24 some of these areas to be problematic.

25 Occupational workers in controlled areas

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1 are well informed and especially trained so that
2 constraints are fairly easy to administer if we choose
3 to appoint some constraints in our areas.

4 It should be pointed out that
5 administrative and support staff should be treated as
6 members of the public. There have been some who have
7 suggested that relative to this issue of designing
8 shields in diagnostic X-ray departments that a
9 receptionist who is going to be sitting right outside
10 the shield perhaps should be classified as an
11 occupational worker, a worker for purposes of
12 occupational dose.

13 The recommendations of ICRP are clearly
14 counter to that.

15 Let's see. We've just talked about the
16 working conditions should make it unlikely that a dose
17 to the fetus would exceed one millisievert, and
18 finally, relative to medical exposure, my second to
19 last slide, no limitation of dose to the individual
20 patient because it may actually reduce effectiveness
21 of diagnosis or treatment. So that clearly falls
22 under the arena of justification.

23 But related to medical exposure,
24 constraints should apply to workers and the public,
25 and this one, this is an area that we should probably

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1 spend a minute on.

2 Some exposure may occur in patient care
3 and support by members of the public, such as family,
4 members of families who are caring for a radioiodine
5 patient, and they're saying that a constraint of a few
6 millisievert -- they don't get very quantitative about
7 that -- a few millisievert is reasonable, but should
8 not be used rigidly. For example, higher doses are
9 reasonable for parents of a sick child.

10 Now, this came up yesterday in
11 conversation, and I think the feeling of the advisory
12 committee is that we should look toward NCRP
13 commentary 11, which I think is dated what, about
14 1995?

15 PARTICIPANT: Yes.

16 MEMBER VETTER: So it's a few years old,
17 but I don't think if you ask NCRP, I don't think the
18 thinking would be much different from what they
19 recommended back then, and they recommended that and
20 the NCRP instituted a rule, in fact, that patients who
21 are administered therapeutic radionuclides could be
22 released to the public under the conditions that a
23 member of the public would not receive more than 500
24 millirem.

25 NCRP also said that for members of the

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1 public who are family members of the patient, that a
2 higher dose would be justified in the care of that
3 patient, and they said it could be as high as five
4 rem, provided you instructed them appropriately in how
5 to keep dose down and monitored them.

6 The NRC didn't adopt that condition, but
7 the ICRP is suggesting without giving any numbers,
8 they're suggesting that that is, in fact, justified.
9 You can justify a higher dose to the parents of a sick
10 child, for example. So there are a couple of
11 constraints here that are saying that certain very
12 small groups, members of the public can get a higher
13 dose than the limit; that it is, in fact, justified,
14 for example, in this case, and you would establish
15 that maximum dose by some sort of a constraint.

16 And they're saying for a member of the
17 public the constraint is a few millisieverts or maybe
18 it's five. That would be the same as -- is that what
19 they're saying now, two?

20 DR. VINCE HOLAHAN: It's a maximum
21 constraint.

22 MEMBER VETTER: That is the maximum.

23 DR. VINCE HOLAHAN: Yeah, the maximum
24 constraint for a caregiver is two millisieverts.

25 MEMBER VETTER: I didn't see that.

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1 DR. VINCE HOLAHAN: Twenty millisieverts.
2 I'm sorry.

3 If you look at the table where they have
4 the maximum constraints --

5 MEMBER VETTER: Two rem, yes. That's two
6 rem.

7 DR. VINCE HOLAHAN: That's correct.

8 MEMBER VETTER: Not 500 millirem, yeah.
9 So that would be the maximum, two rem.

10 DR. VINCE HOLAHAN: That's the maximum
11 constraint per caregiver.

12 MEMBER VETTER: Right. Oh, yes, I do
13 remember seeing that, yeah. the maximum constraint
14 for a caregiver would be two rem.

15 Now, current NRC rule is that the maximum
16 limit is 500 millirem. I'm sorry. That's not quite
17 the right way to put it. You base your release of the
18 patients on assuming that no one would get more than
19 500 millirem.

20 DR. HOWE: Dr. Vetter, is it clear that
21 it's for a whole year or is it per patient?

22 MEMBER VETTER: In this case it's per
23 episode.

24 DR. HOWE: Okay.

25 MEMBER VETTER: For caring of patients

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1 it's per episode. Now, you would normally anticipate
2 that to be once in a number of years.

3 DR. HOWE: And for your other discussion
4 that you had, it was clear that the radiation to the
5 patient for the procedure the patient is receiving is
6 not included. What about the dose from the patient to
7 other people?

8 MEMBER VETTER: Yeah, they address that in
9 two different ways. One is for patients who are
10 sitting like in a nuclear medicine waiting room, that
11 the dose to other people in the waiting room is --
12 they don't use the word "inconsequential," but it's
13 low and it doesn't need to be worried about, and the
14 same thing for transport of radioiodine patients on
15 the way home, that those doses are low enough not to
16 worry about.

17 But then the other group that they talk
18 about is caregivers, from dose from patients. It's
19 caregivers and they're saying a few millisieverts. It
20 would be two rem in our case would be the maximum to
21 caregivers, and possibly higher for parents of a sick
22 child.

23 CHAIRMAN MALMUD: Thank you.

24 Dr. Vetter, you've heard a number of
25 comments from the committee. What is it that you were

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1 seeking in presenting this to the committee as an end
2 result?

3 MEMBER VETTER: What I'm interested in
4 hearing from the committee are their interpretations
5 of when these recommendations could be problematic for
6 the medical community.

7 CHAIRMAN MALMUD: And you've heard that?

8 MEMBER VETTER: I've heard that. I've
9 heard some very good feedback, and that's what I would
10 take to the meeting next week.

11 Now, the meeting next week is the Advisory
12 Committee on Nuclear Waste who is simply trying to get
13 educated on this issue, and they're interested in our
14 perspective.

15 CHAIRMAN MALMUD: And what we've heard is
16 that there's no evidence statistically that radiation
17 workers, despite the fact that they're classified as
18 perhaps a healthier group than the population at
19 large, has a higher incidence of cancer or mutations
20 that result in deformed fetuses than does the
21 population as a whole. Therefore, we are not
22 encouraging reducing the safe limits in a theoretical
23 pursuit rather than a practical one; that, in fact,
24 there may be unintended consequences in reducing those
25 limits, such as the inability of someone to maintain

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1 gainful employment in the course of a pregnancy.

2 And, therefore, we are supporting your
3 transmitting the message that we don't see the need to
4 reduce these limits. Is that a fair summary?

5 Thank you.

6 MEMBER VETTER: We don't see a need to
7 reduce the limits that are currently --

8 CHAIRMAN MALMUD: Currently established.

9 MEMBER VETTER: Right.

10 CHAIRMAN MALMUD: If that's a fair
11 summary, we will accept that. If someone will make
12 that motion other than the Chair, and that will be the
13 message that Dr. Vetter would deliver on behalf of the
14 ACMUI.

15 MEMBER EGGLI: So moved.

16 CHAIRMAN MALMUD: Moved? Did you second
17 it?

18 MEMBER LIETO: I would second it.

19 CHAIRMAN MALMUD: Moved and seconded. Dr.
20 Eggli moved it, seconded by (pause) --

21 MEMBER LIETO: Mr. Lieto.

22 (Laughter.)

23 CHAIRMAN MALMUD: -- Mr. Lieto.

24 Is there any further discussion?

25 MEMBER LIETO: I have a couple of quick

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1 comments. One thing that I think also this does is
2 convey a very negative aspect about radiation. If
3 you're above this constraint level, you know, a few
4 millirems, tens of millirems, it conveys the sense
5 that you failed to meet good radiation safety
6 standards and you're exposing people to harmful
7 amounts of radiation that are within the normal range
8 of variance of background itself, and I think that's
9 a negative connotation that would be relayed by this.

10 Another point is that in looking over this
11 document, we've always talked about dose equivalent
12 and equivalent dose. Well, in their infinite wisdom,
13 ICRP is saying, "Okay. We've not going to use that
14 because it's too confusing. We're going to establish
15 a new term." Okay?

16 So now we're on this merry-go-round of new
17 terminology, and I agree about the confusion with dose
18 equivalent or equivalent dose, but it has got to stop
19 someplace. I mean we need to say this is the
20 terminology and let's stick with it for more than five
21 years.

22 And they've come up with another term, and
23 that's another thing I think is going to, I think,
24 related to a lot of confusion. I think a major change
25 in a lot of the rules the way they're defined and

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1 regulations the way they're written to adopt this new
2 terminology, and again, I just think there's
3 absolutely no benefit being derived from all of these
4 changes. I think it's just a bad piece of -- well, I
5 shouldn't say that, not overall.

6 I can understand the weighting figures,
7 the factors, and some of these lower limits being
8 established for natural sources, but you know, I think
9 that some of these other things are just not very
10 beneficial because I think they determine -- I guess
11 de minimis is not the right term -- but a level at
12 which you don't need to concern yourself, which is
13 like one millirem. What is that? I guess you could
14 climb up to the eighth story and get more than that.
15 I just think it's an absolutely ridiculous number.

16 CHAIRMAN MALMUD: Any other comments with
17 regard to the recommendation that Dr. Vetter will
18 carry with him?

19 If not -- oh, yes.

20 DR. VINCE HOLAHAN: If I could just make
21 one quick clarification, the limits that we're talking
22 about in this draft document for all intents and
23 purposes are not different than ICRP 60. So to go
24 back to the main Commission and say 20 millisieverts
25 for an occupational exposure is unreasonable, well,

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1 they don't care. That's already on the table.

2 What will be important is several years
3 from now, will the NRC adopt these recommendations,
4 and that's the issue to be addressed with the
5 Commission.

6 CHAIRMAN MALMUD: Thank you.

7 And that's your understanding, Dr. Vetter?

8 MEMBER VETTER: Yes.

9 CHAIRMAN MALMUD: Mr. Lieto.

10 MEMBER LIETO: The point is well taken,
11 and the only thing that's new about this is if you
12 don't adopt these or I shouldn't say -- doses above
13 these constraints are considered failures now by the
14 ICRP, which is not the type of terminology that they
15 used before.

16 So I find that very, very negative and,
17 you know, really is sort of almost I don't want to say
18 a strong arming, but sort of a way of trying to coerce
19 national bodies and agencies to adopt their values,
20 which, you know, many countries have not, including
21 ours.

22 CHAIRMAN MALMUD: Thank you.

23 So we are encouraging of not tightening
24 things, in addition to for the ICRP to look at the
25 unintended consequences of some of their actions.

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1 We still haven't given you a nod of
2 approval for what you would like to take with you.

3 All in favor?

4 (Show of hands.)

5 CHAIRMAN MALMUD: Any opposed?

6 (Show of hands.)

7 CHAIRMAN MALMUD: Any abstentions?

8 (No response.)

9 CHAIRMAN MALMUD: It carries the majority.

10 MEMBER VETTER: Just one comment relative
11 to the impact of these, what they really mean.
12 Historically I think the NRC and regulators in this
13 country had looked to the NCRP for guidance as opposed
14 to the ICRP.

15 Now, in large measure they're the same,
16 except that these dose limits have been different
17 since ICRP 60. So in that regard I did ask NCRP when
18 do they plan on taking another look at their
19 recommendations. They are waiting for BEERS-7 to be
20 published, and then they will ask them. Then they'll
21 kind of ask themselves: are the limits that ICRP is
22 proposing here appropriate or do they want to maintain
23 the limits they have in NCRP 116 or whatever?

24 But I just wanted to throw that out for
25 your information.

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1 MEMBER SULEIMAN: When is BEERS-7 supposed
2 to be published?

3 MEMBER VETTER: That's a good question.

4 MEMBER SULEIMAN: I mean a year, five
5 years, ten years?

6 DR. VINCE HOLAHAN: The final chapters of
7 BEERS-7 are being finalized now. The project
8 director, Mr. Rick Jostice (phonetic) or Dr. Jostice,
9 is hoping to put that out to peer review in the
10 National Academies this fall. I would say it's
11 possible to be released as early as the April time
12 frame of next year. I'd feel a little bit better
13 saying maybe June of next year.

14 CHAIRMAN MALMUD: To be precise, Dr.
15 Suleiman, it's in the future.

16 Thank you.

17 May we move on to the next item on the
18 agenda?

19 MR. ESSIG: Yes. The next item on the
20 agenda, if I may introduce it, is the final item on
21 the agenda.

22 CHAIRMAN MALMUD: Before you introduce
23 the final item, may I once again thank Dr. Vetter for
24 all of the effort he went to thus far and will go so
25 again next week on behalf of the ACMUI.

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1 MR. ESSIG: Okay. The final item on the
2 agenda, we had wanted to go over if possible the
3 action items arising from the meeting which based on
4 the way we've captured them, it's going to take a more
5 detailed review, and so we don't think trying to reach
6 agreement on action items here more or less in real
7 time would not be fruitful.

8 So we're not going to propose to you right
9 now that we go over the action items. What we would
10 go over is the recommendations that arose and that
11 were in the form of a motion that was acted upon. We
12 will summarize those. Angela will, and then the
13 second order of business then prior to declaring the
14 meeting adjourned is to discuss the meeting dates for
15 the spring 2005 meeting, which hopefully those who
16 have to leave left a vote sheet with somebody. Dr.
17 Diamond or Mr. Bailey, I'm hoping that they left their
18 preference behind somewhere, but maybe they didn't.

19 Because I think the preferred approach on
20 the 2005 meeting was to either circle the dates that
21 each member preferred or to cross out those that
22 appeared to be unworkable.

23 MEMBER NAG: Tom.

24 MR. ESSIG: Yes.

25 MEMBER NAG: I thought the dates of the

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1 26th and 27th of April was the main one and we wanted
2 to see how many are not able to attend that because
3 there are so many. We'll never come to consensus. It
4 might be better off saying how many cannot make that
5 April 26th-27th, and then go from there.

6 If a lot of people cannot make that, then
7 we look for an alternative. Otherwise, I will be here
8 for certain dates, and you will never have a consensus
9 doing it that way.

10 MR. ESSIG: Okay. We can certainly do
11 that, and we just more or less picked those dates
12 because they didn't appear to conflict with our
13 knowledge of the major society meetings at that time.

14 Now, we have to review our own schedule in
15 house, which we haven't done, against those dates for
16 Dr. Miller and Dr. Holahan's availability. So they're
17 a little bit tentative in that sense.

18 But at least what we know is that the
19 auditorium is available on those two days and we've
20 preliminarily locked it in. So maybe next door to
21 business then would be to discuss the recommendations
22 that arose, and Angela will do that.

23 MS. McINTOSH: Bear with me a little.
24 This is a matter of combing through some very rough
25 information to capture what we believe are the motions

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1 that arose from the committee meeting yesterday and
2 today.

3 The first motion that the committee made
4 was regarding the seeds electron guidance, and that
5 motion basically stated that the seeds electron is
6 appropriately codified in 10 CFR 35.1000, but that the
7 staff should use the regulatory framework in Section
8 35.400 as a model for creating guidance for the seeds
9 electron, adding only those elements of Section 35.600
10 as needed.

11 Looks like everyone is in agreement with
12 that one.

13 The second one, the second motion, the
14 committee motioned to have the 200 hours' worth of
15 training and experience in Part 35.390 reduced to 80
16 hours.

17 CHAIRMAN MALMUD: That is correct.

18 MS. McINTOSH: Another motion that the
19 committee made, it's almost general in nature, but the
20 committee motioned that except for all of those issues
21 identified regarding the draft 10 CFR 35, except for
22 those issues that the committee identified as
23 problematic, the committee motioned to move forward
24 with the draft final rule.

25 CHAIRMAN MALMUD: That is correct.

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1 MS. McINTOSH: And regarding the abnormal
2 occurrence criteria --

3 MEMBER WILLIAMSON: You forgot the one on
4 grandfathering. I think a motion was made on
5 grandfathering of AMPs. There was some suggested
6 rephrasing of the grandfathering text that would allow
7 -- I can't remember exactly what was said.

8 MS. McINTOSH: Okay.

9 MEMBER WILLIAMSON: But that was one of
10 the two problems that was identified with the 35.

11 MS. WASTLER: Let me try it.

12 MS. McINTOSH: We're working from meeting
13 notes. So we don't have the -- the transcript will
14 have the specific. Do you have that?

15 MS. WASTLER: If I can decipher my
16 scribbled handwriting here, I think --

17 CHAIRMAN MALMUD: This is Sandra Wastler.

18 MS. WASTLER: Thank you. Sorry.

19 -- that the recommendation was that
20 physicists authorized to serve as AMPs for HDR, gamma
21 knife -- I messed up the appropriate title -- gamma
22 stereotactic surgery --

23 (Simultaneous conversation.)

24 MS. WASTLER: All right. -- and
25 teletherapy be grandfathered as AMP -- I've got as AMP

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1 modalities. I don't think that's the exact right
2 words -- for AMP modalities.

3 MEMBER WILLIAMSON: That's AMPs in the
4 area in which they are practicing, which they are
5 currently authorized to practice, I think.

6 MS. SCHWARZ: Jeff, was there something
7 also mentioned about being preceptors for those AMPs?

8 CHAIRMAN MALMUD: It says they can
9 supervise trainees.

10 MEMBER WILLIAMSON: They become preceptors
11 automatically, yeah.

12 MS. McINTOSH: And then the last motion
13 that we've been able to identify quickly was the
14 motion regarding the proposed changes to the abnormal
15 occurrence criteria, and the committee basically
16 agreed to move forward with those proposed changes.

17 CHAIRMAN MALMUD: And we just did one for
18 Dr. Vetter.

19 MS. McINTOSH: Okay, and that was a motion
20 for --

21 CHAIRMAN MALMUD: Yes.

22 MS. McINTOSH: Okay.

23 CHAIRMAN MALMUD: And I think that's
24 complete.

25 MS. WASTLER: Doctor.

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1 CHAIRMAN MALMUD: Do you recall another
2 one?

3 MS. WASTLER: Yes. It seems to me that
4 there was a recommendation that you be provided, the
5 committee be provided the research protocol for the I-
6 25 users' markers to allow you to further evaluate
7 that procedure. This was --

8 CHAIRMAN MALMUD: Yesterday.

9 MS. WASTLER: -- Robert Gallagher's
10 presentation.

11 CHAIRMAN MALMUD: That's correct. The
12 committee did request more information bout the use of
13 I-125 seeds as markers for -- the specific indication
14 that was reviewed was for localization of breast
15 masses and breast surgery. And we would appreciate
16 seeing more information regarding the use.

17 MS. McINTOSH: Okay. Can anyone think of
18 anything else that the committee proposed or a motion
19 that the committee made?

20 CHAIRMAN MALMUD: That's all that we
21 recall at this moment.

22 MS. McINTOSH: Okay. And the other
23 administrative item is the setting of the meeting
24 dates for the spring 2005 meeting.

25 CHAIRMAN MALMUD: And we were given a

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1 number of options based upon the availability of this
2 conference room.

3 MR. ESSIG: The auditorium. Correction.

4 CHAIRMAN MALMUD: The auditorium. Excuse
5 me.

6 MS. MCINTOSH: Yes. I have since learned
7 that the auditorium is actually not going to be
8 available on one of those dates in April. So we would
9 still have to go back and set a date for the
10 auditorium.

11 MEMBER NAG: Was that the 26th?

12 MS. MCINTOSH: We proposed the 26th
13 through the 27th.

14 MEMBER NAG: And that is available or not
15 available?

16 MS. MCINTOSH: It's not available on the
17 27th.

18 MS. WASTLER: Excuse me. Can I just
19 point out, I believe -- this is Sandra Wastler
20 again -- that Dr. Miller pointed out, and I think we
21 all agreed, that what we need to do is set a date we
22 can all live with. The place we will deal with. All
23 right?

24 CHAIRMAN MALMUD: Is that your point, Dr.
25 Miller?

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1 MR. MILLER: My point was that, yes, I
2 asked my staff let's focus on setting a date for the
3 meeting. Once that's agreed upon my staff will find
4 a venue where we can hold the meeting, and let's not
5 be restrictive; based upon what I heard yesterday,
6 let's not be so restrictive as to be concerned whether
7 it's in this room or the auditorium or some other
8 suitable venue that's nearby. It's more important to
9 find a date where we can get maximum participation.

10 CHAIRMAN MALMUD: Ralph?

11 MEMBER LIETO: A question for staff. Not
12 knowing the days of the weeks that these are, is
13 Monday-Tuesday better for individuals as opposed to a
14 Tuesday-Wednesday?

15 MS. MCINTOSH: Can I? The dates that are
16 proposed are Tuesday-Wednesday or Wednesday-Thursday.

17 MEMBER WILLIAMSON: It can't be Thursday-
18 Friday?

19 MS. MCINTOSH: Well, it can. It's just
20 that most of the committee members prefer to have it
21 between Tuesday and Thursday because most people don't
22 want to travel on Mondays or Fridays.

23 MEMBER WILLIAMSON: Teaching Monday and
24 Wednesday.

25 MS. MCINTOSH: Okay. Well, traditionally

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1 that's been those days of the week that the committee
2 has been amenable to having the meeting on.

3 MEMBER NAG: Since we had that 26-27
4 April, can we just maybe just have a show of hands
5 whether anybody is not available on those dates,
6 rather than saying when you're available and then
7 you'll have people overlap?

8 MEMBER EGGLI: My concern with that,
9 Subir, is that you've got two members that aren't
10 here.

11 MS. McINTOSH: Well, actually Dr. Diamond
12 did leave me his input, and his input was he's
13 available for everything, for every date except for
14 March 15th through the 17th.

15 MR. MILLER: I know I'm not available as
16 it stands now. I think I have to go to IAEA that
17 week; is that correct, Trish, based upon the
18 information we have now?

19 DR. HOLAHAN: Twenty-fifth to 28th.

20 MEMBER WILLIAMSON: In theory, yes, I am
21 not available on April 27th.

22 MS. McINTOSH: So, I mean, we can go in
23 March if March is a little bit better. There's
24 several March dates, 1 through 2, 2 through 3, 8
25 through 9 or 9 through 10.

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1 MR. MILLER: There are earlier April
2 dates, too, aren't there?

3 MS. McINTOSH: Well, 19th through 20th for
4 the April or 20th through the 21st of April.

5 MEMBER WILLIAMSON: So we have to do it
6 Wednesday-Thursday or Tuesday-Wednesday?

7 MR. MILLER: There's something that I need
8 to introduce to remind everybody of. I need Angela to
9 listen to this to make sure that I've got it correct.

10 Last year, while we talked yesterday,
11 while Tom articulated yesterday that there's no
12 requirement for the committee to meet with the
13 Commission, there are times where the Commission
14 desires to meet with the committee. And last year the
15 Commission dictated a date that they wanted to meet
16 with the committee, which dictated when -- which to a
17 degree dictated when we had the March meeting because
18 it allowed the committee to be in town one time rather
19 than twice.

20 My anticipation will be that the
21 Commission would probably want to meet with -- given
22 where Part 35 has been and is coming, I would
23 anticipate that the Commission would want to meet with
24 the committee again.

25 Have you done any checking on that?

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1 MS. McINTOSH: No, I haven't.

2 MR. MILLER: Because I wouldn't want to
3 set a date for the meeting and then find out that the
4 Commission wants to have a meeting with the committee,
5 and then there's the concern of -- or is that a
6 concern of the committee to come to town a third time
7 for a Commission meeting?

8 MEMBER NAG: I mean, at one time, you
9 know, we had to put this off until you had a tentative
10 date with the Commissioner, and what you can do to
11 speed up, you know, maybe us, not what -- you know,
12 which of these dates we are not available.

13 MR. MILLER: Right, and I think having
14 that information allows us to go to SECY and propose
15 these are dates that ACMUI could be in town for a
16 meeting. Do you want to have a Commission meeting
17 with them?

18 And I guess the question I would ask the
19 committee is: do you want to have a meeting with the
20 Commission on the annual basis? And if so, could you
21 arrange, could we arrange a Commission meeting that
22 suits around one of those dates?

23 CHAIRMAN MALMUD: Well, we still remain --
24 Ralph?

25 MEMBER LIETO: I was just going to say I

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1 personally don't have a problem with Thursday-Fridays.
2 So if that turns out to help out members and the
3 staff, I would be amenable to that just as an offering
4 or a suggestion and, you k now, it might be that --

5 CHAIRMAN MALMUD: Which were the two days
6 that you were offering is first, Angela? April?

7 MS. McINTOSH: Initially we offered April
8 26th through 27th.

9 MEMBER NAG: But now that's out.

10 MEMBER WILLIAMSON: Assuming that's a good
11 date for any of you.

12 MEMBER NAG: And the other thing is I
13 wonder why even, you know, Monday-Tuesday cannot be.
14 I mean, there is really no reason why we can't have
15 that.

16 MEMBER EGGLI: There may be some people
17 who don't want to travel on the weekend day because
18 the people who have to come in from a distance have to
19 come in the day before. For me, you know, I just come
20 down the evening before, but maybe somebody doesn't
21 want to spend all day Sunday flying or something.

22 MR. ESSIG: Which Ed Bailey would have to
23 do coming from California. Coming from California, it
24 would take Ed a whole day, and Robert Schenter has to
25 come from Washington, the other Washington.

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1 CHAIRMAN MALMUD: Next choice after April?

2 MEMBER NAG: Well, I don't think we can
3 solve anything because we don't know when the
4 Commissioners are going to meet. So we have to shelve
5 that. So I think there is --

6 CHAIRMAN MALMUD: I thought it was
7 necessary for us to set a date so that you could get
8 the room.

9 MR. MILLER: Yes, it is.

10 CHAIRMAN MALMUD: We can have this whole
11 thing by E-mail.

12 MR. MILLER: I think what is important is
13 knowing the dates. Angela has offered some windows of
14 opportunity here, and I guess the question becomes are
15 there some proposed dates that we can accommodate and
16 then we can take and see if the Commission is willing
17 to meet around those dates so that we can hold the
18 meeting and have the Commission meeting at the same
19 time.

20 MS. McINTOSH: What I was trying to learn
21 is if out of the proposed dates if there were
22 definitely dates where you knew that you would not be
23 able to be here. Then we could just eliminate those,
24 and we could have some options out of what was left
25 over.

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1 MR. MILLER: Yes, I would encourage you to
2 move expeditiously on this because there was a wide
3 range of dates, and I can't lock all of those dates on
4 my calendar.

5 MS. McINTOSH: Right, right. So we were
6 trying to get a feel of what we could walk away with,
7 if possible right now, what we could walk away with.

8 MEMBER NAG: I know like in March 18th
9 through 30 I'm not available.

10 CHAIRMAN MALMUD: Those weren't in the
11 dates anyway.

12 MS. McINTOSH: I handed out an E-mail, if
13 everyone has a copy of it. It has the range of
14 dates.

15 CHAIRMAN MALMUD: How about April 12th and
16 13th? That's a Tuesday and Wednesday?

17 MS. McINTOSH: Is that fine with everyone?

18 MR. ESSIG: That conflicts with ACR.

19 CHAIRMAN MALMUD: That conflicts with the
20 American College of Radiology.

21 MS. McINTOSH: It does.

22 MEMBER EGGLI: Is anybody planning to go
23 to ACR?

24 PARTICIPANTS: No.

25 MEMBER EGGLI: Again, physicists don't

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1 usually go to ACR. Radiation oncologists usually go
2 to ASTRO rather than ACR.

3 CHAIRMAN MALMUD: The 12th and 13th is
4 okay for us?

5 MS. McINTOSH: Twelfth and 13th.

6 MEMBER NAG: Twelfth and 13th, Tuesday-
7 Wednesday. That's something I can live with.

8 CHAIRMAN MALMUD: Twelfth and 13th,
9 Tuesday-Wednesday.

10 PARTICIPANT: When you're actually doing
11 your taxes.

12 (Laughter.)

13 MS. McINTOSH: Would the committee like to
14 propose an alternate date so that we have two sets of
15 dates?

16 MEMBER WILLIAMSON: What about Thursday
17 and Friday the same week?

18 MR. MILLER: Why don't we take that based
19 upon the information that --

20 PARTICIPANT: Well, actually Thursday and
21 Friday of that same week I'm unavailable.

22 MEMBER NAG: Question. For two days or
23 three days? Usually when we meet with the
24 Commissioners, three days.

25 MR. MILLER: I would argue given where

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1 we've been in the last number of sessions, we can't
2 even get through what's on the agenda in two full
3 days. If you're going to meet with the Commission,
4 you're going to want to have some time, I would think,
5 as a group before you go up and meet with them.

6 MEMBER WILLIAMSON: Yeah.

7 MR. MILLER: So three full days is
8 probably good for planning.

9 MS. SCHWARZ: So 12th, 13th, and 14th?

10 MR. MILLER: Or at least two and a half.

11 MEMBER NAG: Twelfth, 13th and 14th. The
12 last thing you probably want to make it a half day
13 anyway so that people can go home the same day.

14 MS. SCHWARZ: What about 11, 12, and 13,
15 Monday, Tuesday, Wednesday?

16 MEMBER WILLIAMSON: I would advise us,
17 even though at the moment maybe we don't have anything
18 urgent we would like to talk to the Commissioners
19 about, I would urge us to continue having the annual
20 contact with them. I think it's always important to
21 bring to the attention of your superiors the
22 activities you're working on and not turn down
23 opportunities to cultivate a relationship. I think
24 it's just bad politics to not, you know, continue this
25 tradition.

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1 I'm sure we can find something to talk
2 about.

3 CHAIRMAN MALMUD: It should be something
4 of substance.

5 MEMBER WILLIAMSON: Yes, but, I mean, we
6 deal with lots of substantive activities.

7 CHAIRMAN MALMUD: But do we have a firm
8 date for the Commission's meeting?

9 MR. MILLER: No, that's the dilemma. What
10 we're trying to do, what I was hoping to do, and I
11 can't promise that we can deliver on this is get out
12 ahead of what happened last year where the Commission
13 dictated a date, as I recall, and then we had to force
14 the ACMUI meeting to be coincident with that date so
15 that you would only have to come to town once.

16 If we can get some potential dates now
17 perhaps we could propose those to the Commission and
18 get something, if they accept that, that's more under
19 our control than their control.

20 MEMBER WILLIAMSON: Or you can work it the
21 other way around and examine the Commissioners'
22 schedules and come up with several.

23 MS. McINTOSH: I don't think it's out this
24 far ahead.

25 MEMBER WILLIAMSON: Do they meet in April?

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1 MR. MILLER: Pardon me?

2 CHAIRMAN MALMUD: Do they usually meet in
3 April?

4 MR. MILLER: Well, it's a question of a
5 number of things. It's not a question -- the
6 Commission meets whenever the Commission deems that
7 they need to meet, but they try to plan their meeting
8 schedule so that it doesn't interfere with their
9 individual travel activities or other obligations they
10 have. So they try to hold their meetings -- currently
11 there are three Commissioners -- they try to hold
12 their meetings when all three Commissioners are
13 available.

14 CHAIRMAN MALMUD: We will have to wait
15 until they set their meeting date.

16 MR. MILLER: And so what it might mean is
17 if we ask them to set a date, that will dictate when
18 the ACMUI meeting will be, which may interfere with
19 some of your availability. Understand that.

20 I mean, having -- I guess there was one
21 member absent this time. I guess there were two
22 counting Dr. Sukera (phonetic), but having maximum
23 membership at the meetings I find opts for a more
24 healthy, productive dialogue than if we have less
25 members present.

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1 CHAIRMAN MALMUD: Agreed. Ralph?

2 MEMBER LIETO: Would it be valuable, in
3 light of the fact that the Commissioners may not do
4 something or plan their schedule that far in advance,
5 as I think Angela was suggesting, having a primary
6 meeting time and maybe an alternate? In other words,
7 we come up with two groups of dates and then just kind
8 of maybe they can work from there with the
9 Commissioners.

10 MR. MILLER: We will try, and you know, it
11 may or may not fit their schedules. They may come
12 back and dictate something anyway, you know.

13 MEMBER LIETO: That's fine.

14 MS. McINTOSH: But as far as April 12
15 through 13, I think I heard the committee say 12
16 through the 14th and then someone said, well, no,
17 that's not going to work.

18 PARTICIPANT: I did. I'm unavailable on
19 the 14th.

20 MS. McINTOSH: Okay.

21 MS. SCHWARZ: What about the Monday, 11th,
22 12th, 13th?

23 MS. McINTOSH: There was concern about
24 Mondays because of travel, but we could. Should we go
25 with the 11 through the 13th as one proposal?

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1 MS. SCHWARZ: Yes.

2 MS. McINTOSH: Okay, and would there be an
3 alternate proposal perhaps in March?

4 MEMBER EGGLI: You had also the week of
5 the 21st of April.

6 MS. McINTOSH: Yes, I had proposed the
7 20th through the 21st.

8 MEMBER EGGLI: Are the important people,
9 the prerequisite people from NRC staff available that
10 week?

11 MR. MILLER: As far as I know, yes.

12 MR. ESSIG: Okay. So then three days
13 during that week, right?

14 MS. McINTOSH: I haven't heard. I haven't
15 heard one way or the other.

16 MR. ESSIG: You proposed two.

17 MS. McINTOSH: The second one, right.

18 MR. ESSIG: Two days.

19 MS. McINTOSH: The 11th through the 13th
20 is the first proposal.

21 DR. HOLAHAN: We're talking about the
22 second proposal.

23 MS. McINTOSH: Right.

24 MS. McINTOSH: I haven't heard one way or
25 the other if that's okay.

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1 Would the 20th through the 22nd --

2 PARTICIPANT: Of April?

3 MS. McINTOSH: -- of April be okay?

4 CHAIRMAN MALMUD: Any objection to that,
5 20th through the 22nd of April?

6 MEMBER WILLIAMSON: No.

7 CHAIRMAN MALMUD: As an alternative. Dr.
8 Nag?

9 MEMBER NAG: Right now that looks okay
10 now.

11 MS. SCHWARZ: What was the date again?

12 CHAIRMAN MALMUD: The 20th through the
13 22nd.

14 MS. SCHWARZ: Of March?

15 CHAIRMAN MALMUD: April.

16 MS. McINTOSH: As the alternative.

17 PARTICIPANT: And what's the primary?

18 MS. McINTOSH: The primary would be the
19 11th through the 13th of April.

20 MR. MILLER: So why don't we take those
21 two proposals?

22 CHAIRMAN MALMUD: April 20th to 22nd?

23 MR. MILLER: Yeah.

24 CHAIRMAN MALMUD: I think that might be a
25 problem. We have to reappoint the new modality

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1 subcommittee, by the way.

2 MR. ESSIG: Yes.

3 CHAIRMAN MALMUD: April 20th to 22nd,
4 what's our schedule look like?

5 MEMBER WILLIAMSON: I thought there were
6 two other action items we had. Something I'm supposed
7 to do with the medical event criteria.

8 MR. ESSIG: Jeffrey, are you speaking of
9 action items or motions? We didn't talk about action
10 items. We're going to dig those out.

11 MS. McINTOSH: Right.

12 MR. ESSIG: It was too much trouble to dig
13 those out of the transcript at this point.

14 MS. McINTOSH: Okay. So the 20th through
15 the 22nd.

16 CHAIRMAN MALMUD: Yes.

17 MS. McINTOSH: So the 20th through the
18 22nd is going to be the alternate proposed date for
19 the spring meeting.

20 MEMBER WILLIAMSON: What is the initial
21 date or primary date?

22 MS. McINTOSH: Eleventh through the 13th
23 of April.

24 MR. MILLER: What we will do is we will
25 check to see if we could arrange a Commission meeting

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1 at that time. If the Commissioners offer an
2 alternative date that they want to meet, well, then I
3 think we'll probably need to get back to you and see
4 if you can accommodate that.

5 It's always a challenge to do both.

6 CHAIRMAN MALMUD: Thank you.

7 The next item is the new modality
8 subcommittee, which needs to be reappointed. Its
9 chair has left the committee; is that not correct?

10 MS. SCHWARZ: Yes.

11 CHAIRMAN MALMUD: And who was on the
12 previous subcommittee on modalities? Dr. Nag, Dr.
13 Williamson, and Dr. Schwarz? Would one of you wish to
14 be the successor to chair the committee?

15 Dr. Schwarz has been nominated by Dr.
16 Williamson for that position.

17 MEMBER NAG: I second it.

18 (Laughter.)

19 CHAIRMAN MALMUD: Dr. Nag seconds it. Do
20 we need one more member or is three adequate?

21 PARTICIPANT: It probably would help to
22 have the agreement state person on.

23 MEMBER WILLIAMSON: The agreement state
24 person.

25 CHAIRMAN MALMUD: Why don't we nominate

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1 Mr. Bailey in his absence and essentially agree?

2 Yes, Dr. Nag.

3 MEMBER NAG: I would like Dr. Diamond
4 taking out (unintelligible). I want to know if the
5 NRC has talked to the board and tried to appoint a new
6 Commissioner as part of this.

7 MR. MILLER: I think I can address that.
8 One of the things that I am working with my staff to
9 do is to address that issue. Of concern to me and I
10 think to everyone is not to wait until people are
11 rotating off in order to try to find a replacement.
12 Do that ahead of time.

13 Also, recognizing that in some years there
14 are multiple members that are rotating off, and that
15 can really impact the committee, I've asked my staff
16 to do thinking on how can we minimize that, and if
17 there are some innovative ways we could minimize that,
18 including coming up with proposals for extending
19 people's terms beyond two terms in order to get
20 through the initial dilemma that we found.

21 We're exploring all of that, and thirdly,
22 the nomination process itself. There are some steps
23 that we've looked at in the nomination process that we
24 think make it more torturous than it needs to be. In
25 other words, how many times we have to go to the

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1 Commission during the process to seek approvals.

2 What we have to do is send a policy paper
3 up to the Commission and get their vote on any changes
4 to the process and to new nominations, and we're
5 actively working that. As Mr. Essig can tell you,
6 I've pushed to try to get that done.

7 So I hope to get that done in the very
8 near term.

9 PARTICIPANT: And just to add to that, I
10 know some of you had been approached probably a year
11 or so ago and asked if we received approval from the
12 Commission would you be willing to serve beyond your
13 two term limit, and several of you indicated that you
14 would be interested and available to do that.

15 We haven't forgotten about that. What
16 we're probably going to have to do is because that was
17 about a year ago, we would cast the net out once
18 again, make sure that your offer if you did offer to
19 serve beyond the two terms and we have Commission
20 approval of that conceptually, take that offer that
21 you still were willing to do that.

22 And so that will all be included in this
23 effort.

24 MEMBER WILLIAMSON: I was under the
25 impression that in my own case I was already beyond

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1 the two term limit and I am now in my terminal years.

2 (Laughter.)

3 MEMBER WILLIAMSON: That this is now my
4 fourth year of my -- I believe. Am I wrong?

5 MS. McINTOSH: No, you're in your second
6 term.

7 MEMBER WILLIAMSON: I am? Oh, okay. I
8 stand correct.

9 MEMBER NAG: Because you took six months
10 off and you were reappointed. So you restarted on
11 your reappointment.

12 MEMBER WILLIAMSON: No, I understand that.

13 MEMBER NAG: The old one was off.

14 MEMBER WILLIAMSON: So when does my term
15 end?

16 MS. McINTOSH: In 2006.

17 MR. MILLER: So along those lines what
18 we're also trying to think through is rather than just
19 asking members who are rotating off if they're willing
20 to serve more, we may be looking at staggered terms
21 for reappointment so that we don't find ourselves in
22 a continuing dilemma of having five people rotating
23 off at the same time.

24 So we're trying to do some thinking in
25 that regard as to what's the most logical path forward

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1 on that so that we get continued representation from
2 the various specialties that we have here and also
3 seek new people, get some fresh ideas to the table
4 that also are willing to serve and can work
5 productively in this environment.

6 CHAIRMAN MALMUD: To that end, you might
7 develop a matrix with the existing membership, their
8 specialties, and their terms and then begin the
9 preparation for exception.

10 MR. MILLER: And as we move forward and do
11 that, if it's okay with the committee, we will
12 probably have some initial discussions with your
13 chair, who he can then decide how he wants to share
14 those kinds of issues with the rest of the committee,
15 but it's kind of part of the role of the chair, I
16 think, to have some administrative discussions
17 concerning that.

18 CHAIRMAN MALMUD: Fine. Dr. Schwarz.

19 MS. SCHWARZ: One other item that we
20 appointed a group was for the best practice where we
21 were looking at the I-131 events and some others.

22 CHAIRMAN MALMUD: Yes.

23 MS. SCHWARZ: And Dr. Eggli was appointed
24 the chair and then Dr. Vetter, Malmud, and myself.

25 CHAIRMAN MALMUD: Correct.

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1 MS. SCHWARZ: So that was --

2 CHAIRMAN MALMUD: That's in the minutes.
3 I wasn't certain that the other one was, but I think
4 that they both are in the minutes.

5 Thank you for --

6 MEMBER WILLIAMSON: It will take six weeks
7 to find all of that stuff.

8 CHAIRMAN MALMUD: Oh, it won't take that
9 long.

10 MS. SCHWARZ: It's due back in two months.

11 CHAIRMAN MALMUD: I have the minutes from
12 the meeting, our phone conversation of last week, a
13 week and a half ago, and they've already been
14 processed.

15 MR. MILLER: We were told we can get the
16 transcript in how many days? Three.

17 CHAIRMAN MALMUD: In how many days?

18 MS. MCINTOSH: Three business days.

19 CHAIRMAN MALMUD: And Angela will get it
20 out to me, and welcome back.

21 MR. ESSIG: Just one additional point on
22 the committee appointments. What we have done in the
23 past is that since the appointments have been on a
24 fiscal year basis, the new appointments would take
25 effect October 1 of this year. For example, Dr. Van

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1 Decker is now on the -- I mean, his appointment was
2 effective October 1st. Had Dr. Sukera been able to be
3 here, this would have been a transition meeting. Dr.
4 Sukera would have been able to do a mind meld or
5 something to that order with Dr. Van Decker, and
6 likewise Mr. Bailey. This was to be his. Had Ruth
7 McBurney been able to attend, but she couldn't because
8 of other obligations, this would have been her ability
9 or opportune time to transfer her knowledge, and in
10 the same way with the public advocate or patient
11 advocate representative.

12 Unfortunately neither one could be here,
13 the new nor the old this time, but that we'd like to
14 have as kind of the transition meeting, but
15 unfortunately it didn't work as well this time.

16 I just mention that for background
17 information.

18 CHAIRMAN MALMUD: Well, if we get the
19 matrix together, we can see whose terms might be
20 extended by an odd number of years, if possible, and
21 then create the transition, the smooth transition that
22 you're seeking.

23 MR. MILLER: Right, and also it's probably
24 time we do think about does the committee see any
25 specialties that aren't represented here that might be

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1 important to regulatory activities to be added to the
2 committee or replace the specialty if one is not being
3 utilized anymore.

4 So we're interested in your thoughts on
5 that.

6 CHAIRMAN MALMUD: Yes. Dr. Eggli, are you
7 going to address that issue?

8 MEMBER EGGLI: Yes. The question is do
9 you have a statutory limit on the size of this
10 committee, and if not --

11 MR. MILLER: No.

12 MEMBER EGGLI: -- again, the other thing
13 to look at --

14 MR. ESSIG: Budgetary.

15 MEMBER EGGLI: Yes, but from the point of
16 view of clinical practice, diagnostic radiologists are
17 a major number of practitioners of activity in both
18 Subpart 200 and Subpart 300, and it might be worth
19 considering having a member of the diagnostic
20 radiology community.

21 Although I am also a Board certified
22 radiologist, in addition to being a Board certified
23 nuclear medicine physician, I think my attitudes more
24 represent the nuclear medicine community than the
25 radiology community, although in the absence of a

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1 radiologist member, I have been, in fact, quite
2 vociferously, I think, representing the interests of
3 the radiology committee or the radiology community.

4 But it might be useful to have that
5 community speak for itself.

6 MS. MCINTOSH: Might I also add that your
7 self-evaluation is due in the spring, due next spring,
8 the spring of 2005. So if you have any issues or
9 suggestions about the composition of the committee,
10 you can always add those comments to your self-
11 evaluation that we forward to the Commission.

12 CHAIRMAN MALMUD: Thank you.

13 MR. ESSIG: And on that same topic, I know
14 recently we broached the subject of endocrinologists
15 and whether or not one was wanted, and I think the
16 consensus was or the comment I got back was that, no,
17 one was not.

18 CHAIRMAN MALMUD: We've heard nothing from
19 that community regarding wanting to be on the
20 committee, and they seem to be covered by the current
21 regs. well; and we've heard no requests for exemptions
22 or changes to practice.

23 I'm an inclusionary person, but I don't
24 see the need for that at the moment.

25 If I may take the Chairman's prerogative,

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1 it's 3:20, and it would be an astonishing
2 accomplishment to finish before the adjournment time
3 at 3:30. And we would like to thank all of those who
4 have remained here to the end, as well as to the
5 members of the NRC who are here: Dr. Miller, Mr.
6 Essig, and staff, Angela and staff. We very much
7 appreciate the opportunity to share and -- excuse me,
8 Dr. Howe and Zelac.

9 We really appreciate the opportunity to
10 exchange all of these ideas and to try and reach
11 consensus on issues that are very difficult.
12 Representation of this committee, excluding the NRC
13 staff, is very diverse with very different interests
14 and concerns.

15 At one extreme perhaps are the states'
16 representatives, who are very concerned about
17 prescriptive definitions, and on the other hand, there
18 are those who are from the training programs which
19 feel that those kinds of standards are best
20 established by the boards.

21 So that reaching consensus isn't easy.
22 You've made it a constructive engagement for us, and
23 we appreciate that, and in the breaks that we've had
24 at lunch and so on, the members of the committee of
25 the ACMUI have commented on the improved relationship,

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1 if you will, between NRC and the committee by virtue
2 of the presence of the two of you, and we're very
3 appreciative of that and your leadership role.

4 MR. MILLER: Thank you.

5 CHAIRMAN MALMUD: And so thank you and
6 thank all of the members of the committee. And is
7 there a motion for adjournment?

8 MR. MILLER: Before you do --

9 (Laughter.)

10 MR. MILLER: -- I'd like to reciprocate.
11 One of the things that we've been designed to do more
12 of is to get issues on the table that are important to
13 you so that we can move to have a dual dialogue as
14 opposed to the NRC staff puts issues on the table and
15 you just comment on it.

16 And I think having presentations this time
17 by Dr. Nag and Dr. Vetter moves the ball in that
18 direction. So I think from our perspective, we were
19 pleased with that, and we'd like to see continued
20 activity in that area in the future.

21 CHAIRMAN MALMUD: Thank you.

22 Is there a motion?

23 MEMBER SULEIMAN: I so move.

24 CHAIRMAN MALMUD: Dr. Suleiman. Second to
25 the motion?

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1 PARTICIPANTS: Second.

2 CHAIRMAN MALMUD: All in favor?

3 (Chorus of ayes.)

4 CHAIRMAN MALMUD: Thank you very much.

5 (Whereupon, at 3:20 p.m., the meeting was
6 concluded.)

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