

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Wednesday, February 20, 2002

Work Order No.: NRC-248

Pages 81-384

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
+ + + + +
ADVISORY COMMITTEE ON THE MEDICAL
USES OF ISOTOPES
(ACMUI)
+ + + + +
WEDNESDAY,
FEBRUARY 20, 2002
+ + + + +
ROCKVILLE, MARYLAND
+ + + + +

The Advisory Committee met at the Nuclear
Regulatory Commission, Two White Flint North, T2B3, 11545
Rockville Pike, Rockville, Maryland, at 8:00 a.m., Manuel
Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

MANUEL CERQUEIRA, M.D., Chairman
DAVID A. DIAMOND, M.D.
NEKITA HOBSON
RALPH P. LIETO
RUTH McBURNEY
SUBIR NAG, M.D.
SALLY WAGNER SCHWARZ

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 COMMITTEE MEMBERS PRESENT (Continued):

2 RICHARD J. VETTER, Ph.D.

3 JEFFREY WILLIAMSON, Ph.D.

4 ALSO PRESENT:

5 JOHN W.N. HICKEY

6 ANGELA WILLIAMSON

7 SUSAN FRANT, Ph.D.

8 ROBERT AYERS, Ph.D.

9 MARJORIE ROTHSCHILD

10 PATRICIA RATHBUN

11 NANCY DALY

12 DONALD A. COOL, Ph.D.

13 PAUL LOHAUS

14 JAMES MYERS

15 WILLIAM UFFELMAN

16 CATHERINE HANEY

17 JOSEPH DeCICCO

18 FREDERICK BROWN

19

20

21

22

23

24

25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

	C-O-N-T-E-N-T-S	
		PAGE
1		
2		
3	Action Item No. 1	93
4	Action Item No. 2	94
5	Action Item No. 3	101
6	Discussion of Board Certification	104
7	Action Item No. 4	128
8	Presentation by Dr. Susan Frant	130
9	Action Item No. 5	164
10	Status of NRC Web Site, Dr. Patricia Rathbun	164
11	Status of Electronic Forms, John Hickey . .	179
12	Distribution of ACMUI Minutes	184
13	Update of ACMUI Bylaws	187
14	IAEA Patient Protection, Dr. Donald Cool . .	190
15	Status of Board Recognitions, Dr. Robert	
16	Ayers	208, 266
17	Report of National Materials Program, Paul	
18	Lohaus	214
19	Security of Radioactive Materials, Catherine	
20	Haney	318
21	Update on New IVB Devices, John Hickey . . .	342
22	Mixed Doses, Joseph DeCicco	353
23	ACMUI Vacancies	364
24	Meeting Summary	368
25	Next Meeting	369

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

(8:12 a.m.)

MR. HICKEY: Good morning.

PARTICIPANTS: Good morning.

MR. HICKEY: While we're waiting for Dr. Cerqueira, I'm going on the record to make the formal announcements of the meeting.

I'm John Hickey, Chief of the Material Safety Branch for NRC.

This is an open meeting of the Advisory Committee on Medical Uses of Isotopes. It's a transcribed meeting, and it's being conducted in accordance with the Federal Advisory Committee Act.

And we'll go off the record until Dr. Cerqueira gets here, and we'll begin the discussions.

(Whereupon, the foregoing matter went off the record at 8:13 a.m. and went back on the record at 8:15 a.m.)

CHAIRMAN CERQUEIRA: I'd like to welcome everybody, and I guess we have sort of a follow-up discussion from the Commission briefing yesterday. I'd also like to sort of reiterate the policy that we've adopted in the past for these meetings. I'd really like to generate action items.

In going through the material for today's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 meeting, there's quite a bit of missing stuff there, and
2 I'd like to avoid that in future meetings. What we
3 really need to do is identify action items from the
4 discussions, and then have clear follow-up.

5 And I think the discussion we had yesterday
6 about making motions, taking a vote on something if we
7 need to, which makes it a little bit more formal, and
8 then I think as Dr. Williamson requested, perhaps sort of
9 for the record getting some writing back from the NRC
10 staff Commissioners on specific items that the Committee
11 has brought to their attention just procedurally, I
12 think, would be very important to do that.

13 And at some point during the day, hopefully
14 before open discussion, but I think there were two issues
15 that came up yesterday that we really need to sort of go
16 forward with, and that's the issue related to the health
17 physicist and the authorized medical physicist, radiation
18 safety officers, in terms of trying to resolve some of
19 these issues.

20 If it's, indeed, going to take a new
21 rulemaking, then it's better to initiate the process now
22 rather than waiting, and at some point I'd actually like
23 to form a subcommittee that would look into these issues
24 and then try to move it forward, working with the staff
25 and the Commissioners to try to identify the most

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 expedient way to get the problem resolved.

2 I think it would be very important to do
3 that.

4 As a result of yesterday's discussions also
5 with some of you, some of you have close flights time-
6 wise to catch, and we'll try to keep the agenda moving as
7 much as possible, and I certainly don't want to cut
8 anybody off during the discussions, but I think if people
9 will sort of bear with me, if we're saying the same thing
10 or people are perhaps taking too long to get to the
11 point, I will sort of take the Chair's initiative and try
12 to keep things moving.

13 DR. DIAMOND: Would you like us to suggest
14 as a first motion today that we actually take a formal
15 vote that as a policy we go and generate a list of action
16 items for the result of our discussions, and that at the
17 conclusion of that meeting each of those action items
18 generates a written response from the staff?

19 CHAIRMAN CERQUEIRA: I think that's a good
20 idea. Do we have a second on that?

21 MS. WAGNER SCHWARZ: I second.

22 CHAIRMAN CERQUEIRA: Okay. Any discussion?
23 John?

24 MR. HICKEY: If I could just state, the
25 staff has no objection to that. In fact, that is our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 intent, that any resolution or action item will be
2 responded to in writing and we'll do it in a format that,
3 as Dr. Nag suggested, that a separate response provide
4 responses just to resolutions and action items so that
5 you don't have to wade through a larger document to
6 provide those.

7 CHAIRMAN CERQUEIRA: And I will attempt to
8 work with Angela Williamson to try to make these points,
9 you know, basically so that we capture it, but I think if
10 we make the motions, vote on it, she'll have all of the
11 wording that's appropriate for it, and that will sort of
12 trigger what items we need specific responses to.

13 Jeffrey?

14 DR. WILLIAMSON: Well, I was just going to
15 ask: is there a mechanism for somebody to go through the
16 transcript and identify all of these items? I believe
17 that's been a problem in the past.

18 MR. HICKEY: Well, I think the answer to
19 that is yes, but in terms of resources, I think it's
20 better to make sure we identify them during the meeting.
21 It's a problem for, you know, one person or two persons
22 to characterize what, in fact, constitutes an action item
23 after the fact. It's better, I think, if we address that
24 during the meeting.

25 CHAIRMAN CERQUEIRA: Well, again, I think if

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 we end up taking a formal vote on it, that clearly is an
2 item, and if there are other things that we're discussing
3 and people feel that they want follow-up, I think it
4 would be appropriate at the conclusion of the discussion
5 to make a motion and take a formal vote on it.

6 That would make it very clear-cut for both
7 the Committee as well as the NRC staff.

8 MR. HICKEY: Yes. If there is a vote,
9 there's no question, but also if the Chairman and I, as
10 designated official, just announce at the end of the
11 discussion that we agree this is an action item, that
12 also will be documented for the record.

13 CHAIRMAN CERQUEIRA: Sure.

14 Again, jeffrey.

15 DR. WILLIAMSON: Is it necessary to maybe
16 appoint somebody as a recording secretary to make a list
17 during the meeting of these items? It sounds like what
18 you're proposing now.

19 CHAIRMAN CERQUEIRA: Somebody from the
20 Committee, Jeffrey?

21 DR. WILLIAMSON: Not necessarily. It could
22 be somebody from the staff.

23 CHAIRMAN CERQUEIRA: Perhaps Angela could.

24 MR. HICKEY: We already have a contractor
25 making notes and a transcriber. We already have two

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 people tracking the meeting. We've found that's an
2 adequate mechanism, and in fact, we have a memo from the
3 early 2001 meeting that responded to all of the items
4 that were brought up in that meeting.

5 So we feel we have adequate tracking of
6 this. As long as it's clearly stated in the meeting, it
7 will be followed up on.

8 CHAIRMAN CERQUEIRA: Well, then perhaps it's
9 my fault that I didn't sort of try to enforce that for
10 this meeting, but I just didn't get the feeling that
11 we've got specific action items that we need to get out.

12 I think the other thing that's important is
13 the minutes of the meeting. I think all of us should
14 look at those things ahead of time, and it's important to
15 get it out I would say at a minimum of two weeks before
16 the meetings. Is that a reasonable time?

17 Ralph.

18 MR. LIETO: I would just say all of that is
19 pretty much laid out in the bylaws of the Committee. We
20 can just follow what our bylaws state, and I think that
21 has the time lines and everything like that.

22 I think what John is suggesting is more than
23 adequate for support.

24 CHAIRMAN CERQUEIRA: Okay. That sounds like
25 it's a reasonable plan.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Any other follow-up from the Committee from
2 the meeting with the Commissioners yesterday?

3 MR. HICKEY: If I could just add, Mr.
4 Chairman, I also believe there was an important
5 discussion on the amount of time it's going to take to
6 implement the rule and if there's a six month deadline
7 specified, the NRC staff needs to make sure the guidance
8 is completed well in advance of that six month deadline.

9 There were several discussions of concern
10 about that issue.

11 DR. DIAMOND: I'd also like to state that I
12 believe the frequency of last meeting with the
13 Commissioners in October 1999, I believe, was overdue and
14 we should make a policy to do it more frequently than
15 that, perhaps on an annual basis, and in an effort to aid
16 with scheduling, perhaps we should go in next year's
17 Commission briefing as soon as possible so that we can
18 best coordinate it.

19 CHAIRMAN CERQUEIRA: That's a good point.

20 But getting back to the initial discussion
21 with the guidance documents, I think this is sufficiently
22 important as we identified with debriefing yesterday.
23 I'd sort of like to get a formal motion that guidance
24 documents be completed in a timely fashion.

25 And you know, I asked the Commissioners

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 would it be possible, but I think the Committee should go
2 on record officially as saying that it's important to get
3 the guidance documents out, you know, prior to the
4 implementation and come up with a reasonable time period.

5 DR. NAG: Yes, I make a motion that the
6 guidance document be at least three months ahead of the
7 implementation, at least three months and not just a few
8 days.

9 CHAIRMAN CERQUEIRA: So, John, a suggestion
10 has been made and a motion has been put forward that --
11 do we have a second on the motion just procedurally?

12 MS. WAGNER SCHWARZ: Second.

13 CHAIRMAN CERQUEIRA: Okay, and so for
14 discussions.

15 You know, with Dr. Nag's motion, is three
16 months realistic?

17 MR. HICKEY: Well, what I want to suggest is
18 we hold the vote until the nine o'clock agenda item where
19 we're going to be talking about the issuance of NUREG
20 1556, Volume 9, which is the guidance.

21 CHAIRMAN CERQUEIRA: Okay. I should have
22 known that, but I didn't.

23 So, Dr. Nag, do --

24 DR. NAG: I will hold it.

25 CHAIRMAN CERQUEIRA: Okay. So we'll --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. WILLIAMSON: Mr. Chairman.

2 CHAIRMAN CERQUEIRA: Yes.

3 DR. WILLIAMSON: Could we vote? We have to
4 vote on Dr. Diamond's motion, which is still on the
5 table.

6 CHAIRMAN CERQUEIRA: That's true. We did.

7 DR. WILLIAMSON: So could we repeat the
8 motion, what it is?

9 CHAIRMAN CERQUEIRA: Okay.

10 DR. DIAMOND: As **Action Item No. 2**, the
11 Advisory Committee recommends that annual meetings be
12 held to brief --

13 MS. McBURNEY: It was the other one. We
14 haven't even voted on the first one.

15 DR. DIAMOND: Oh, I thought we took a formal
16 vote on it.

17 MS. McBURNEY: No.

18 DR. DIAMOND: I'm sorry. **Action Item**
19 **No. 1**, the Advisory Committee recommends that during
20 the course of each meeting a list of action items be
21 generated expressing the wishes and the intent of the
22 Committee, and that these action items generate a written
23 and prompt response from the staff so as to demonstrate
24 their feelings on the matter.

25 CHAIRMAN CERQUEIRA: Okay. I guess we've

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 sort of all agreed to it, but perhaps a motion.

2 So a motion has been made, was seconded.

3 There has been discussion. Any further discussion?

4 (No response.)

5 CHAIRMAN CERQUEIRA: If not, I call for a
6 vote. All in favor.

7 (Chorus of ayes.)

8 CHAIRMAN CERQUEIRA: Opposed?

9 (No response.)

10 CHAIRMAN CERQUEIRA: No abstentions, and so,
11 John, this will clearly be an action item.

12 And then we have still on the table the
13 motion regarding the guidance document. So we'll sort of
14 defer that until after the discussion at nine o'clock by
15 Susan Frant.

16 DR. DIAMOND: And that would bring us to
17 **Action Item No. 2**, which was that the Advisory
18 Committee recommend that annual briefings be held with
19 the Commissioners to update them with the activities of
20 this Committee, and that the Advisory Committee suggest
21 that this date be scheduled as far in advance as possible
22 so as to best facilitate the scheduling of that meeting.

23 CHAIRMAN CERQUEIRA: Do we have a second on
24 that?

25 Second. Okay. Discussion? Jeffrey.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. WILLIAMSON: I think that is covered in
2 our bylaws, that we have an annual briefing with the
3 Commission. Is that not so?

4 CHAIRMAN CERQUEIRA: Yeah, I think Ralph's
5 point is a valid one. The procedure is there, and it was
6 included in the book this time, and so basically what we
7 need to do is basically just get sort of compliance with
8 the bylaws.

9 I guess the one issue that does come up,
10 David, in terms of scheduling and appointment with the
11 Commissioners, it's hard to predict the schedule. I
12 think an attempt has to be made to have all five
13 Commissioners present, and so it's hard to figure out
14 schedules, you know.

15 A year in advance may be difficult, but at
16 least if we sort of, you know, try to get it as close as
17 possible, that's reasonable.

18 MR. HICKEY: Well, Dr. Diamond said as far
19 in advance as possible, which I think is reasonable. I
20 don't think it will be done a year in advance, and if it
21 is, it would be subject to change, but six months in
22 advance certainly at least can be tentatively scheduled.

23 CHAIRMAN CERQUEIRA: All right. Dr. Nag and
24 then Jeffrey.

25 DR. NAG: Well, one thing. I mean

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 ultimately we should like to have the meeting with all
2 the Commissioners, but if it fails, at the very least, we
3 should have one Commissioner invited to the ACMUI
4 meeting. One of the things that when we were informally
5 discussing with the Commissioners after the meeting that
6 we have a meeting, we have no problem if one of us comes
7 to a meeting and at least be a representative.

8 So if a meeting cannot be held within
9 reason, then we can do it by having a meeting with a, one
10 or more, Commissioners.

11 CHAIRMAN CERQUEIRA: I just would like to
12 get clarification. I think in the past when we've
13 brought up that possibility, there is some rule for
14 government committees, that we have to meet with all five
15 Commissioners. John, am I hallucinating on that?

16 MR. HICKEY: I would have to check on that.

17 CHAIRMAN CERQUEIRA: Is there anybody from
18 the staff?

19 MR. HICKEY: Our attorneys are here, but I
20 don't know. I can check during a break to see.

21 DR. VETTER: Manny?

22 CHAIRMAN CERQUEIRA: Yes

23 DR. VETTER: I also received the message
24 that Dr. Nag just reflected. One of the Commissioners
25 mentioned to me that if at any time we would like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 visit with one of them, we are free to invite them to
2 come and meet with us as part of the meeting.

3 Now, that's not an official meeting with the
4 Commissioners. That's inviting one of the Commissioners
5 to come here to discuss an issue.

6 CHAIRMAN CERQUEIRA: Okay. I think that
7 would be appropriate, and perhaps, you know, John, if we
8 could get counsel to give us some information on this.

9 MR. HICKEY: We could include that.

10 CHAIRMAN CERQUEIRA: On what the rules are.

11 MR. HICKEY: Yeah, I might be able to get
12 you an answer today, but if not, we could include that in
13 the response to the resolution.

14 CHAIRMAN CERQUEIRA: Okay. But this is an
15 action item. Hopefully by the end of the day, and if not
16 by the end of the day, we should probably capture it.

17 Do we want to make a motion on this, David?

18 DR. VETTER: David already made the motion.

19 CHAIRMAN CERQUEIRA: Oh, he made the motion.
20 There was a motion.

21 Okay. Just in terms of the meeting. Well,
22 but there's several portion of it. One is the meeting
23 with the Commissioners annually, but then there was the
24 additional item in terms of infrequent meetings.

25 Okay. All right. So do we take a vote on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the formal motion? We did to meet with the
2 Commissioners, yes, and we didn't vote on it.

3 PARTICIPANTS: No.

4 CHAIRMAN CERQUEIRA: Okay. Any further
5 discussion?

6 (No response.)

7 CHAIRMAN CERQUEIRA: And why don't you
8 restate your motion?

9 DR. DIAMOND: Sure.

10 CHAIRMAN CERQUEIRA: And I think what Ralph
11 is going to say is it's in the procedure, but it's just
12 not being enforced, but I think this will at least
13 identify it as something that needs to be addressed.

14 DR. DIAMOND: I'll try and restate then.

15 **Action Item No. 2**, for the sake of the
16 transcriptionist, would be that the Advisory Committee,
17 in accordance with its bylaws, requested that an annual
18 meeting be held with the Commissioners so as to update
19 them on the activities of this Committee, and that this
20 meeting be scheduled as far in advance as possible so as
21 to facilitate this meeting.

22 Should the Commissioner not be able to hold
23 this meeting, the Advisory Committee may invite as their
24 guests to one of these meetings the Commissioners to
25 attend for informal discussions.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Okay. Shall we get a
2 second on that?

3 DR. DIAMOND: Do you want to -- wasn't that
4 the sense? The sense was that we would try and do it in
5 accordance with the bylaws. If that were not possible,
6 that we would invite individual members to attend. Is
7 that the sense that I had?

8 MS. McBURNEY: Well, I think we can do that
9 anyway. I mean in addition to a formal meeting, we can.

10 CHAIRMAN CERQUEIRA: Invite them for
11 specific issues that --

12 MS. McBURNEY: If it's not possible.

13 DR. DIAMOND: Okay.

14 DR. WILLIAMSON: I would propose amending it
15 and deleting the clause --

16 CHAIRMAN CERQUEIRA: We don't have John
17 Graham who is so great at making --

18 DR. WILLIAMSON: Well, we do our best.

19 MS. McBURNEY: That's right.

20 DR. WILLIAMSON: I would suggest an
21 amendment that we drop the second provision of the
22 motion, which suggests we could substitute a formal
23 briefing with an informal visit. I don't think that's
24 appropriate.

25 DR. DIAMOND: Okay. Would you like me to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 restate it again with that amendment?

2 DR. NAG: But then what happens in the
3 situation where all of us might not meet and where we
4 never hold any meeting at all?

5 DR. WILLIAMSON: We'll just put pressure on
6 the staff to -- you know, I don't think that all five of
7 them have to be there. What is the legal requirement,
8 three or four of them to hold a formal briefing?

9 MR. HICKEY: Three.

10 DR. WILLIAMSON: Three. So I think we have
11 to be satisfied with that minimum, but I believe there's
12 a legally quite different status according to a briefing
13 than an informal visit, and we should take advantage of
14 the formal briefing.

15 CHAIRMAN CERQUEIRA: So I guess in essence
16 what we're saying is that, you know, we need to reinforce
17 that there should be a briefing between the ACMUI
18 Committee and the Commissioners on an annual basis as
19 stated in the bylaws.

20 Is that the essence of what we're --

21 DR. DIAMOND: Yes.

22 DR. WILLIAMSON: Yes.

23 CHAIRMAN CERQUEIRA: So, David, do you want
24 to make that your motion?

25 DR. DIAMOND: Sure. All right. Amended

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 **Action Item No. 2** would be the Advisory Committee
2 in accordance with its bylaws requests to hold an annual
3 briefing with the Commissioners so as to update them with
4 the Committee's activities.

5 In addition to this formal meeting with the
6 Commissioners --

7 CHAIRMAN CERQUEIRA: Let's maybe take a vote
8 on the formal meeting.

9 DR. DIAMOND: Okay.

10 CHAIRMAN CERQUEIRA: Okay. A second on
11 that?

12 Second. Any further discussion on this?
13 (No response.)

14 CHAIRMAN CERQUEIRA: If not, we'll take a
15 vote. All in favor?

16 (Chorus of ayes.)

17 CHAIRMAN CERQUEIRA: Opposed?

18 (No response.)

19 CHAIRMAN CERQUEIRA: Anyone abstaining?

20 (No response.)

21 CHAIRMAN CERQUEIRA: Okay. So we have that
22 formal motion, and then --

23 DR. DIAMOND: And then **Action Item No.**
24 **3** would be in addition to this annual Commissioner
25 briefing, the Advisory Committee wishes to, from time to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 time, invite individual members of the Commission to join
2 us for this meeting, period.

3 Jeff?

4 CHAIRMAN CERQUEIRA: Could we have a second?

5 DR. WILLIAMSON: That's not a motion.

6 CHAIRMAN CERQUEIRA: Well --

7 DR. DIAMOND: I'm trying to -- it has to be
8 an informal meeting. It cannot be -- it's not a
9 Commission briefing, of course.

10 MS. McBURNEY: But we can do that without a
11 motion.

12 DR. WILLIAMSON: We can do that without a
13 motion.

14 CHAIRMAN CERQUEIRA: Well, the reason we're
15 doing the motion is to try to capture it. Unless there's
16 some other mechanism by which we actually state that
17 there's going to be a formal action item on this.

18 I mean, I don't want to get too formalistic
19 on all of this, but I think this will simplify things a
20 little bit in terms of getting feedback, and what I
21 propose is in subsequent meetings --

22 DR. DIAMOND: I agree.

23 CHAIRMAN CERQUEIRA: -- we go back at the
24 beginning of the meeting on these action items.

25 Ruth?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. MCBURNEY: Well, I think it's pretty
2 much a consensus of the Committee that we do that, and
3 I'm not sure that a formal motion is necessary.

4 CHAIRMAN CERQUEIRA: All right, but then we
5 want this as an action item.

6 MS. MCBURNEY: Right, but as a consensus
7 rather than --

8 CHAIRMAN CERQUEIRA: Okay. So for the
9 transcriptionist, if you could somehow identify this.

10 MS. MCBURNEY: That it's the consensus of
11 the Committee that --

12 DR. WILLIAMSON: That we meet informally
13 with the Commissioners as well as the formal briefing.

14 CHAIRMAN CERQUEIRA: Right. That the
15 appropriate -- that the Committee request attendance at
16 the ACMUI meetings of Commissioners who have an interest
17 or "expertise" isn't the word, but what are we looking
18 for, Jeffrey? Help me out here.

19 DR. WILLIAMSON: Okay, yes. The --

20 CHAIRMAN CERQUEIRA: John Graham in the
21 making.

22 DR. WILLIAMSON: -- ACMUI desires that
23 Commissioners who have an interest in the regulation of
24 medical use of byproduct materials attend the ACMUI
25 meetings on an informal basis.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Okay. I think we get
2 the sense of it, and we can see. You know, maybe, John,
3 your staff could look at that and what the mechanism
4 would be for us to invite -- I guess we could just invite
5 them. I'm sure that there's some --

6 MR. HICKEY: Yeah, we can respond to that.

7 CHAIRMAN CERQUEIRA: Okay.

8 MR. HICKEY: When we call for agenda items,
9 we can also get suggestions as to whether you want to
10 invite a Commissioner.

11 CHAIRMAN CERQUEIRA: Okay, all right. Any
12 other items in terms of the follow-up from yesterday's
13 meeting?

14 DR. WILLIAMSON: Do we want to hold the item
15 about creating a subcommittee and so forth for the Board
16 certification until we come to that topic with Bob Ayers
17 here or do you want to do that now?

18 CHAIRMAN CERQUEIRA: I propose we do that
19 now, and then when Bob comes we can basically, you know,
20 review that.

21 You know, in thinking about it, you know,
22 clearly it was an oversight on the part of the Committee.
23 In talking to some of the former staff for the Committee,
24 and I have to admit I don't recall the discussion, some
25 of the issues related to this were we had long

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 discussions about trying to make the training and
2 experience requirements specific for the isotope, the
3 technique as much as possible so that we didn't have
4 somebody who had just kind of general training be able to
5 operate on a system with which they had no familiarity.

6 And I guess some of the discussion amongst
7 the staff had been how do we put some teeth into the fact
8 that we needed training on specific equipment, and you
9 know, that still needs to be addressed in terms of, you
10 know, if you've got Boards, the Boards don't specifically
11 require you to have experience with certain isotopes or
12 devices.

13 And so how do we assure that somebody who
14 has a general approval, i.e., Boards, meets some specific
15 training requirements?

16 Richard, and then --

17 DR. VETTER: I don't think the proposed Part
18 35 answers that either because it says you're either
19 Board certified or you have training, and it specifies
20 the type of training, you know, 200 hours, et cetera, et
21 cetera.

22 So I guess without looking at -- having the
23 words in front of us, I think what we need to take a look
24 at is how we can change that regulation so that a person
25 can be Board certified and have that specific experience

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 without having the detailed listing of training and
2 requirements incorporated into the Board.

3 Because, for instance, let's just pick ABMP
4 for one board. For medical health physics, they require
5 a Master's degree in the appropriate area, plus five
6 years of experience, and you have to pass three exams.

7 But they don't say you have to have
8 experience with HDR. So perhaps the direction we need to
9 head and one of the alternatives, the Board certified
10 plus that specific experience or at least some area of
11 experience that covers most of those without prescribing
12 that they have 200 hours in the following subjects
13 because that's telling the Boards what they have to have
14 for content.

15 That's the part that's problematic.

16 CHAIRMAN CERQUEIRA: Okay. Jeffrey.

17 DR. WILLIAMSON: Well, just a suggestion as
18 a philosophical approach, how to address the issue I
19 guess John raised, which is if NRC wants specific
20 training to be addressed, how could that be done.

21 So the approach could be to decouple the
22 concepts of authorized user and authorized medical
23 physicist from the required modality specific training
24 requirements, you know, restore Board certification as
25 the default pathway for AMP, AU, or RSO, and then in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 appropriate subsections of 35, 35.4.600, for example, one
2 could have in there as part of the operating procedures
3 or regulations some kind of a requirement for continuing
4 education in initial modality specific education.

5 MS. McBURNEY: In that modality.

6 CHAIRMAN CERQUEIRA: In that specific.
7 Okay. So modality specific training.

8 DR. WILLIAMSON: So one might say, you know,
9 for example, put in some kind of a regulation that
10 captures the essence of the initial training that a
11 physician who has no experience doing gamma stereotactic
12 would have to undergo.

13 CHAIRMAN CERQUEIRA: I guess just in terms
14 of what's been done to date now, is this something we
15 could deal with in the guidance documents?

16 DR. WILLIAMSON: Potentially we could, but
17 the desire of the staff -- I'm speaking for them now --
18 I think has been to avoid having de facto regulations in
19 guidance space and have them in regulatory space. So
20 rather than have a separate set of de facto regulations
21 in a licensing guide, which is now what we have, we have
22 requirements for authorized user and authorized medical
23 physicist to have some kind of training with HDR and
24 gamma stereotactic, and that's done by license condition
25 today.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And so I think the desire of the staff is to
2 have essential license conditions mentioned in the
3 regulations; is that not correct?

4 MR. HICKEY: That is correct, and I'm not
5 sure, however, that even if we allowed for the guidance
6 to be the determining factor that we could do it in this
7 case because of the way that the rule is worded.

8 DR. WILLIAMSON: I think we're talking in
9 the context of the rulemaking initiative, John.

10 MR. HICKEY: Okay. So you would have a rule
11 change plus guidance?

12 DR. WILLIAMSON: We would have a rule change
13 that would address the training and experience
14 definitions of AMP authorized user and radiation safety
15 officer, plus some supplementary changes in 35.600 that
16 would address the NRC's concern about the AU and AMP not
17 having modality specific specialized training.

18 MR. HICKEY: Right, but then would you need
19 guidance?

20 DR. WILLIAMSON: Well, you always need
21 guidance, don't you?

22 MR. HICKEY: Well, no. But I mean would the
23 substantive issue be dealt with by the rule change or
24 would you need guidance to deal with the substantive
25 issue?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Our intent -- my sense is we at least --
2 maybe we don't even need to talk about it. My sense is
3 we at least need a rule change to deal with the
4 substantive issue the way that the new Part 35 is worded
5 now.

6 DR. WILLIAMSON: My preference would be to
7 have such specifics of training probably in a guidance
8 document rather than making a hard and fast rule so that
9 at least individual institutions could negotiate the
10 specifics of what their training would be.

11 MR. HICKEY: Okay.

12 CHAIRMAN CERQUEIRA: We'll go around, but so
13 we've given up on the idea that there's any way we could
14 do this within the Part 35 revisions. My typo comment
15 yesterday was not --

16 MR. HICKEY: I wouldn't characterize giving
17 up on anything.

18 CHAIRMAN CERQUEIRA: Right. Well, but it's
19 important because we could certainly expedite it if we
20 could do it within guidance documents at this point, and
21 who would know that, John? Would that be counsel? Would
22 that be the staff?

23 MR. HICKEY: Well, I think I know, and I
24 think some of the committee members know that the way the
25 rule is worded, I don't think guidance can fix the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 problem.

2 CHAIRMAN CERQUEIRA: So we're saying we need
3 a new rulemaking.

4 DR. WILLIAMSON: I think so, and we don't
5 have to propose wording for the rule.

6 CHAIRMAN CERQUEIRA: Sure.

7 DR. WILLIAMSON: I think we should make a
8 motion to the effect that NRC as soon as possible
9 initiate rulemaking to restore Board certification for
10 authorized user, radiation safety officer and authorized
11 medical physicist as the default pathway.

12 CHAIRMAN CERQUEIRA: Well, just
13 procedurally, you know, we're going to form a
14 subcommittee, and it's going to work with the staff, and
15 so maybe that will be the first step, but let's get some
16 more discussion, and then we'll try to-- yes?

17 DR. NAG: I think the other thing, if we are
18 going back to a rulemaking, it would be very important to
19 -- the requirement for Board certification and the
20 requirement for using in NRC. The reason is for the
21 Board exam you need a certain body of knowledge, which is
22 what the Board certification requires.

23 For example, you don't need gamma knife
24 training to be Board certified, but the way we are making
25 the Board certification, we are trying to push them to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 recruit all of these with training to become Board
2 certificate. Rather than doing that, if we decouple
3 (phonetic) them, a Board certification, the essential
4 minimum required, and then if we are going to handle
5 gamma knife or you're going to handle some of these
6 specific things, you show your additional training that
7 you had, which can be a very -- you know, the
8 manufacturer's training or whatever. You supplement the
9 Board requirement.

10 So if we are going to start from de novo, I
11 think we should not be trying to push the Board to show
12 you have training in all of these things. Otherwise we
13 wouldn't allow Board certification to meet the de facto
14 standard.

15 CHAIRMAN CERQUEIRA: Now all of the
16 discussion has really dealt with therapeutic radiation.
17 I mean, do we feel that as written, the diagnostic
18 requirements are okay?

19 MR. HICKEY: Mr. Chairman, I think there is
20 an issue with the statement about a preceptor. I'm not
21 sure that all of the certification Boards understand that
22 the rule requires the preceptor statement be part of the
23 Board certification process.

24 So as far as what training and experience
25 the people have, I think the rule is okay, but I think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 there still is an issue with the requirement for a
2 preceptor statement.

3 CHAIRMAN CERQUEIRA: I thought the preceptor
4 statement was pretty clear. It had to be, you know, an
5 authorized user who basically signed off on having been
6 exposed, and in addition, being competent.

7 We spent quite a bit of time discussing
8 that. We're trying to put more teeth or more liability
9 upon the preceptor's statement, and let them, you know,
10 assume some responsibility for the people that they're
11 signing letters for.

12 MR. HICKEY: Yes, that's correct, and there
13 are already requirements in the old Part 35 for preceptor
14 statements. I'm just not sure whether the Board that
15 certifies the person requires the preceptor statement as
16 part of the certification process or whether they view
17 that as another step.

18 CHAIRMAN CERQUEIRA: Well, I think when I
19 guess Bob is going to be presenting things this afternoon
20 -- so we can get back to it.

21 Richard.

22 DR. VETTER: Just to confirm what John just
23 said, at least in the physics area, radiation safety
24 officer area, the Boards feel that is a separate process,
25 the preceptor statement. They do not require a preceptor

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 statement for the Boards.

2 MS. MCBURNEY: Right.

3 MR. HICKEY: Yeah, that was clear for the
4 American Board of Health Physics. I'm just not sure
5 whether the Medical Boards have that understanding.

6 CHAIRMAN CERQUEIRA: Jeffrey?

7 DR. WILLIAMSON: For American Board f
8 Radiology and American Board of Medical Physics, and I
9 think this covers radiation oncology, as well as physics,
10 there is a requirement. It's part of the application
11 process that letters from diplomates of the Boards
12 attesting to the competence in character of the applicant
13 be made.

14 But I do think there is a legal problem here
15 because it really doesn't say that these individuals have
16 to be authorized users or authorized medical physicists
17 on an agreement state or NRC license.

18 So I believe John may be right that even
19 though there is sort of a preceptor requirement
20 associated with many of these Boards, I'm not sure it
21 complies with the letter of the law.

22 DR. NAG: One other problem with that is
23 there is the preceptor statement, but that's done by the
24 director of the training program. It does not make
25 separately in all of the areas. You know, I will certify

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that I have trained him in radiation oncology, but not a
2 separate statement that can handle unsealed isotope; he
3 can handle, you know, each of those things separately.

4 CHAIRMAN CERQUEIRA: All right. Who are the
5 stakeholders in this now? We've talked about authorized
6 medical physicists. We've talked about radiation safety
7 officers.

8 DR. NAG: Authorized users also.

9 CHAIRMAN CERQUEIRA: Okay.

10 DR. NAG: It depends on which, definitely of
11 authorized users.

12 CHAIRMAN CERQUEIRA: For diagnostic or
13 therapeutic?

14 DR. NAG: Therapeutic.

15 CHAIRMAN CERQUEIRA: Okay.

16 MR. HICKEY: I think that all of the Boards
17 have a potential stake. They're on the record as of
18 today as saying that there's not a problem with the rule,
19 but in looking at the preceptor issue, I think on second
20 review there may also be a concern. They're not on the
21 substance of the training but on the requirement for a
22 preceptor statement.

23 CHAIRMAN CERQUEIRA: Rather than -- you
24 know, because we have Bob Ayers here, who's kind of part
25 of the NRC staff that's looking at this, maybe we can

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 conclude this discussion and bring it up with Bob. But
2 I think there was a motion to form a subcommittee that's
3 going to look at the issue of training and experience.

4 Initially we were talking about the
5 authorized medical physicist, the radiation safety
6 officer, and the authorized medical user with
7 therapeutic. So I think forming a subcommittee that
8 would have, you know, members from those various groups,
9 plus maybe one or two other people, would be important.

10 Ruth?

11 MS. McBURNEY: Richard or Ralph, correct me
12 if I'm wrong, but I think there is a model for the rule
13 of decoupling the Board certification from additional
14 training required for the different modalities under
15 MQSA. Isn't that right that they accept Board
16 certification as the training for the medical physicist,
17 but then if you're going to be doing a different
18 modality, you need additional continuing ed. for that?

19 DR. VETTER: I think that's correct.

20 MR. HICKEY: Could you identify that
21 organization for the record, please?

22 MS. McBURNEY: The Mammography Quality
23 Standards Act under the Food and Drug Administration.

24 CHAIRMAN CERQUEIRA: All right. Well, so I
25 propose that maybe we have Jeffrey, Dick, you know, be on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 this committee, and since Dick has more gray hair that
2 Jeffrey, maybe we could let him be the chair of this
3 committee.

4 And I think we should get a radiation
5 oncologist. David, is that something --

6 DR. DIAMOND: I'd be happy to do it, sure.

7 CHAIRMAN CERQUEIRA: So maybe David could be
8 on that committee, and I guess maybe we're going to add
9 two new members to the committee. I guess we have to
10 vote on them at this meeting.

11 MR. HICKEY: No.

12 CHAIRMAN CERQUEIRA: What's the time line?
13 We've gotten approval.

14 MR. HICKEY: No. The selection for the two
15 vacancies is still in process, and as Commissioner
16 McGaffigan mentioned yesterday, well, we have to appoint
17 a nuclear medicine physician to fill a vacancy, and then
18 as Commissioner McGaffigan mentioned yesterday, we're
19 going to add an interventional cardiologist at the
20 direction of the Commission, and those are in process.

21 So we think prior to the next meeting you'll
22 have those appointees.

23 CHAIRMAN CERQUEIRA: Right, but I was sent
24 a list of people who had been nominated, and they were --
25 you know, by professional medical societies, and the NRC

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 staff had sort of sent me the names of two individuals
2 for those positions, and I basically concurred that I
3 thought --

4 MR. HICKEY: Well, that's still in process.
5 We can't have anymore specific public discussion while
6 that's still in process, but the process has not yet been
7 completed.

8 CHAIRMAN CERQUEIRA: But why is it taking so
9 long?

10 I think one of the things we had discussed
11 was basically trying to facilitate, and Angela certainly
12 made a --

13 MR. HICKEY: Yes. The reason that the
14 interventional cardiologist is not complete is because
15 that's fairly recent. The nomination period, I believe,
16 did not close until January for that one, and the other
17 one has been delayed by the other things that the
18 Commission has been dealing with following 9/11 or it
19 would have been resolved.

20 CHAIRMAN CERQUEIRA: Is there any way we
21 could fast track it, John? I mean, in a sense, you know,
22 the professional societies have made nominations.
23 They've been reviewed by the NRC staff. They've been
24 sent to the committee chair who basically agreed with the
25 staff on these people.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. HICKEY: Yes. We're doing every -- I
2 mean, you can form an action item or resolution, but
3 we're doing everything we can to complete that process.

4 CHAIRMAN CERQUEIRA: Well, I guess I don't
5 fully understand why it's taking so long. I mean, we had
6 discussions to try to minimize the lag time between a
7 vacancy and filling it.

8 MR. HICKEY: Well, as I said, the
9 interventional cardiologist one should be completed
10 within 60 days of the nomination period closing, which I
11 think is reasonable, but the other one has not been
12 timely. I agree.

13 CHAIRMAN CERQUEIRA: Okay. So give me a
14 time line then. Where do we stand?

15 MR. HICKEY: I would say within 60 days
16 we'll have an announcement on both, but again, the
17 Commission has to review these. So that's assuming the
18 Commission responds promptly, which they have done in the
19 past on these.

20 CHAIRMAN CERQUEIRA: And I guess, you know,
21 all of these things like security checks and everything
22 will be all --

23 MR. HICKEY: That can be done afterwards.

24 CHAIRMAN CERQUEIRA: Okay. You know, it's
25 a little disturbing because we really had emphasized at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the previous meetings of trying to minimize the time
2 between people going off and new people, and I had every
3 expectation based on the material that I had been sent
4 that we would have people in these positions, you know,
5 at the end of this meeting.

6 So Dr. Nag?

7 DR. NAG: At the same line, anyone who will
8 be moving off about a year from now, we should be
9 starting the process from now. So anyone from this
10 committee who is supposed to be going off about a year
11 from now? Do we have anyone?

12 DR. DIAMOND: Jeff, how much longer? ARE
13 you in your second term? Is that right?

14 DR. WILLIAMSON: I think so.

15 DR. DIAMOND: You're in your second term.

16 MR. HICKEY: I think everybody is going at
17 least until 2003, but we agree that we need --

18 DR. NAG: One year.

19 MR. HICKEY: -- to plan better on these.

20 CHAIRMAN CERQUEIRA: Well, what I would like
21 to do is at least get a list of just Committee members,
22 when they came on, whether it's first term, second term,
23 and when their term expires, and distribute that to the
24 Committee.

25 MR. HICKEY: Yes, we have that. That's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 already made. We can copy it and give it to you.

2 CHAIRMAN CERQUEIRA: Well, if somebody could

3 --

4 MR. HICKEY: We can give that to you today.

5 CHAIRMAN CERQUEIRA: -- just give it to us
6 today.

7 MR. HICKEY: yes.

8 CHAIRMAN CERQUEIRA: That would be useful.

9 DR. WILLIAMSON: We can make plans.

10 CHAIRMAN CERQUEIRA: But again, I'd really
11 like to, you know, identify the fact that the Committee
12 has been moving forward. I certainly have dealt with
13 some materials sent to me, and I think in order for the
14 Committee's work to be done, we certainly need a nuclear
15 medicine representative, and I think we've agreed that an
16 interventional cardiologist is an important, you know,
17 member of the Committee, given some of the things that
18 are going to be coming up.

19 And so I think we need to move forward as
20 quickly as possible to get these people appointed.

21 Jeffrey.

22 DR. WILLIAMSON: So with regard to the
23 subcommittee, the charge is to --

24 CHAIRMAN CERQUEIRA: Okay. Well, again, I
25 got sidetracked there. So --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. HICKEY: Well, let me just interject
2 that some of these items have been useful because we
3 intended to take them up later in the day, and we'll save
4 time later on having discussed them now.

5 CHAIRMAN CERQUEIRA: Okay. That's true, but
6 still I think, you know, we've identified three people.
7 I think it would be important if we're going to deal with
8 the whole issue of intravascular brachytherapy if we
9 could have the interventional cardiologist be part of
10 that committee. That would be useful.

11 That would bring us up to four people, and
12 it's always good to have somebody who's not necessarily
13 a stakeholder on the subcommittee, i.e., Ruth or Niki.
14 Niki is pointing, but, Ruth, would you be willing to?

15 MS. MCBURNEY: I certainly would.

16 CHAIRMAN CERQUEIRA: Okay. So I think the
17 committee would then consist of Jeffrey, Ruth, Richard,
18 and David Diamond with Richard acting as the subcommittee
19 chair.

20 And the charge of the committee -- and I
21 think we could have a little bit of discussion on this --
22 but basically, you know, would address the issue of
23 training and experience for authorized medical
24 physicists, authorized physician users, and radiation
25 safety officers, and you know, really look at the whole

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 issue of the Boards and the training and experience,
2 trying to deal with both, you know, kind of general, as
3 well as specific training.

4 And maybe we could spend a few minutes
5 trying to fine tune the charge to the committee.

6 Jeff and then David.

7 DR. WILLIAMSON: Well, I'm wondering if it
8 would be useful to have some staff members also be on
9 this subcommittee. I think this is so highly juridical
10 that I wonder if the attorney from NRC shouldn't join us
11 and one of the staff members who's conversant with these
12 issues.

13 MR. HICKEY: As a procedural matter I don't
14 think that's a good idea. I think the subcommittee needs
15 to speak for the ACMUI, but we will designate contacts,
16 both technical and legal contacts, for the subcommittee
17 to work with on a day-to-day basis.

18 DR. WILLIAMSON: Good.

19 CHAIRMAN CERQUEIRA: So I think it would be
20 good within two weeks to have those people identified so
21 that Richard could make contact with the people and, you
22 know, to try to get some useful information to at least
23 define what the requirements for sort of new rulemaking,
24 to explore the possibility can any of this still be done
25 under the revised Part 35, which we're all working on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 under the assumption that it's going to be implemented in
2 six months, or do we need to go to new rulemaking, which
3 it's Jeffrey's feeling, and I concur with him, it
4 probably will be required.

5 David.

6 DR. DIAMOND: My sense is just as I'm
7 thinking about this is that this subcommittee is really
8 going to be looking at a new rulemaking initiative in
9 which there's going to be a sense that we restore Board
10 certification in a parallel structure as the default
11 pathway for the AMPs, the RSOs, and in this process
12 attempt to decouple general from overly prescriptive site
13 specific or modality specific training, which will give
14 us the flexibility that we need to address new
15 technologies, which will be parallel amongst these
16 different fields, and which will go and maintain the
17 status of the Boards as the premier methodology for
18 expressing to the public an individual's competency and
19 safety in performing the task.

20 I would also like to point out as an aside
21 it's very important that the staff understand that any
22 time -- and I'm only speaking for physicians now because
23 that's my area of expertise -- any time a physician is
24 desirous to obtain a hospital privilege to perform a
25 specific modality, regardless of the Board certification,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they need to prove to the hospital that they do have a
2 certain experience in that particular field.

3 So, for example, if one wanted to do
4 stereotactic radiosurgery as a physician, before a
5 hospital would grant a privilege to do that, there is
6 always a final safeguard in effect that you must prove to
7 the bylaw committee or the credentialing committee that
8 you have that, and that goes on for many, many different
9 areas.

10 So just since you may not deal with this in
11 your particular role or practice, it is important for you
12 to know that there is another set of safeguards in effect
13 to protect the public in these very specific modalities
14 when it comes to the public.

15 DR. WILLIAMSON: For example, at Washington
16 University, the radiation safety committee also serves as
17 an independent safeguard in this respect because our
18 license mandates certain annual training be given to
19 authorized users and AMPs for gamma stereotactic and for
20 HDR as a condition of our license.

21 And so they monitor that, and there are
22 separate lists of authorized users and AMPs for these
23 different modalities.

24 DR. DIAMOND: Jeff, would you concur with my
25 general sense that I was trying to convey? Was I on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 track basically with the parallel structure trying to
2 keep the Board as the premier pathway and so forth?

3 DR. WILLIAMSON: Yeah, absolutely.

4 CHAIRMAN CERQUEIRA: I think we're starting
5 to get into the specifics, and I think sort of the
6 discussion is to form the committee, and we've agreed
7 that the subcommittee consisting of Dr. Williamson,
8 Vetter, Diamond, the interventional cardiologist who will
9 come on the Committee, and Ruth McBurney, and I kind of
10 hate -- you know, you kind of want to give a charge to
11 the committee rather than having the committee come back,
12 you know, with what they're going to do.

13 But the basic charge is to develop --

14 DR. WILLIAMSON: A draft rule.

15 CHAIRMAN CERQUEIRA: We need John.

16 -- draft rule for what? For?

17 DR. WILLIAMSON: Yeah, so to develop, you
18 know -- a subcommittee would be charged with developing
19 the outline of a draft rule to restore --

20 CHAIRMAN CERQUEIRA: Just something general.

21 A draft rule --

22 DR. VETTER: I think that captures it. A
23 draft rule to capture what Dr. Diamond had said.

24 CHAIRMAN CERQUEIRA: But that was too much.

25 Who can remember that?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: We can do it in one sentence.

2 DR. WILLIAMSON: The subcommittee's charge
3 is to develop the concept of a draft rule that restores
4 Board certification as the primary pathway for becoming
5 authorized user, authorized medical physicist and
6 radiation safety officer.

7 CHAIRMAN CERQUEIRA: All right. Does that
8 sound like a motion?

9 PARTICIPANTS: Yes.

10 CHAIRMAN CERQUEIRA: Second?

11 MS. WAGNER SCHWARZ: Second.

12 CHAIRMAN CERQUEIRA: And any further
13 discussion?

14 MR. HICKEY: I have a comment and a
15 question, Mr. Chairman. The committee is time is of the
16 essence, and this has high visibility with the Commission
17 now. So I will tell Dr. Vetter right now I will be the
18 contact. I will let you know who other contacts are, but
19 two weeks is not going to go -- this isn't going to sit
20 for two weeks.

21 We're going to be continuously working on
22 this between now and the time the rule is published.

23 CHAIRMAN CERQUEIRA: All right, but we don't
24 anticipate that we're going to be able to get this
25 resolved and certainly with the rulemaking, but I think,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 you know, basically we've formed a committee, and we
2 should have them come back to us at the next meeting.

3 So a motion has been made. We've had a
4 second. Any more discussion?

5 (No response.)

6 CHAIRMAN CERQUEIRA: Okay. I call for a
7 vote. All in favor?

8 (Chorus of ayes.)

9 CHAIRMAN CERQUEIRA: Opposed?

10 (No response.)

11 CHAIRMAN CERQUEIRA: No one is abstaining.
12 So all right.

13 DR. DIAMOND: That was **Action Item No.**
14 **4**, then.

15 CHAIRMAN CERQUEIRA: Right.

16 MS. HOBSON: Did you mean like our next
17 ACMUI meeting?

18 CHAIRMAN CERQUEIRA: To come back and give
19 us at least a progress report on, you know, some of the
20 issues and sort of a game plan.

21 MS. HOBSON: Well, I felt a sense of urgency
22 that we need to move faster than that if possible, you
23 know. Was I reading it wrong?

24 CHAIRMAN CERQUEIRA: No. I guess part of
25 the question is I don't know, you know, what's involved

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 in the rulemaking process. I mean, having been involved
2 in Part 35, which is, in a sense, you know, NUREGs --

3 DR. WILLIAMSON: I think our charge is
4 sufficiently open ended that, you know, we're not locked
5 into any specific time frame. So I think this is just
6 great. If the staff is geared up to move fast on this,
7 we're going to support and help them.

8 CHAIRMAN CERQUEIRA: One last comment from
9 Ralph, and then we have to move on.

10 MR. LIETO: I have a question for John since
11 this is a subcommittee of the Advisory Committee that's
12 working on this. Is it acceptable that if they come back
13 -- say they have something to present within the month.
14 Does the full Committee have to vote on that? And if so,
15 can it be done by electronically via E-mail?

16 MR. HICKEY: Yes. The actions can be done
17 by E-mail or by telecon. and, in fact, I think we're
18 going to have to plan on doing a lot of that.

19 CHAIRMAN CERQUEIRA: Yeah, I would recommend
20 that we don't necessarily need to have face-to-face
21 meetings.

22 Okay. All right. So I think we've dealt
23 with most of the procedural ways we would like the
24 Committee to proceed in the future. We've discussed the
25 Commission briefing, and maybe we can go on to the NUREG

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 1556, Volume 9.

2 MR. HICKEY: Mr. Chairman, Dr. Susan Frant
3 is here. She's the Deputy Director of Industrial,
4 Medical, and Nuclear Safety.

5 DR. FRANT: Hi. They even got a name tag so
6 that in case you forgot me.

7 (Laughter.)

8 DR. FRANT: And I have one for me so that in
9 case I forget.

10 Good morning. I've met some of you
11 individually, but not all of you as a group. So I'm
12 happy to be here this morning.

13 I've been with the Industrial Nuclear
14 Medicine Safety -- I think those are all of the words for
15 the division -- since April. Before that I worked as a
16 deputy for another division in NMSS, and before that, I
17 was in Region I, which is the northeast, as the deputy
18 that had licensing of medical licenses.

19 So I have a little familiarity, but not a
20 lot, and I come to this area with maybe a different
21 perspective than some of the folks who have been working
22 in it.

23 Part 35. We've been working on how we're
24 going to implement it, and we've been standing at the
25 starting gate for a long time waiting to kind of okay,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 okay. As you know better than I, that has been a
2 torturous time to get it into a position where it's going
3 to be published and going to be final.

4 And I gathered from the meeting you had with
5 the Commission yesterday that there are still some issues
6 that are significant that are not settled by the current
7 final rule as it will be published. And the Commission
8 certainly pledged that we will work through those issues
9 in a timely way.

10 And the discussion I heard when I came in
11 was one of the mechanisms to do that, and I'm glad that
12 you'll have a subcommittee, and if you draft language, it
13 doesn't have to be exactly rulemaking language, but if
14 the language is what will work to have qualified people
15 who can protect the public in terms of radiation safety
16 doing the procedures, regardless of whether we know what
17 they are today or they come on the horizon, that will be,
18 I think, a significant move forward for Part 35 as it
19 stands.

20 In terms of what we're doing now to move
21 forward in implementing Part 35, I can tell you what
22 we're doing and take hopefully some suggestions from you
23 on how ACMUI can be most involved effectively for us and
24 for you and efficiently for us, hopefully efficiently for
25 you, too.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Susan.

2 DR. FRANT: Yeah.

3 CHAIRMAN CERQUEIRA: If I could just
4 interrupt for a minute now, so we're talking about the
5 guidance documents in part.

6 DR. FRANT: We're talking about implementing
7 Part 35 so that we --

8 CHAIRMAN CERQUEIRA: Right, which includes
9 guidance documents?

10 DR. FRANT: It includes guidance. It
11 includes inspection, and let must briefly go through --

12 CHAIRMAN CERQUEIRA: Sure. Go through.

13 DR. FRANT: -- and then after I run through
14 this, then you can ask me questions, and we can talk
15 about --

16 CHAIRMAN CERQUEIRA: Is there a handout or
17 slides on this?

18 DR. FRANT: No.

19 CHAIRMAN CERQUEIRA: No?

20 DR. FRANT: No.

21 CHAIRMAN CERQUEIRA: Okay.

22 DR. FRANT: As you know, we have Volume 9 of
23 the consolidated guidance, the 20 volume set that we've
24 pulled together over the last -- I don't know -- several
25 years, and Volume 9 identifies those aspects that would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 be necessary to be licensed under Part 35.

2 And the current draft Volume 9 responds to
3 all of the comments that were made on a draft that went
4 out with the proposed rule and reflects the changes made
5 to Part 35 from the proposed rule to the final rule.

6 And I think you've seen that, have you not?

7 MS. WAGNER SCHWARZ: Yes.

8 DR. FRANT: Yes. Okay. It still has many
9 things in that I would say are highly prescriptive. The
10 phrase that some people have used is that there's a group
11 of practitioners who might need "Part 35 for Dummies,"
12 that is, a very detailed, pick your hand up, move it
13 here, do this.

14 I think that that is very different from
15 other aspects of NRC that I've been involved in. In the
16 reactor world that I was in for 20 years, we never put
17 out procedures. We always left it to licensees to
18 develop procedures to implement the regulations.

19 And I have to tell you that it was kind of
20 strange for me to see these model procedures. At the
21 same time, the staff who have been working with this, I
22 think, believe that there was a very strong need for this
23 by some practitioners.

24 So you have a tension between providing
25 detailed guidance and allowing mature professionals to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 choose the way in which they're going to implement
2 regulations.

3 I think we're trying to strike that balance,
4 and to do that, we're going through Volume 9 now with an
5 eye towards making it a basic document and taking these
6 model procedures and perhaps putting them in some other
7 form.

8 It would be good, I think, if the societies
9 in the community would help us do that, and maybe it
10 would have been better to have joint documents, which
11 we've done in other -- I worked with NEI and I've worked
12 with other groups where we've put out joint documents.

13 For a long time I was responsible for
14 training and procedures in the reactor world, and the
15 Institute of Nuclear Power Operations developed the
16 guidelines for training programs, and we endorsed them.
17 So we had a joint document that was basically developed
18 by the industry and then reviewed and accepted as an
19 acceptable way to implement the regulations.

20 There's no reason why we couldn't do that
21 here, too, but it requires a commitment on the part of
22 the community to do some of the work. And I'm not sure.
23 I don't know where we are with that.

24 To that end --

25 CHAIRMAN CERQUEIRA: Well, if I could --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. FRANT: Yeah.

2 CHAIRMAN CERQUEIRA: -- I think the
3 community is willing to work, but there's a time frame
4 that's involved, and if we haven't initiated the process,
5 I don't know realistically --

6 DR. FRANT: Well, let me tell you what.

7 CHAIRMAN CERQUEIRA: Sure.

8 DR. FRANT: I don't know how many of you
9 know Chip Cameron, but I know he's worked with Part 35.
10 So Chip and I have worked together on many things over
11 the years, and what we discussed was taking the current
12 Volume 9, making some modifications -- and Roger Brotus
13 who's sitting in the back is taking a few minutes out of
14 his schedule where he's totally immersed in Volume 9,
15 with a small cadre of folks -- to make some
16 modifications, but to get it out by March 15th as a
17 document for comment.

18 At the same time, Chip and I will be having
19 a planning meeting on March 14th to plan for two public
20 meetings, actually three, I think. One meeting would be
21 some kind of a workshop on Volume 9, the totality of it.

22 A second -- probably these are both at the
23 end of April. One is planned for April 23rd, and the
24 other is planned for April 30th. The second meeting
25 would be on guidance, some kind of diagnostic only

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 guidance that would be just a few pages that would focus
2 on what the diagnostic practitioner would need to know
3 and would not have all the volumes of material that deal
4 with all the variations within the therapeutic community.

5 That guidance, I think, to the extent that
6 we can get help and maybe produce a joint document, that
7 would be excellent. If we can't, maybe we'll take a
8 crack at it and have it reviewed, the point being that
9 there would be two documents. There would be Volume 9,
10 which would cover everything to implement Part 35, and
11 that's necessary and we have to have something like that.

12 But then there would be this subset, and it
13 may be that the therapeutic community or parts of it feel
14 that there should be some stand alone documents for other
15 than diagnostic, and we can work those out in the future.

16 I'm not precluding them. It's just in terms
17 of time, they seem to be the things that are most needed
18 now.

19 We also plan to develop inspection
20 procedures, and I think from the discussions yesterday
21 and what I know about the way NRC does business, this
22 will be clear to having a clear message of how Part 35
23 represents some kind of paradigm shift.

24 We also plan on conducting training for both
25 our license reviewers and our inspectors, and we'll be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 doing that in late May based on the guidance documents
2 and the public meetings. And I already have that set up
3 with a woman named Bev Silverberg.

4 Do any of you live in Washington? Oh, no.
5 Okay. Well, Bev was the voice of Metro. She used to be
6 the one that would come say, "The trains are running, and
7 it's okay." But anyway, only in snow storms mostly.

8 Anyway, Bev has been working with NRC for a
9 long time, and she does a really good job in terms of
10 helping people get the message across. So we are going
11 to take people, and we have a Part 35 team that we've
12 developed, people who will become the trainers.

13 MS. McBURNEY: A question. Will this
14 training also be available to agreement state personnel?

15 DR. FRANT: Sure, sure. And we'll probably
16 set it up in the four regions and invite appropriate
17 agreement states at the same time. I don't know why we
18 can't do it concurrently. Sure.

19 So that's our plan, is to train the trainers
20 some time in late May, and then hold a workshop on
21 inspection guidance; finalize the inspection and
22 licensing guidance, and of course, that will include
23 ACMUI participation, and we can talk about at what key
24 points and at what point you want to be in a review mode,
25 at what point you want to be in a comment.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 You know, I think there are lots of roles to
2 be played, and then we'll do our regional training in
3 June through August, depending on when -- hopefully that
4 will be on finalized guidance, but certainly guidance
5 that's close to final.

6 So that what we're working towards is an
7 October implementation date in which we will have final
8 licensing guidance by the end of spring; final inspection
9 guidance also by the -- this is the government. So if I
10 say late spring that could be July, you know -- but we'd
11 be working -- you know how you write "late spring"?
12 Okay.

13 But the goal is to have the training over
14 the summer based on the finalized guidance and inspection
15 procedures, and what I heard yesterday in the discussion
16 with the Commission is it may be that we have to have a
17 transition period, and when they're enforcement
18 discretion, and we work our way through that guidance and
19 some of the issues that may come up as we look at the
20 rule when it's real, so to speak, you know.

21 And I don't understand. I hope to learn
22 more about how the training and education issues are
23 evolved, but there they are, and so we have to fix them.
24 There may be others that we find that we have to fix.

25 So that's our plan. It's looking towards an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 October implementation effective date, but some questions
2 have come up, and we're working through them now. Some
3 applicants for renewal have already said, "Can I be
4 renewed against the new Part 35?"

5 Well, no, you can't be renewed against
6 something that doesn't exist. It's not published. On
7 the other hand, you can be in timely renewal, and we can
8 look at what it would look like once it's published, but
9 it can't be effective until it's effective.

10 So that's a simple answer, you know. It can
11 only be soup when it's soup, but on the other hand, you
12 can't deny the fact that you can see what's coming on the
13 horizon. So you try to work that, and we'll work that
14 through.

15 We have a counterpart meeting tomorrow with
16 the Regional Division Directors, and these are some of
17 the issues I've got to talk through this schedule with
18 them, get their comments, and the reason there's no
19 handout, Dr. Cerqueira, is because I wanted to keep it
20 fluid enough to get comments from you all, comments from
21 the Regional Directors, and have a schedule that
22 everybody can work with and live with, and get to the
23 implementation date with guidance that's workable in
24 hand, inspection procedures, license reviewers, and
25 inspectors trained and thinking new Part 35 with the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 performance based, risk informed mindset.

2 CHAIRMAN CERQUEIRA: Susan, that's --

3 DR. FRANT: I was glad the Commissioners
4 were so confident we could do it.

5 CHAIRMAN CERQUEIRA: Well, this has been an
6 excellent presentation in the sense that you've given us
7 details. You've given us dates, and I think this is
8 tremendous.

9 I think it would be helpful if perhaps, you
10 know, when you've had a chance to sort of -- certainly
11 some of these dates we've been writing down, but if we
12 could get an E-mail or a copy of these out to the
13 Committee --

14 DR. FRANT: Of course.

15 CHAIRMAN CERQUEIRA: -- that would be very
16 useful.

17 I'd also like to --

18 DR. FRANT: I'll get it to Angela, who will
19 get it to you al.

20 CHAIRMAN CERQUEIRA: Yeah, that would be
21 useful.

22 I'd also like to say that, you know, we had
23 these writing pads yesterday, and they've gone for some
24 reason. All I've looked around and everybody is trying
25 to write notes on these yellow pads.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So, Angela, what happened to the white --
2 they were here yesterday.

3 MS. WILLIAMSON: Oh, it was the
4 Commissioners.

5 DR. NAG: In the Commissioner meeting.

6 CHAIRMAN CERQUEIRA: Well, it would be nice,
7 especially since if we don't have notes --

8 DR. FRANT: Well, Angela is off. We have a
9 supply room and --

10 CHAIRMAN CERQUEIRA: Good. Okay.

11 DR. FRANT: You know, we've been on a tight
12 budget, but I think we --

13 (Laughter.)

14 CHAIRMAN CERQUEIRA: No, I think that would
15 be helpful.

16 But, again, you've done a great
17 presentation, and if we can live up to those time lines,
18 that would be ideal. And I think you're bringing in an
19 approach certainly from the reactor area which I think
20 would work well within medical. And I think if we could
21 implement that, that would be great.

22 DR. FRANT: Let me ask you. The planning
23 meeting on March 14th, I would like someone from ACMUI,
24 if it's possible, to be part of that planning meeting
25 with Chip and with myself so that we could have your

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 insights on who should be included in these meetings.

2 You know, Chip has a way of running the
3 meetings, and he's very inclusive, and he's already made
4 some phone calls. I don't know if he's talked to any of
5 you, but --

6 CHAIRMAN CERQUEIRA: I don't think any of us
7 have been contacted about the meeting. I mean, March
8 14th is fairly close, but we certainly would, you know,
9 try to get a representative there. Since I'm only a bus
10 ride away, I could almost do it.

11 But I think it would be important, again, if
12 -- the Committee wants to be involved in these kind of
13 things, and the more notice we have, the better.

14 Now, do we have questions? Jeffrey has been
15 --

16 DR. FRANT: I'm sorry.

17 CHAIRMAN CERQUEIRA: -- chafing at the bit
18 here.

19 DR. WILLIAMSON: No, that's okay. Well, I
20 think that, as you know, the issue of training experience
21 and Board certification is sort of a mess, and I guess
22 you will be responsible for drafting the guidance that
23 the regions will be using to determine under the existing
24 rule as written --

25 DR. FRANT: Right.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. WILLIAMSON: -- how to basically work
2 through all of these problems of deciding how a Board
3 certified physicist or physician needs to qualify for the
4 different modalities.

5 So I think there's an opportunity to
6 ameliorate this circumstance by trying to write
7 reasonable guidance which would take into account
8 existing Board certification, satisfying many of the
9 requirements and having a realistic requirement for
10 supplementary training beyond Board certification.

11 DR. FRANT: Right.

12 DR. WILLIAMSON: Which comes close to what
13 we do in the field.

14 DR. FRANT: I guess you all know Bob Ayers,
15 and he'll be talking to this. When, Bob?

16 DR. AYERS: One o'clock.

17 DR. FRANT: Okay. One o'clock, and he and
18 I have been talking about what kind of mechanism we could
19 develop that would allow for some relief while there's a
20 rulemaking in progress, and that that needs our Office of
21 General Counsel to sort of help us understand what
22 options are available that are all within, you know --
23 I could speculate. I mean, there are several of them,
24 and this isn't the first time that there has been a need
25 for some kind of relief related to a regulation.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So that we have some mechanisms and will
2 have to come up with one and maybe, Dr. Williamson, you
3 can help us. If you're working on draft language, then
4 we can also talk about how that would -- what we would do
5 in the interim to --

6 CHAIRMAN CERQUEIRA: I don't know if you
7 captured the discussion that we had before you came on,
8 but we are sort of forming a subcommittee.

9 DR. FRANT: Right.

10 CHAIRMAN CERQUEIRA: And then looking at the
11 ways to address the issue.

12 DR. FRANT: But the permanent solution is
13 rulemaking to amend the current -- no, rulemaking to
14 amend the not current, but soon to be Part 35. Okay.

15 CHAIRMAN CERQUEIRA: Other questions for
16 Susan? Niki.

17 MS. HOBSON: Well, you probably told us and
18 I just missed it. You're going to have the revised
19 document out for comment by about the middle of March?

20 DR. FRANT: Roger? Yes.

21 MS. HOBSON: And then when do you expect to
22 have the final document ready for publication or whatever
23 you do with it so that the users --

24 DR. FRANT: Right.

25 MS. HOBSON: -- out there will know what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they're up against?

2 DR. FRANT: Exactly. I think though, just
3 to be clear, the rule will be published at the end of
4 March, and it's the rule that you have to comply with.

5 So one of the things that we're going to
6 have to say in the guidance is that it's guidance on one
7 way to comply with the rule, and that what a licensed
8 reviewer has to make sure that you're doing is complying
9 with the rule, not the guidance.

10 That's an important part of the way we
11 implement our rules.

12 Marjorie, did you?

13 MS. ROTHSCHILD: Marjorie Rothschild from
14 the Office of General Counsel.

15 Just a couple of things. First of all, I
16 think the Commission's intent is to publish the rule in
17 mid-March 30 days from the submission of its report to
18 Congress, but you know, that's not a certain date because
19 it's possible that, you know, we could hear otherwise
20 from Congress.

21 So I just wanted to make sure. That, I
22 think, is the Commission's intent, but it's not entirely
23 certain or up to the Commission.

24 And one other comment I just wanted to make.
25 In terms of meeting with a Commissioner, I think some

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 lines may have been blurred in terms of if committees are
2 just talking about inviting Commissioners to their formal
3 meetings. That's one thing, but I think it's another
4 issue if you're talking about the Committee in whole
5 meeting, you know, privately with a Commissioner.

6 So I just want to -- I think --

7 CHAIRMAN CERQUEIRA: Yeah, I don't think
8 that was our intent to have private meetings.

9 MS. ROTHSCHILD: Yes.

10 CHAIRMAN CERQUEIRA: It was basically to
11 have them show up at a session like this to get their
12 specific input or to, you know, address issues that are
13 of concern to the Committee directly.

14 MS. ROTHSCHILD: Right. Well, that's what
15 I assumed, but I just thought it maybe needed to be said
16 just once again.

17 And then as far as any future rulemaking,
18 there are different means for initiating rulemaking, but
19 we just have to be aware that there are certain
20 procedures and limitations actually as far as staff
21 contact if you were talking about a, you know, petition
22 for rulemaking from outside parties.

23 So I just wanted to emphasize that once
24 again. I think it may not, you know, have been as clear
25 possibly in some of the earlier discussions this morning,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 but I just wanted to clarify that.

2 Thank you.

3 CHAIRMAN CERQUEIRA: Okay. Thank you.

4 DR. FRANT: Everybody knows Marjorie
5 Rothschild.

6 CHAIRMAN CERQUEIRA: I think she should
7 actually have a seat at this table here because --

8 DR. FRANT: Right.

9 CHAIRMAN CERQUEIRA: -- so many of these
10 issues would be -- you know, if we could address her
11 directly it would be -- but we can call on her, can't we,
12 John, if we have --

13 MR. HICKEY: Yes. That can be arranged. We
14 have another microphone up here.

15 CHAIRMAN CERQUEIRA: Yeah, well, definitely
16 because it would save us quite a bit of time on, you
17 know, just some of these procedural issues

18 DR. FRANT: Okay. Well, the planning
19 meeting March 14th, I think it would be good if you had
20 somebody at that meeting.

21 CHAIRMAN CERQUEIRA: What's the time of the
22 meeting?

23 DR. FRANT: I'll have to get back to you.

24 CHAIRMAN CERQUEIRA: Okay.

25 DR. FRANT: I know the room, but we'll

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 probably spend a good portion of the day.

2 CHAIRMAN CERQUEIRA: Again, if Angela could
3 get an E-mail out to people with time and location, and
4 we should see if somebody is interested in attending and
5 can free up their schedule to do so. I think that would
6 be important.

7 DR. FRANT: Okay, and the other role that --

8 CHAIRMAN CERQUEIRA: And then on March 15th,
9 you said you would have a draft rule, a draft guidance
10 document available, and will that be put on the Web?
11 Will it be sent out to --

12 DR. FRANT: Both.

13 CHAIRMAN CERQUEIRA: -- the Committee
14 members?

15 DR. FRANT: It will be published and
16 distributed to all medical licensees through our
17 distribution center. It will be on the Web, and it will
18 be sent to the ACMUI Committee members as part of your
19 Committee membership.

20 CHAIRMAN CERQUEIRA: Okay.

21 DR. FRANT: So it will be all three of those
22 things.

23 CHAIRMAN CERQUEIRA: Niki, you had one?

24 MS. HOBSON: Yeah, I was wondering. Between
25 now and March 15th, do you have plans to work with the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 professional societies that you alluded to earlier, that
2 they have a lot to contribute if they have the time and
3 willingness?

4 DR. FRANT: No, I think what we're trying to
5 do is just take the document that we have, clean it up
6 based on the comments that we've gotten recently, and put
7 it out, and then at that point work with --

8 MS. HOBSON: Okay, but there will be
9 involvement by the professional societies at some point?

10 DR. FRANT: Yes, and that's what these
11 meetings in April are about and the planning meeting on
12 March 14th is for how to engage that community.

13 CHAIRMAN CERQUEIRA: Just again one comment.
14 And I feel kind of bad. We don't have a nuclear medicine
15 representative on the Committee because the SNM ACNP
16 really had the most comments, criticisms of the guidance
17 document.

18 DR. FRANT: Right, but I think Chip has been
19 calling some of those folks, and the Chairman certainly
20 has corresponded with them. So I think that they're
21 aware of March 14th and will be part of the comment
22 process.

23 CHAIRMAN CERQUEIRA: Again, I think it would
24 be important to get it out to all of the professional
25 societies.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. FRANT: Exactly.

2 CHAIRMAN CERQUEIRA: In the past, this
3 Committee has in some ways been sort of a battleground
4 between various interests from physician groups and
5 everything, and I think we really should make the
6 information available to all the stakeholders,

7 And sort of in terms of these dates, if
8 people want to send -- now the meeting on March 14th, is
9 that open to the public?

10 DR. FRANT: Yes, of course, it would be.

11 CHAIRMAN CERQUEIRA: Okay. Again, it would
12 be important --

13 DR. FRANT: It would be a noticed meeting.

14 CHAIRMAN CERQUEIRA: Right.

15 DR. FRANT: And what I guess I want to
16 insure, that we have a cadre of folks that are important
17 to be part of the planning process, and then it will be
18 noticed.

19 CHAIRMAN CERQUEIRA: Good. Again, I think
20 if you could send out information to the specific groups
21 who have representation on the ACMUI, but to all other
22 stakeholders and people who have sent comments, I think
23 that would make certain that everybody with an interest
24 knows about it and can organize sending people.

25 DR. FRANT: To some extent I'm relying on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Chip Cameron because I think he has a long history with
2 different groups.

3 CHAIRMAN CERQUEIRA: Okay. John, you wanted
4 to?

5 MR. HICKEY: Yeah. Mr. Chairman, I just
6 wanted to clarify, first of all, to repeat that the
7 guidance document will be published for public comment,
8 not as a final document.

9 CHAIRMAN CERQUEIRA: Sure.

10 DR. FRANT: In March.

11 MR. HICKEY: And that we will be going out
12 for input and sending invitations to all stakeholders and
13 organizations. It's not our intent that ACMUI will be
14 the vehicle by which we communicate with other
15 stakeholders. The ACMUI is free to do that, and we will
16 solicit input from the ACMUI, but we are in no way saying
17 that the ACMUI is the organization that's responsible for
18 going to the other stakeholders and --

19 CHAIRMAN CERQUEIRA: Sure. No, and I'm not
20 suggesting that, but I'm just saying that for all of the
21 stakeholders, they need notice to send people.

22 MR. HICKEY: Yes.

23 CHAIRMAN CERQUEIRA: And March 14th is
24 relatively close. It's three weeks away. So I think
25 it's important to get it out.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And I realize that this is a draft, but you
2 have gotten comments. The SNM ACNP was very specific in
3 terms of the guidance documents, and so the closer the
4 draft can be to a final the better off it will be for
5 everybody.

6 So all right. Other questions or comments?
7 Jeffrey.

8 DR. WILLIAMSON: Well, I think in preparing
9 the draft, when I reviewed the document as it existed
10 about a month ago, I guess, I didn't think enough effort
11 was made to try and indicate the spectrum of
12 possibilities that users could have in implementing. I
13 was too focused on one set of model procedures.

14 You know, I think a lot could be done to
15 ameliorate that by adding paragraphs here and there,
16 indicating the areas where a lot of flexibility exists so
17 that it's whoever reads that manual indicates -- realizes
18 that this is just a possibility, and that other options
19 can be implemented and the licensee won't be punished for
20 doing it.

21 CHAIRMAN CERQUEIRA: I liked your comment
22 about sort of a minimalist document which gives people a
23 certain amount of responsibility. Obviously, you know,
24 it's performance based, risk adjusted. I think they're
25 very important, key words, and if taken to heart, I think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 it would certainly reduce the amount of information
2 that's there for diagnostic and even for the therapeutic
3 community as well.

4 DR. FRANT: But at the same time, I guess,
5 I'm conscious of the fact that I've heard from many staff
6 members, particularly license reviewers, that they're
7 asked: is there a place I can go to --

8 CHAIRMAN CERQUEIRA: Right.

9 DR. FRANT: -- and find a model procedure
10 that gives me an idea about what is expected?

11 And that, as I said, is a tension, and to
12 the extent that we could have joint documents or that it
13 could be produced by someone other than NRC as, you know,
14 this is a recommended way to go. That would be fine, and
15 we've done that in other areas.

16 In the meantime, there's a vacuum and
17 something will fill that and perhaps we can take these
18 model procedures and have them someplace else that are
19 available, but they're not seen as required even with a
20 little r.

21 CHAIRMAN CERQUEIRA: I think the
22 professional medical societies would certainly all give
23 you their cooperation in an effort to get this done. The
24 only point I would make is to try to get sort of a broad
25 representation.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 You know, for the reactors, you had a single
2 entity, I guess, produce a document. I think --

3 DR. FRANT: You would think they are more
4 monolithic than they are, but each utility has its own
5 philosophy.

6 CHAIRMAN CERQUEIRA: Right, right. I think
7 just to keep us on time, again, being cognizant of the
8 flight schedules, I'd like to thank --

9 DR. FRANT: Okay. Well, I'm going to stay
10 because I have a role in the next presentation. So --

11 CHAIRMAN CERQUEIRA: Okay, but again, I
12 think it was an excellent presentation. I especially
13 like the specifics with the dates, the time lines and
14 everything else, and it would be very useful to the
15 committee if we could get Angela to E-mail those out to
16 us so that we can go back to our constituents.

17 DR. FRANT: Okay.

18 CHAIRMAN CERQUEIRA: Thank you, Susan.

19 Ralph.

20 MR. LIETO: Dr. Frant, just to clarify, the
21 March meeting and its purpose, is it to get stakeholders
22 there and how to best get the revised document addressed
23 or is it to address how these public meetings are going
24 to be conducted?

25 I'm still unsure as to what the March 14th

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 meeting --

2 DR. FRANT: It's more about what the public
3 meetings -- what role they can play in influencing the
4 guidance document, you know, and who should be there and
5 how we can best get comments and incorporate them into
6 the final document. So it's a planning meeting for the
7 meetings in April. Is that clear?

8 MR. LIETO: Thank you.

9 CHAIRMAN CERQUEIRA: Dr. Frant, you've done
10 such a great job with time lines. I guess the one thing
11 I'm still unclear on is that, you know, we saw the
12 submission that the Commissioners sent to Representative
13 Callahan, and have they heard back? When will they hear
14 back? That's kind of a key question in this, isn't it?

15 DR. FRANT: I agree.

16 CHAIRMAN CERQUEIRA: The answer is?

17 DR. FRANT: The answer is that in the letter
18 we sent to Congress, and I guess it's been stated enough
19 times, and the Chairman, I believe, made some phone calls
20 to key congressional representatives, to make it clear
21 that the intent of the Commission was to publish the rule
22 30 days after the date it was sent to Congress.

23 So we hold our breath because if there's
24 some strong sentiment among the legislators to tell us,
25 no, you don't have permission to use the monies in your

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 budget to implement Part 35 and you're not to publish it,
2 that may happen. And that's what Marjorie, I think, was
3 alluding to.

4 There's no guarantees except if you buy a
5 washing machine from Sears, and -- sorry.

6 CHAIRMAN CERQUEIRA: Okay.

7 DR. FRANT: But, I mean, it's the truth.
8 And so at the same time, I think that just my personal
9 sense is that the Chairman and the Commissioners did some
10 leg work and fully intend to publish it and believe that
11 they won't have a legislative change, you know, with some
12 legislation.

13 So I think the optimistic glass half full
14 view is that within 30 days of sending the report to
15 Congress, we will send the Part 35 as it stands to the
16 Federal Register to be published and to be effective six
17 months after the date of publication.

18 We're working to that. You're assuming
19 that.

20 CHAIRMAN CERQUEIRA: Right.

21 DR. FRANT: But it isn't there until it's
22 there.

23 CHAIRMAN CERQUEIRA: That's great. That's
24 very useful then.

25 All right. Well, so this section is now

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 status of the NRC Web site in terms of security
2 restrictions, and John Hickey is going to cover
3 electronic forums; is that --

4 MR. HICKEY: Correct.

5 CHAIRMAN CERQUEIRA: And the Web site is?

6 MR. HICKEY: Dr. Rathbun is here to talk
7 about the Web site.

8 DR. FRANT: Okay. Pat, before you start, I
9 want -- Dr. Diamond, you made some comments yesterday
10 about bad people using good stuff to do bad things, and
11 you know, there's --

12 DR. DIAMOND: I like that. I like that.
13 (Laughter.)

14 DR. FRANT: So I've been working with FEMA,
15 and John Hickey has been working on a lot of not for
16 public discussion or not for public release information
17 about things that could be done with radioactive
18 material, not therapeutic and not diagnostic. And the
19 issue is I know the advisory that went out to all of our
20 materials licensees said that you should safeguard the
21 material more so than you have in the past, and I think
22 the suggestion in the advisory says something about
23 looking at it as a controlled substance and some of the
24 safeguards you have for controlled substances.

25 I have the sense that you're working on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 guidance to send out to medical licensees on what they
2 can do to sort of implement that request of the
3 advisories to look at more safeguarding of radioactive
4 material when it's used in medical applications.

5 DR. DIAMOND: Not specifically. My general
6 comments regarding bad people doing bad things with good
7 materials was more of a general informative point that
8 the societies are trying to go and just educate their
9 constituent members as far as basic resources and
10 procedures that are out there in case one of these events
11 should happen.

12 DR. FRANT: Oh, okay. So this would be in
13 response to.

14 DR. DIAMOND: More of a response. I can
15 tell you that in many, many radiation safety
16 organizations or committees across the country there is,
17 however, a formal move to safeguard these materials much
18 more cautiously. For example, our institution, where the
19 board scope holder really serves to oversight many, many
20 smaller facilities, we've taken steps to take some
21 programs where very, very little manual brachytherapy is
22 done and go and consolidate those materials into a
23 central location where obviously safekeeping and
24 oversight is much better.

25 Perhaps I can ask a member of the audience.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Nancy Daly is here. Nancy, do you happen to know offhand
2 any more specifics with respect to if Dr. Frant's
3 questions is actually being looked at in that committee?

4 MS. DALY: No.

5 MR. HICKEY: Step to the microphone and
6 identify yourself.

7 MS. DALY: Nancy Daly from Astro.

8 Again, we're more specific to if it were to
9 happen what would be the mechanism that would be put in
10 place, and what resources could radiation oncologists
11 offer to the communities where it happens, and --

12 DR. DIAMOND: All right. Could I -- I'm
13 sorry.

14 DR. FRANT: What I was going to say is,
15 okay, so I misconstrued what you said because what I was
16 going to offer is if we could play a role in having our
17 safeguards group review things for you, we would be glad
18 to facilitate that.

19 DR. DIAMOND: And I was going to say that I
20 think that as you bring this up, this is an excellent
21 point that would be welcomed.

22 DR. FRANT: Okay. Because we have, of
23 course, a safeguards group that's been working with the
24 intelligence community and with others about issues
25 related to radiological dispersion devices, radiological

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 emitting devices, REDs, RDDs, and of course,
2 independently developed nuclear devices, which I think is
3 not an issue --

4 DR. DIAMOND: Correct.

5 DR. FRANT: -- because it's fissile
6 material, but the RDDs and the REDs are things that I
7 guess there are medical use isotopes that could be
8 involved.

9 DR. DIAMOND: I think we all recognize just
10 as you're alluding to that if a bad person wanted to do
11 bad things with good materials, that going after hospital
12 supplies or materials would be, unfortunately, a way to
13 go, and therefore, we could certainly welcome that
14 advice.

15 DR. FRANT: Well, I guess if as a community
16 there's some work, then we could put you in touch with
17 some of our safeguards people.

18 MS. DALY: Yeah, and we're also working with
19 the American College of Radiology and the physics AAPM.
20 So --

21 DR. FRANT: Okay.

22 CHAIRMAN CERQUEIRA: Dr. Nag had a comment.

23 DR. NAG: Dr. Cerqueira and Dr. Frant, at
24 the last ACMUI meeting there was some discussion that if
25 something bad were to happen, the ACMUI would probably be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 one of the first ones contacted, and much discussion
2 about that. And there should be some formal mechanism
3 how the ACMUI should behave should anything happen.

4 DR. FRANT: Well, we can talk about having
5 some kind of a secure briefing.

6 DR. NAG: Right, and I think one of the
7 things at the last meeting, that an action item was that
8 the NRC would come back to whether we will have some
9 training session or at least some briefing session so
10 that we can know how to react to the news media, how to
11 react to the people nearby, and you know, how we can
12 train the other people.

13 DR. FRANT: Well, we have some materials
14 that we've prepared with many other federal agencies,
15 including HHS and FEMA that are for federal government
16 use. Let me see if that can be distributed. I'm not
17 sure. It's official use only, but I'm not sure how other
18 -- I'm learning about the different levels of protection.
19 I know classified and nonclassified. There's a new one
20 coming up that I guess Pat can talk about, which is the
21 Office of Homeland Security is coming up with a homeland
22 security sensitive designation, and that's something
23 we're working through. That would be a new designation.

24 DR. NAG: At the last meeting we were
25 talking about some official training and official

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 briefing that the ACMUI should receive.

2 DR. FRANT: Okay. Well, I'm going to let
3 John and Angela work that out.

4 CHAIRMAN CERQUEIRA: So do we want to make
5 that an action item then?

6 PARTICIPANTS: Yes.

7 CHAIRMAN CERQUEIRA: To basically --

8 DR. NAG: It was made the last time. So I
9 think we would just repeat the same thing.

10 CHAIRMAN CERQUEIRA: Again, for the
11 transcribers, if you could somehow highlight this, it
12 would be important.

13 DR. NAG: The **action item** would be that
14 ACMUI members have a training session and/or a briefing
15 for any untoward accident in nuclear --

16 DR. FRANT: Well, it would be potential --

17 DR. NAG: I don't want to use the wrong
18 word.

19 DR. DIAMOND: Malevolent.

20 DR. FRANT: I can never pronounce that.

21 DR. DIAMOND: Malfeasant.

22 DR. FRANT: Right. You know, in Great Neck
23 High they never taught me that. Anyway --

24 CHAIRMAN CERQUEIRA: All right. We should
25 -- I really want to try to keep on schedule. So why

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 don't we go on to this section, and maybe, Ms. Rathbun,
2 if you could, we've got 15 minutes, John, to do this
3 section.

4 MR. HICKEY: Yeah, that's fine.

5 DR. RATHBUN: It will be very short, not a
6 problem.

7 Thank you very much.

8 This is my name tent. Well, that's all
9 right. "Answers to the name of Pat frequently." Okay.
10 All right.

11 As you probably know, after September 11th,
12 in consultation with the Justice Department, the NRC did
13 close down the public Web. Access to ADAMS was still
14 available to those people who had already had access to
15 ADAMS.

16 CHAIRMAN CERQUEIRA: I'm sorry. What's
17 ADAMS?

18 DR. RATHBUN: All right. ADAMS is a
19 document management system for the agency called ADAMS,
20 and it's essentially where the NRC stores electronically
21 all of its documents, and if you -- it's available to the
22 public. You can just simply come in and look at whatever
23 documents are in there, and theoretically it is the
24 official record system of the NRC.

25 So you can see immediately there were some

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 interesting paradoxes because we had the Web closed, but
2 we had availability of ADAMS to people who had already
3 had it.

4 So time passed, and Susan began to head a
5 project whereby we were making decisions about what
6 should come back to the Web, when it's available, and
7 what should be if not removed from ADAMS, at least
8 significantly safeguarded.

9 Now, as you can imagine, this was a huge
10 task. It was also carried out very rapidly because, you
11 know, people were very, very concerned. It involved both
12 the reactor side, as well as the NMSS side.

13 What did we really take down that could be
14 of interest to you?

15 In our fact sheets, we had a fact sheet on
16 the medical use of radioisotopes. The reviewer said
17 drawings attention to the fact that some medical
18 facilities have some very hot sources.

19 At that time, that document was taken and
20 classified. Well, "classified" is the wrong word. And
21 marked sensitive.

22 We also had another fact sheet on the
23 biological effects of radiation, which the reviewers at
24 that time, and you can see they were very cautious, said,
25 "Contains language concerning cancer threat."

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So the current decision on these things is
2 to put the biological effects of radiation fact sheet
3 back out onto the Web, but so far not the medical use of
4 radioisotopes. So that's something that you may or may
5 not want to comment on, not necessarily here, but we're
6 going to hold that back.

7 The ACMUI transcripts are public
8 information, and they are available. IMNS Management
9 prior to you actually reviewed that and felt there was no
10 reason to pull that back. So unless I hear, you know,
11 violent opposition here today, that will be going back on
12 the Web.

13 NUREG 6642, the risk document which, you
14 know, contains the detailed we feel kind of scenarios or
15 how to make trouble, that was removed. It is still off
16 the Web. No plans to go back.

17 Now, so that's where -- yes, sir.

18 MR. LIETO: So none of the NUREGs are
19 available? Because it's my understanding --

20 DR. RATHBUN: No.

21 MR. LIETO: -- the RegGuides and the NUREGs
22 are not available.

23 DR. RATHBUN: Well, let me go to that part.

24 At the same time that this was going on in
25 response to closing the Web due to the terrorist

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 activities, there was an activity going on to more or
2 less straighten out the Web and come up with a new
3 design.

4 What's happening now is documents are
5 returning to the new Web, but with this sort of cloak of
6 security. I don't know today if the NUREGs are back, but
7 unless --

8 PARTICIPANT: They're not.

9 DR. RATHBUN: They're not. Okay. Unless
10 they're marked "sensitive" in ADAMS you should be able to
11 get them, but they are coming back.

12 MR. HICKEY: Excuse me. Another way to say
13 that is if they were previously public, they will be put
14 back on the Web public with a few exceptions --

15 DR. RATHBUN: Right.

16 MR. HICKEY: -- generally that won't affect
17 medical licensees.

18 DR. RATHBUN: Yeah, I think the only one is
19 that 6642, and if there were implications in any of the
20 risk work, I know Lawrence Kokajko has spoken to you
21 about the activities of the Risk Group, the results of
22 that project are being withheld until we determine if
23 there are risk scenarios that could simply lead the way
24 to a terrorist.

25 Now, I mean, as you well know, this puts us

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 in quite a balance between what people really need to do
2 their business and what, in fact, might be used by bad
3 people to do bad things with good material. So what's
4 happening?

5 Well, we're working on definitions and
6 policies sort of very, very, very hard. I mean, there's
7 a group of people whose major job is now to work on this
8 and try to get as much information back out on the Web as
9 we possibly can.

10 We are working on this both within NRC, but
11 also with Homeland Security, and what Susan was referring
12 to is called -- it's a new classification for
13 information, and it's called sensitive homeland security
14 information, which people are calling "sushi." So if you
15 hear people speaking of "sushi," that's what they're
16 talking about.

17 And Homeland Security's definitions
18 currently are pretty general, but it's not at all clear
19 to us exactly where they're going.

20 Un-huh?

21 DR. WILLIAMSON: I'm a little concerned at
22 what you've just said. It seems to me --

23 DR. RATHBUN: I'm not surprised.

24 DR. WILLIAMSON: -- that it's totally
25 ridiculous to take the medical use fact sheet off of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Web. You can go to any textbook on radiological sciences
2 and learn that high intensity radiation sources are used
3 for radiotherapy or for nuclear medicine.

4 DR. RATHBUN: I totally agree with you.

5 DR. WILLIAMSON: And so I think a more
6 realistic screening of the material needs to be made. I
7 think it's appropriate to withhold details about the
8 operational characteristics of specific sites, such as
9 power plants that would perhaps aid in someone, you know,
10 launching a specific attack or action.

11 DR. RATHBUN: Right, exactly.

12 DR. WILLIAMSON: But to withhold general
13 material about the operation of the NRC, about the use of
14 radioactive materials in general, and its activities, I
15 mean, I think that's infringing upon your charge --

16 DR. RATHBUN: You're absolutely right.

17 DR. WILLIAMSON: -- as an open and public
18 agency. So I --

19 DR. RATHBUN: In that one we totally agree
20 with you, and there are about six fact sheets that at the
21 time it seemed like -- you know, it seemed like a good
22 idea at the time right after September 11th to pull
23 everything that even, you know, had any hint.

24 There's a whole pile of them, about seven,
25 that I suspect will go back just next week. So, you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 know, I totally agree with you. If we erred in the
2 beginning, I think we erred on the side of probably
3 overly cautious, and I think that what you see from the
4 Commission is a move now to be much more realistic.

5 DR. FRANT: The Commission has directed us
6 to go back and make sure that we're not doing exactly as
7 you're suggesting. At the same time, the Sealed Source
8 and Device Registry, for instance, we've made that
9 password protected, and only if you have a password can
10 you used the Sealed Source and Device Registry, on the
11 assumption that there are detailed drawings that can give
12 somebody an idea on how a device could be dismantled or
13 whatever.

14 It may be that unless you know where the
15 device is it wouldn't matter if you knew what to do with
16 it, and you would only get that if you put one and one
17 together, one being the Sealed Source and Device Registry
18 with its detailed documents and then found licensees'
19 names and who is using that device and a map of where
20 they were.

21 On the other hand, it's clear from some of
22 the intelligence that we get that there are people who
23 are willing to do all of that leg work. So you want to
24 make it a little more difficult.

25 And we did have many, many evidences of hits

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 coming from all over the world to different parts of the
2 NRC Web site, and it may be things that are in a
3 textbook, but the Web is very accessible, and so there
4 was a very conservative decision made right after 9/11
5 that we'll just put the Web down and wait until we figure
6 out what we can put back up.

7 And as Pat said, we're doing two things at
8 the same time, which sometimes confuses the issue, which
9 is putting things back up, but putting it back up on our
10 new Web format. So it's taking a little longer to get
11 some of the NUREGs back up, but they are slated to go
12 back up, and I don't know exactly what the date is, but
13 they've been in waves.

14 And as with the rest of what we do here, the
15 reactor stuff went back up stuff, and the medical stuff
16 will follow.

17 CHAIRMAN CERQUEIRA: Richard, did you have
18 a question?

19 DR. VETTER: Yeah. The information in the
20 public document room is also readily accessible.

21 DR. FRANT: Absolutely.

22 DR. VETTER: And I'm not sure how that --
23 sure, it's easier to go on a computer, and you can do
24 that --

25 DR. FRANT: From anywhere in the world.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. VETTER: -- from anywhere in the world,
2 but the public document room is also there. My question
3 relates to information that at least in the past has been
4 available in the public document room, and that is: is
5 there information either in the license literature or in
6 enforcement literature that would reveal the location of
7 radioactive materials at a medical center?

8 DR. FRANT: I'm sure there is, and I'm sure
9 in enforcement documentation this is something we have
10 been looking at. There are discussions of
11 vulnerabilities that need to be corrected, and that's
12 also problematic. Because if it hasn't been corrected
13 yet, then it says you have a problem.

14 I was leading the team that did the review
15 at NIH when they had the P-32 contamination, you know,
16 and we had documents on what the security issues were.

17 DR. VETTER: Yeah, personally I would view
18 that as more problematic than having NUREGs and so forth
19 out on the Web.

20 DR. FRANT: Yeah, and I think you're exactly
21 right, and it's one of Pat's issues, is to come up with
22 guidance that helps us make those decisions so that we
23 don't make it on each document, but we make it on
24 categories of documents.

25 Right now --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. RATHBUN: If possible, if possible.

2 DR. FRANT: Right now the things are in the
3 public document room partially because you have to go
4 there. You have to sign in. We know who's looking at
5 the stuff, and that's part of what we're looking at, is
6 who has access, not only --

7 DR. WILLIAMSON: Maybe that is a better
8 approach to your problem, is to try to define -- make an
9 application system for people to get passwords so that
10 they could have access to a broader scope of information.

11 Rather than trying to classify every single
12 document, you could screen people who have access and
13 supply passwords to users from the medical center who
14 need to get into this stuff.

15 DR. FRANT: Yeah, well, we have to be
16 careful --

17 CHAIRMAN CERQUEIRA: Just in terms of --

18 DR. FRANT: -- that we don't use criteria
19 that --

20 CHAIRMAN CERQUEIRA: Right. In terms of the
21 Committee, I need to give John some time for his forms.
22 What specific questions do you have for the Committee
23 relative to this?

24 DR. RATHBUN: Honestly, I didn't have any
25 questions. I just wanted --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Just information.

2 DR. RATHBUN: -- to inform you, and I'd love
3 to hear from Dr. Lieto.

4 MR. LIETO: First of all, I use ADAMS fairly
5 frequently because you can use it to confirm training and
6 experience, credentials of new users at your facility as
7 to whether they were actually licensed or not and what
8 licenses they were on.

9 Regarding Dick's question, yes, there are
10 floor plans and locations of where stuff is because
11 basically a license application is full copied in its
12 entirety. So that information is there.

13 My concern is that there's a lot of
14 information as an RSO and a physicist that you want
15 access to the regs., you know, current versions of the
16 regs., which are sometimes very difficult to get, and I
17 --

18 DR. FRANT: Those should be up there. Those
19 should be up now.

20 MR. LIETO: But lots of times though --

21 DR. FRANT: We'll check.

22 MR. LIETO: Part of the issue is like if you
23 want a copy of Part 35, you've got to go through and copy
24 each section. There are not entire parts that you can
25 download for distribution to users and for training

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 purposes, and so forth. The same thing with like Part
2 20, Part 19.

3 DR. WILLIAMSON: Oh, it's terrible.

4 MR. LIETO: Those types of things. So it's
5 very difficult, and I would think that that would be very
6 helpful.

7 Another comment regarding what you're
8 planning to do with the NUREG revision. To me there's
9 going to be a lot of people who can't get to these
10 meetings and so forth, and I would see that the Web site
11 is going to be really critical because of the time frame
12 for people to make comments and suggestions and want to
13 get input to the NRC.

14 So I know that when the original Part 35
15 revision when out there was a site, and I think it was at
16 Lawrence Livermore, but I could be wrong, where people
17 could have dialogue on the issues, and it was monitored,
18 I think, by the NRC staff for comment.

19 I don't know how beneficial it was to the
20 staff or not, but there's got to be, I think, that Web
21 site mechanism for communication on this Part 35 revision
22 that I think is really important.

23 And I know I'm being looked at over here
24 about the clock and so forth, but, hey, I've got the mic.

25 DR. FRANT: You bet.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: So I think the Web site is a
2 very --

3 CHAIRMAN CERQUEIRA: I could cut you off.

4 MR. LIETO: -- is very important.

5 DR. FRANT: Well, I think we intend to use
6 that. I don't see Roger, but the last I heard, the staff
7 planned to have that Web site up.

8 MR. LIETO: Now, the other issue is
9 regarding ADAMS. Because of the way of accessing ADAMS,
10 if you have firewalls, it's very, very difficult to
11 access ADAMS, especially for like large centers and so
12 forth. In fact, the only way I can do it is via a modem.
13 I can't do it via our hospital network, which is a very
14 slow process.

15 And so if you've got a sizable document, I
16 mean, you've got to basically kind of do this overnight.
17 So, you know, to look at get sizable NUREGs and things
18 like that to download, it is not easy. In fact, it's
19 very difficult to do it because you've got to do it via
20 modem.

21 DR. FRANT: Yeah. We'll pass that on to our
22 CIO folks who have done the Web redesign. I think they
23 tried to address that. This has been a complaint by
24 many, many groups. We've been accused of using the Web
25 as a way to disenfranchise people who didn't have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 computers and elitists and all of that.

2 CHAIRMAN CERQUEIRA: I suggest that we take
3 a break. Let John cut into Don Cool's time a little bit,
4 and if people have --

5 DR. RATHBUN: That's fine.

6 CHAIRMAN CERQUEIRA: No, but if people have
7 specific questions for Dr. Frant and Rathbun, just ask
8 them now. Okay?

9 DR. RATHBUN: Yeah.

10 DR. FRANT: We'll be here.

11 CHAIRMAN CERQUEIRA: Thank you very much.

12 (Whereupon, the foregoing matter went off
13 the record at 10:06 a.m. and went back on
14 the record at 10:22 a.m.)

15 CHAIRMAN CERQUEIRA: I was talking to John
16 during the break, and we have every intent of being
17 completed by three o'clock. A lot of the items after the
18 three o'clock break were really sort of dealt with to
19 some extent.

20 I'd also like to mention that, you know, I
21 think the Committee meets. Most of us, this is not our
22 main line of work, and for some of these this was very
23 informative, but it would be very useful if we had some
24 questions that they wanted to ask us specifically, and if
25 they're going to sort of update us on something, having

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the material sent to us ahead of time would allow us to
2 view it on the plane, if nothing else, so that we could
3 provide some useful input into the NRC on these items.

4 So, again, I think some of these updating
5 the Committee on factual items, we should get the
6 material ahead of time, and if there are specific
7 questions that they have for the Committee, I think
8 these, again, should be clearly stated. Otherwise we
9 just have a nice dialogue and we get a little bit of
10 information and we exchange cards, but we could be much
11 more useful and productive if we knew ahead of time what
12 they're going to present and what information they want
13 from us specifically.

14 MR. HICKEY: Yes, we agree with that, but
15 let me just point out a couple of considerations. One is
16 this was in response to a request from the Committee to
17 place this on the agenda. It wasn't that the staff --

18 CHAIRMAN CERQUEIRA: Right.

19 MR. HICKEY: -- had questions they wanted to
20 bring to the ACMUI.

21 The other is we agree that we need to
22 provide you with material advance, but an example in this
23 particular case is where it involves security
24 considerations we have to be careful what we put down on
25 paper.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Sure.

2 MR. HICKEY: And was you heard, this is a
3 dynamic situation where it's unclear what's being release
4 to the public and what's not.

5 CHAIRMAN CERQUEIRA: That's understood, and
6 we are certainly aware of those factors, but again, to
7 get more business done, it's important to have it.

8 All right. Well, the next item then is
9 going to be John with the electronic forms.

10 MR. HICKEY: Yes. Dr. Cool is in a meeting
11 that should have ended by now. So we're expecting him
12 momentarily, and Mr. Lohaus is in a meeting also, but we
13 expect him to be here on time.

14 With respect to the electronic forms, and I
15 think some of Ralph Lieto's remarks were a good
16 introduction to this, we would like for the Web site to
17 be more user friendly and more useful, and so we will be
18 putting electronic forms, in general, up ont he Web more,
19 and in particular in the medical area where there are
20 forms that are useful, such as an application form or a
21 reporting form.

22 We're going to have that as part of the
23 medical tool kits, Web tool kits, so to speak, that
24 that's another resource that instead of having to get the
25 forms through the mail in hard copy or Xerox them out of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 something, you can download them and fill them out, and
2 perhaps even submit them electronically.

3 So that is one thing we're working on, and
4 we're also looking at other user friendliness issues.

5 Ralph pointed out one that's come up before,
6 the issue of our regulations. If you're reading them the
7 way that they are on the Web, if you're just reading them
8 on the Web it's fine, but if you want to download the
9 whole document, you can't just click Part 20 download.
10 You've got to click 20.201, 20.203 and download each one
11 of those individually.

12 So that's an agency-wide issue, not just a
13 medical issue, but that's something else we'll have to
14 work on.

15 CHAIRMAN CERQUEIRA: Good. So that's it on
16 forms.

17 MR. HICKEY: That's it. I'll take any
18 questions.

19 CHAIRMAN CERQUEIRA: And Dr. Cool is still
20 not here.

21 MR. HICKEY: Unfortunately. We just called
22 up there. He's going to come down as soon as he gets out
23 of his other meeting.

24 DR. VETTER: Can I just make one comment?

25 CHAIRMAN CERQUEIRA: Yes, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. VETTER: The public document room does
2 provide -- I don't know if that's -- it's some electronic
3 connection of the public -- not public document room.

4 The Government Printing Office. You can
5 download entire chapters from that. At least, unless
6 something happened since September, I have done that in
7 the past.

8 MR. HICKEY: From the Code of Federal
9 Regulations.

10 DR. VETTER: Yes.

11 MR. HICKEY: Yes, but that's not user
12 friendly for you to have to go -- you know, we'd like to
13 have it you go to the NRC Web site; you go to the medical
14 area; and it's all right there. That's our goal.

15 DR. VETTER: Can you link?

16 MR. HICKEY: We can, but I don't know if
17 that's the best way to do it because that involves, you
18 know, relying on another server and going out of the
19 system and coming back into the system.

20 CHAIRMAN CERQUEIRA: Yes. Now for the sake
21 of time, it looks like the next two speakers are not
22 going to be here. Bob Ayers is here. John and I had
23 talked that there's some sort of stakeholders. I guess
24 is there -- is there a reason we couldn't move that up on
25 the agenda now?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. AYERS: I don't have my slides here.

2 CHAIRMAN CERQUEIRA: Okay. So I guess we
3 can't do that.

4 DR. AYERS: I can go up and get them, but it
5 would take a few minutes.

6 CHAIRMAN CERQUEIRA: Well, maybe you should,
7 and what about na update on new IVB devices?

8 MR. HICKEY: I can go ahead and talk about
9 intravascular brachytherapy.

10 CHAIRMAN CERQUEIRA: Yeah.

11 MR. HICKEY: Before you do that, would you
12 like to talk about the three o'clock, to see if we could
13 --

14 CHAIRMAN CERQUEIRA: We could touch --

15 MR. HICKEY: To the extent that the three
16 o'clock items need further discussion, we could close
17 those out.

18 DR. WILLIAMSON: Or we could decide the next
19 meeting date.

20 CHAIRMAN CERQUEIRA: Okay.

21 DR. WILLIAMSON: There are some other
22 administrative things we could prepare.

23 CHAIRMAN CERQUEIRA: All right. So the
24 distribution of ACMUI meetings.

25 MR. HICKEY: Minutes.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Minutes. I think we've
2 agreed that it's, you know, two weeks before the time of
3 the meeting itself, if not sooner, is idea, so people can
4 review it if there are issues.

5 And I'm certainly willing to look at the
6 items as they come to me. I will not commit to going
7 through the transcript of the entire meeting. I think
8 we've simplified it, you know, with Dr. Diamond's
9 suggestion to try to come up with specific agenda items.
10 So --

11 MR. HICKEY: To be clear, the minutes will
12 be clear on what the action items and resolutions were
13 and what the staff's response was to those as a separate
14 document.

15 CHAIRMAN CERQUEIRA: So, again, we've got a
16 policy, and we just have to enforce it.

17 Ralph?

18 MR. LIETO: I just had a question. Where
19 are the transcripts of the minutes or -- excuse me -- of
20 the meetings? They're in ADAMS only? Is that where
21 they're at or are those supposed to get distributed to
22 the members?

23 MR. HICKEY: Well, let me ask Angela. I'm
24 not sure you want them distributed, but go ahead. Speak
25 into the mic.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Trust me. You don't.
2 It's huge.

3 MR. LIETO: Well, I was just thinking of --

4 MR. HICKEY: Well, let Angela answer the
5 first questions.

6 MS. WILLIAMSON: The transcript is placed
7 into ADAMS after Dr. Cerqueira certifies it, and that can
8 typically take from the time that we get the transcript,
9 that can typically take about 30 days.

10 Yes, Dr. Williamson.

11 DR. WILLIAMSON: Is it possible we can have
12 access provided to ADAMS for the members of the Committee
13 and then E-mail given to us to direct us or to inform us
14 when the transcript and minutes are available, and then
15 we could go look at them on line?

16 MS. WILLIAMSON: That's a routine
17 announcement that's made in the Federal Register notice
18 about when the transcript is available. So you're asking
19 for us to notify you precisely when it's available?

20 DR. WILLIAMSON: Right, because we don't all
21 read the Federal Register every day.

22 MS. WILLIAMSON: Right, but it is in your --

23 MR. HICKEY: We can notify you by E-mail of
24 the availability and how to access it. Anybody can
25 access ADAMS. You don't have to be given access to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 ADAMS. Any member of the public --

2 DR. WILLIAMSON: Okay, but if you can tell
3 us when and where --

4 MR. HICKEY: And how, yes.

5 DR. WILLIAMSON: -- it's on the Web, and
6 how, that would be really nice because we're not going to
7 read the Federal Register every day to find out.

8 MR. HICKEY: Go ahead.

9 MR. LIETO: I was going to say because
10 usually documents have sort of a weird ID number, if I'm
11 not mistaken, in ADAMS. So you know, if we even have
12 that number so that we can go in and find it.

13 CHAIRMAN CERQUEIRA: Okay. Dr. Cool is
14 here, and while he's getting set up, an update of the
15 ACMUI bylaws. What did we change? Were there any
16 changes or is this --

17 MR. HICKEY: It was pointed out that there
18 needs to be an update with respect to the terms. The
19 length of terms of members has been changed, but the
20 bylaws haven't been updated. So we will update that and
21 any other administrative changes.

22 And I would suggest that we contact the
23 Committee by E-mail with the revision, and then for the
24 next meeting the approval of the change would just be a
25 formality. It would have already been reviewed.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 But the main concern was they did not
2 reflect the correct length of terms. They just had not
3 been updated.

4 CHAIRMAN CERQUEIRA: Okay. I have to admit
5 I haven't read them for a while, but they're here now.

6 Is this a revision that -- okay.

7 MR. HICKEY: Can you explain what's been
8 handed out, Angela?

9 MS. WILLIAMSON: To save time, I handed out
10 the proposed change to the bylaws so that when we get to
11 the point in the agenda when we talk about updating the
12 bylaws you can read what the proposed change is, and you
13 have the current version of the bylaws already in your
14 briefing binders.

15 So that's all that that is.

16 CHAIRMAN CERQUEIRA: So the only thing
17 that's changed is the term of an appointment to the
18 Committee is three years and the Commission has
19 determined that no member may serve more than two
20 consecutive terms, or a total of six years.

21 MS. WILLIAMSON: Right. The total amount of
22 time hasn't changed. It's just that the terms have been
23 lengthened.

24 CHAIRMAN CERQUEIRA: Okay.

25 MS. WILLIAMSON: That's the only difference.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Does anybody have any
2 concerns about that, questions or disagreement with those
3 changes?

4 MR. LIETO: No, I think we've just got to
5 vote on it.

6 CHAIRMAN CERQUEIRA: Yeah. Do I hear a
7 motion to approve?

8 MR. LIETO: I make a motion to amend the
9 bylaws, Section 3.1, to reflect the Committee appointment
10 term length as documented here.

11 DR. NAG: One question.

12 CHAIRMAN CERQUEIRA: Yes.

13 DR. NAG: How would those who are appointed
14 for two years and now we have a three year -- I mean the
15 new appointee, no problem. What happens to the old
16 appointees?

17 MS. WILLIAMSON: Can I answer that? It's
18 simply an administrative change so that the appointment
19 process --

20 MR. HICKEY: No, the question is: is there
21 anybody on the Committee now that was appointed for two
22 years?

23 DR. NAG: Yes.

24 CHAIRMAN CERQUEIRA: I think most of us.

25 DR. NAG: All.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. WAGNER SCHWARZ: All of us.

2 CHAIRMAN CERQUEIRA: Was it for three years?

3 DR. WILLIAMSON: The bylaws are out of step
4 with the current process.

5 MS. MCBURNEY: With the process.

6 CHAIRMAN CERQUEIRA: So it sounds like, you
7 know, the process was changed, but the bylaws weren't.

8 MR. HICKEY: Correct.

9 CHAIRMAN CERQUEIRA: I have to -- okay. All
10 right. So that's been clarified.

11 MR. LIETO: Second Ralph's motion.

12 CHAIRMAN CERQUEIRA: Second Ralph's motion.
13 Any discussion?

14 (No response.)

15 CHAIRMAN CERQUEIRA: All the vote. All in
16 favor?

17 (Chorus of ayes.)

18 CHAIRMAN CERQUEIRA: Opposed? Abstentions?

19 (No response.)

20 CHAIRMAN CERQUEIRA: Okay. So this has been
21 passed, and we've dealt with that.

22 Dr. Cool, I apologize for taking some of
23 your time, but we'll give it to you if you need it.

24 DR. COOL: Thank you, Dr. Cerqueira.

25 And let me welcome you here. With the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 number of the other things going on in the agency I
2 haven't had the time I would have liked to have had to be
3 with you on the large variety of subjects today. This
4 may, in fact, not necessarily need as much time as may
5 have been on the agenda. So I may, in fact, be able to
6 help you just a little bit.

7 On the other hand, this is an area which is
8 a little bit different from that which the Committee
9 typically has an opportunity to get a view of because I
10 wanted to spend a few minutes and let the Committee have
11 a little bit of information about some of the activities
12 that are going on internationally because there is a
13 great deal of activity going on outside of the United
14 States, outside of this particular set of activities that
15 we have here in the Nuclear Regulatory Commission.

16 And both because it is of general interest
17 because of the interactions that we and the states and
18 various professional societies may be engaging on in
19 another one of our lives, as well as the potential
20 implications that this may have long term for some of the
21 activities or interactions that we may have, and because
22 I believe it poses a new opportunity for us to at least
23 consider ways to influence activities on a broader scale,
24 and so for those variety of reasons, I wanted to give you
25 a little bit of background information of some of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 things that are going on and some of the recent
2 discussions that have taken place.

3 The particular event which tripped my
4 request to spend a few minutes was an International
5 Atomic Energy Agency Technical Committee meeting which
6 took place about two and a half weeks ago, and it was
7 titled the "Development of an Action Plan for
8 Radiological Protection of Patients."

9 Now, that might seem like a very strange
10 title for someone from the Nuclear Regulatory Commission
11 to then be headed overseas on, but, in fact, under that
12 title lies the current set of IAEA, International Atomic
13 Energy Agency, activities related to the practice of
14 medicine and radiation.

15 IAEA, as the states have here in the United
16 States, has a view for all of the different kinds of uses
17 of radiation in medicine. This is everything from the
18 esclorays (phonetic) and the fluoroscopy to the biopartic
19 (phonetic) materials to the PET, to the entire gamut of
20 activity. So it goes well beyond NRC's particular
21 jurisdiction.

22 And they have had in place for almost as
23 long as the agency has been in place a series of
24 activities that they've been looking at to try and
25 support their member states in the safe use of radiation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and radioactive materials.

2 The International Atomic Energy Agency is a
3 U.N. agency, and so their member states constitute in the
4 broadest terms the membership of the United Nations. In
5 more specific terms, there are a set of member states of
6 IAEA, somewhat of a subset, but it's still some 150 or so
7 different countries, and so they face a rather
8 interesting challenge of everything from things like the
9 United States and Great Britain, France, the various
10 folks in the European Union, and others who have rather
11 developed and refined programs, longstanding sets of
12 regulations, practices, and activities and focuses, to
13 folks in some of the smaller countries, some of the newly
14 independent states in a variety of places where the first
15 and foremost question is: is there any sort of
16 regulatory infrastructure and information? Does anyone
17 know what they actually have and what they're actually
18 doing in using the radioactive materials not only in
19 medicine, but in all of the various attributes, a lot of
20 the industrial sources, radiography and other things?

21 But medicine tends to be the area where they
22 are more likely to actually have large sources in some of
23 these under developed or just developing member states as
24 a result of teletherapy units or other things. A
25 physician, a physicist, some combination of folks

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 returning to their country, having been educated here or
2 in Europe, and taking with them sources and equipment in
3 order to set of practices, and that has over the course
4 of time, of course, gotten people into trouble in various
5 and sundry forms both in terms of the securing and
6 control of the material -- witness, for example, the
7 Guyana event for now more than ten years where a
8 teletherapy unit was no longer being used, was more or
9 less abandoned. Some thieves came in and thought this
10 would be wonderful scrap metal, got into the source, and
11 saw, oh, what cool stuff. This cesium powder glows in
12 the dark, and several people died, and they made a
13 horrendous mess of a large number of acres there in
14 Guyana, to similar sorts of things where teletherapy
15 heads, for example, in Thailand here a couple of years
16 ago, three of them picked up by scrap brokers. Again,
17 they didn't know what they had. There was no ongoing
18 accountability and control, and there were a number of
19 individuals who got very severe exposures to rather
20 serious consequences as a result of actually attempting
21 medical treatment. Witness, for example, the most recent
22 couple of cases in Costa Rica and Panama, for example,
23 where there have been rather severe consequences, a
24 number of individuals actually dying as a result of not
25 being aware that a treatment planning system output was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 not what they had thought they were putting in. The
2 system didn't respond the way they thought it was going
3 to.

4 So there's a whole set of issues that are
5 going on. The International Atomic Energy Agency and its
6 Board of Governors in a general conference back several
7 years ago, the Board of Governors challenged the IAEA
8 Secretariat to convene an international conference to try
9 and examine the issues and lay out some recommendations
10 for how to move forward in the area.

11 That resulted in a conference that was held
12 in Malagra, Spain back a bit over a year ago.
13 Commissioner Diaz from here; Dr. Fred Metler actually
14 chaired the conference, University of Mexico. A number
15 of other individuals from various places within the
16 United States attended the conference. There were over
17 800 participants.

18 That resulted in a series of recommendations
19 coming out of the conference, documented in the
20 proceedings which are publicly available. It's a book
21 about yea thick, a couple inches thick. A wide variety;
22 contains all of the text of the talks and the dialogue
23 sessions.

24 The general conference in September of last
25 year asked the IAEA Secretariat, the staff to then move

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to the next step, which in typical international
2 activities is to more formulated specific action plan,
3 which the IAEA could then engage specific actions on over
4 some period of time.

5 That's the short history that got to the
6 meeting that was held the end of January, the first few
7 days of February this year, taking the results of that
8 conference and taking a look at the current IAEA programs
9 and what things could be done and what things should be
10 done by whom. Because the IAEA is only one of a large
11 number of organizations that have international roles.

12 The conference and this technical committee
13 was attended by representatives of the World Health
14 Organization, WHO, Pan American Health Organization,
15 PAHO, a whole series of various international
16 professional societies, the International Organization of
17 Medical Physics, International Radiation Protection
18 Association, International Society of Radiation Oncology,
19 International Society of Radiographers and Radiological
20 Technologists, International Society of Radiology.

21 That gives you a flavor, a wide variety of
22 these, all of whom have various activities going on to
23 one extent or another, trying to look at improving the
24 delivery of medical care internationally.

25 The discussions during the week and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 focus of the action plan being developed. I have a very
2 drafty draft that I brought back, which they were going
3 to go work on, polishing and adding to some things, picks
4 up on the primary mechanisms that the IAEA can utilize to
5 influence member states, which is coordinating research
6 where that may be appropriate to gain a better knowledge
7 of the things to do; promoting education and training,
8 which was, in fact, one of the primary focuses of this
9 activity; providing assistance to member states, which is
10 something that the IAEA does through both technical
11 assistance activities, some peer review activities, a
12 variety of things that they do with developing member
13 states; fostering information exchange, such as the
14 conference and other activities; and in some cases
15 actually specifically rendering some services to some of
16 the member states, where they will actually come in and
17 perform certain functions for a period of time.

18 The outgrowth of that is a whole series of
19 suggestions for actions to be taken, some of them over
20 the next year, some of them a little bit longer time
21 frame.

22 Once I have a better version of this draft
23 or if that's not forthcoming from the IAEA within the
24 next couple of weeks, I will circulate this particular
25 version around. I will get you a copy recognizing what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 it is, that it is a draft.

2 The process in IAEA is then to have this
3 proposed action plan approved by the Board of Governors,
4 and what would then transpire is over the next year,
5 couple of years, the IAEA in coordination and cooperation
6 with some of the other international agencies,
7 particularly folks like WHO and PAHO, would be looking to
8 try and implement some of these activities.

9 Many of the things in this action plan are
10 not actually things which the Nuclear Regulatory
11 Commission in and of itself would likely play any
12 specific role in. They are nevertheless good things,
13 trying to foster education and training, trying to look
14 at what are good practices in terms of some of the
15 protocols that they can give to folks to be able to
16 utilize to improve information, how to foster getting the
17 right kind of information into the hands of the people
18 who need it.

19 There are some things related to some of
20 IAEA's activities in standards and guidance. There the
21 planning activity looks very much like the directionality
22 that we have here with NRC and in the United States to
23 move towards performance based sort of activity, to be
24 trying to look at the relative risks associated with it.

25 And at this point in IAEA, their primary

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 focus is things like the fluoroscopy, some of the
2 interventional radiology, some of the very high dose rate
3 procedures where their view of risk is perhaps a number
4 of years behind some of the thinking and views that ours
5 would be.

6 They will have some efforts to revise some
7 of the guidance documents that have been used in working
8 with member states, their so-called model program.

9 To give you a quick side bar related to
10 that, their model program is an effort with now some 58
11 member states where they have gone in and started from,
12 in essence, scratch. There's no regulatory structure;
13 there's no regulatory authority. There's no
14 understanding of the sources and uses and activities.

15 Through a series of steps working to build
16 a basic infrastructure, a basic understanding, a basic
17 capturing of registration or licensing of the kinds of
18 sources that are to gradually move to a point where there
19 is a basic system of control, inspection, and licensing.

20 They've developed associated with that some
21 documents that a member state could use, not necessarily
22 unlike model procedures. If someone doesn't have the
23 capability to work on developing their own, they can use
24 these .

25 They've committed to doing some revisions

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 related to those, to in a number of cases make them less
2 prescriptive and to provide some flexibility. There were
3 a number of observations that a bunch of the places here
4 couldn't do everything that was in the list of some of
5 those best practice documents that existed out there, and
6 how could you possibly expect someone in Ghana or some
7 other very small developing place to ever be able to
8 implement that sort of program?

9 So I bring this to your attention not that
10 it requires specific action by the part of the Committee,
11 but to make you aware that there is a whole other sphere
12 of activities, and that I would expect a number of things
13 that the IAEA and the WHO and others to be doing and
14 moving forward with this might well be things which you
15 as individual Committee members and some of the societies
16 and groups that you represent would want to become
17 involved in.

18 Ruth is shaking her head up and down. I
19 think the states and both OAS and particularly CRCPD will
20 want to get into a number of these because they are
21 actually more closely aligned with some of the work that
22 IAEA will be doing.

23 We, in fact, thought that Paul Schmitt
24 might be able to attend this, and when Paul was not able
25 to, that's why we defaulted back on a relatively short

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 time frame. We made the decision that this was the kind
2 of meeting developing actions where the U.S. simply
3 couldn't afford not to have some representation or to
4 make sure that they didn't move in a direction which
5 would get to be prescriptive and might have ramifications
6 coming back for our particular programs.

7 So there are going to be a lot of ongoing
8 opportunities. If this action plan is anything like some
9 of the other action plans that the International Atomic
10 Energy Agency has, it will assume a life of its own for
11 at least some period of time.

12 It will likely go through some updates and
13 revisions over the next two years as things start to be
14 accomplished and they start to look to what additional
15 things might be done. I would expect that they would
16 want to have a follow-up international conference to take
17 a look at progress that's being made.

18 No such thing has been scheduled, but I
19 would guess by 2004 or so they might be looking to have
20 another conference to assess the activities.

21 And with that I would be glad to entertain
22 questions or you might want to go with this other area of
23 activities.

24 Dr. Nag.

25 DR. NAG: I've been involved with the IAEA

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 consulting for the last about eight years, and I have
2 been involved in the developing section on the research
3 program, and one of the things they have done is taking
4 developing countries and pairing them with a number of
5 developed countries.

6 And we formulate what are the protocols that
7 can be used in developing countries to treat cancers, and
8 we develop the guidelines and we sort of supervise the
9 treatment there.

10 I think that's a very good exchange. We
11 give some of the brain power, and they have different
12 problems and different kinds of basic populations, and
13 you know, we help develop those.

14 We also do guidelines for things like
15 guidelines for developing countries, for HDR. Many
16 places are now using HDR, but they don't know how to use
17 them, and we had to develop guidelines for them.

18 And we have also done publications to
19 standardize brachytherapy in developing countries. So
20 those are things that have been ongoing now for the last
21 eight years.

22 DR. COOL: Yes, and this action plan will,
23 I think, continue those, maybe give them a little bit
24 higher hat in terms of some visibility and focus and
25 trying to move forward. A number of the things related

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to education, training, the best practices, guidelines,
2 a number of those things are the key components that
3 relate to this action plan and trying to get those sorts
4 of things available for use.

5 There was a recognition in the conference,
6 and I think it's also reflected in what Dr. Nag just
7 said, for some of these folks, I think it's fair to say
8 they don't have clue or they have very little clue.
9 They're out there on their own.

10 And that which we take for granted in terms
11 of being able to interact with peers, understand where
12 best practices are going doesn't exist. They don't have
13 an ongoing access to that kind of information.

14 So the first step and one of the themes of
15 this whole thing was can we arrange a system which will
16 enable anyone to make progress from where they are, and
17 some of the tools which now we might not want to have at
18 a very forceful level are, in fact, necessary to have
19 perhaps a higher degree of force within a country that's
20 just starting in order to be able to leverage the initial
21 steps of the process.

22 CHAIRMAN CERQUEIRA: Don, I saw the minutes
23 of the meeting and then some subsequent drafted minutes,
24 and PET got singled out quite a bit. There was quit an
25 emphasis on PET.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 But if you look at sort of penetration and
2 usage, it's relatively small. Did you get some idea as
3 to why PET was sort of identified as an area of concern
4 or need to monitor?

5 DR. COOL: It was viewed as something that's
6 emerging. At the risk of sounding just a little bit
7 silly, it was also a pet of several of the folks who were
8 there.

9 (Laughter.)

10 DR. COOL: As with all meetings of this
11 type, the individual specialties of some of the
12 representatives and their particular concerns tended to
13 show up in some of the discussions and activities.

14 So one of the things that I have found
15 interesting in a variety of international forums that I
16 have had the opportunity to participate in is the need to
17 actually sit back and literally change your hat, to take
18 a view with regard to where things need to go and the
19 things that are necessary in an international context,
20 which may be different from the local contexts.

21 And the degree to which the committee of the
22 whole was doing that varied a bit across the week, as you
23 might expect. So there was some discussions of all sorts
24 of modalities.

25 There was a great deal of focus on medical

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 physicists and the need to get more medical physicists,
2 and quite a bit of actually side bar discussion on the
3 fact that a number of the legislation and other
4 activities don't allow a medical physicist to be
5 recognized.

6 And so none of the regulatory authorities
7 believe that a medical physicist is necessary, and they
8 just draw a little arrow, and somewhere they're over
9 here, and how to get a recognition of the importance of
10 some of the components, again, that we more or less take
11 for granted as being important to a team, which for
12 various legal or other reasons haven't got that same
13 degree of recognition some other places.

14 CHAIRMAN CERQUEIRA: Jeffrey.

15 DR. WILLIAMSON: Yeah, well, it really is
16 challenging. I, too, have been involved in the IAEA
17 activities, and they're really trying to not just create
18 a regulatory system, but they're trying to leverage and
19 create basic quality assurance standards --

20 DR. COOL: Precisely.

21 DR. WILLIAMSON: -- and standards of
22 practice.

23 And you know, in this country standards of
24 practice arose independently and the regulatory system
25 came later as, you know, it was felt necessary to have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 oversight as a consequence of various instances. So they
2 really have a different challenge.

3 DR. COOL: Yeah, and just to reinforce that
4 point, something that I was attempting to allude to, but
5 you've made it a little bit more clear. A lot of the
6 standards and practices, standards of practice and
7 guidelines which we have at a level of the users in the
8 professional societies in which the NRC and others
9 deliberately stay out of so that you can continue to move
10 your best practices, in the international context at this
11 point need a much higher level.

12 They're actually talking about them in terms
13 of the regulator and others in order to get the initial
14 step of even getting anything in place. It's a bit
15 jarring, except for the recognition of the situations
16 which they're dealing with.

17 And part of what I was attempting to do was
18 to make sure that in the action plan and in the
19 activities that the descriptions and the flexibility was
20 such that that couldn't in some way inadvertently come
21 back to haunt us. And I think it's a challenge for all
22 of us as we participate in some of the various forums and
23 consultants and otherwise just to continue to promote
24 that message and help everyone make progress.

25 CHAIRMAN CERQUEIRA: Other questions for Dr.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Cool?

2 (No response.)

3 CHAIRMAN CERQUEIRA: Well, if not, thank you
4 for sharing your information with us.

5 DR. COOL: I appreciate the opportunity, and
6 as I said, I do hope to circulate some version of this.
7 If I don't have a final version within a few days, I'm
8 going to put out the report with the version that I got,
9 and at that point we will make sure that individual
10 members of the Committees have a copy of that so that you
11 can see where it is in its drafty state, unapproved by
12 the Board and heaven only knows.

13 CHAIRMAN CERQUEIRA: Thank you.

14 Now, is --

15 MR. HICKEY: I'm not sure if Mr. Lohaus is
16 going to be here on time, but Dr. Ayers is ready to
17 proceed in the meantime in any case.

18 CHAIRMAN CERQUEIRA: Good. Now, is anyone
19 aware of any groups that were coming to this meeting
20 specifically to hear the information on the Board
21 recognition who may be disadvantaged by having to switch
22 the time?

23 PARTICIPANT: Bill Malagan (phonetic) was
24 going to be here about 11:15.

25 CHAIRMAN CERQUEIRA: Yeah. I think he can

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 get enough feedback.

2 DR. AYERS: Good morning. I managed to get
3 my slides down.

4 Just to preface my presentation, my
5 presentation and what I'm going to talk about, the
6 Boards, is all predicated on the current draft new Part
7 35, not any dealing with any of the discussions which I
8 think were useful, and you're heading in the proper
9 directions on modifying the rule language, but for what
10 I have to work with now is what we have for the current
11 rule language.

12 CHAIRMAN CERQUEIRA: And, Bob, I think
13 realistically that's what we're going to deal with
14 because all that we've talked about with these other
15 changes would require a rulemaking, and that's going to
16 take some time.

17 DR. AYERS: Yeah.

18 CHAIRMAN CERQUEIRA: Is that --

19 DR. AYERS: Well, if I can have the next
20 slide, the Boards, just to review, that have applied in
21 one form or another for recognition are the nuclear
22 medicine, pharmaceutical specialties, medical physics,
23 health physics, Board of Radiology, and in the next slide
24 several others.

25 If I can have the next slide, please.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 The Board of Nuclear Medicine Radiology,
2 Science and Nuclear Medicine, and the Certification Board
3 of Nuclear Cardiology.

4 Next slide.

5 The American Board of Medical Physics
6 applied for recognition under 3551(a), which is authorize
7 medical physicist, and we're all aware of the problems
8 with the full recognition is not possible under the Board
9 system because of the specific requirements for training
10 in each of the modalities.

11 But it certainly does look like partial
12 recognition may be possible to work with the Board, and
13 what one or more of the components does the Board have
14 sufficient training in that could grant recognition?

15 And the recognized physicist could come in
16 as has been discussed previously with specific training
17 and experience, say, on the gamma knife for a teletherapy
18 unit or a vendor's training on the remote after loader
19 and add those authorizations.

20 CHAIRMAN CERQUEIRA: Bob, just how would
21 that be done? How would partial recognition be done?

22 DR. AYERS: Well, we're in the process of
23 preparing letters to the Board, and we ask -- and the
24 letter, the draft letter in this case says, "Well, okay.
25 Come back and tell us which one of these components does

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 your current Board recognition process encompass."

2 And if they can show us that it encompasses
3 one or two or more, we should be able to work towards
4 granting the recognition for 35, 400 manual brachytherapy
5 plus teletherapy, whatever the combination might be.

6 DR. WILLIAMSON: So when you say partial
7 recognition you mean four more modalities.

8 DR. AYERS: For modality based recognition,
9 yes.

10 DR. WILLIAMSON: Modality based recognition.
11 Well.

12 CHAIRMAN CERQUEIRA: Jeffrey, does that
13 answer some of the issues that we've brought up and how
14 could --

15 DR. WILLIAMSON: Not really. I mean, I'm
16 not sure that there is -- is there a requirement for an
17 authorized medical physicist in 35.400 at all, except for
18 decay of Strontium-90?

19 DR. AYERS: That's one of the requirements.

20 DR. WILLIAMSON: That's the only
21 requirement, right?

22 DR. AYERS: I'd have to review it in a
23 little more detail to answer your question.

24 DR. WILLIAMSON: But I don't believe that
25 they will be able to comply with any of those three.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. AYERS: Okay. Well, I mean, it's an
2 option if they are, and the letter is starting the
3 process of going back and forth to find out where we are.

4 DR. WILLIAMSON: I, frankly, think a more
5 fruitful approach or an additional approach you might
6 consider is to give them credit for if someone has this
7 ABMP certification, that that automatically takes care of
8 the various years of experience and is evidence for
9 having an appropriate degree.

10 DR. AYERS: Well, that's what you're talking
11 about in the rulemaking space.

12 DR. WILLIAMSON: No, I was talking about in
13 guidance space. You could use it as a criterion for
14 determining who meets the basic training and experience
15 requirements and, you know, hours of experience per se,
16 and having the degree. You could accept that.

17 DR. AYERS: Well, that's another form of
18 partial recognition, yeah. We can --

19 DR. WILLIAMSON: That's a form of partial
20 recognition.

21 DR. AYERS: Yeah, we could say four plus --

22 DR. WILLIAMSON: I believe you could
23 implement in guidance space to preserve some recognition
24 of the Board's certification process, and then you would
25 have to ask on top of this. You'd have to have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 reasonable criteria for supplementary training in these
2 three modalities.

3 DR. AYERS: Yeah, that's a form of the
4 partial recognition. The partial recognition imbeds in
5 it none of the specific modalities, but it says it meets
6 all of the training experience requirements, except the
7 specific device.

8 DR. WILLIAMSON: Yes.

9 DR. AYERS: The material which -- and that's
10 another four. This is what the process that we can work
11 on. That's one direction we can go.

12 CHAIRMAN CERQUEIRA: Dr. Nag.

13 DR. NAG: Yeah. One important thing, in
14 your impartial recognition, you have to give the credit
15 that when you have gone through a Board, you may not have
16 specifically done remote after load (phonetic), that
17 you're not getting your credit for after load, but you
18 got the 500 hours separately for the --

19 DR. AYERS: Yeah, that's what we were
20 talking about, yeah. That's a possibility, yeah. The
21 process is on hold now to start the information exchange
22 between us and the Board until the rule's status is
23 clarified.

24 CHAIRMAN CERQUEIRA: Bob, I kind of hate to
25 have brought you up here and now our other speaker is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 here. I think this is important and we should come back
2 to it and see if it could help us out of our dilemma to
3 some extent, but, John, do you think we should switch
4 gears here?

5 MR. HICKEY: Yeah. Mr. Lohaus is here. So
6 I think we should proceed.

7 DR. AYERS: And I just started.

8 MR. HICKEY: And Bob can come back to his
9 presentation later.

10 DR. AYERS: Right. I just started. I can
11 pick it up again after lunch.

12 CHAIRMAN CERQUEIRA: A few more
13 opportunities to skewer him. Okay.

14 DR. AYERS: No problem.

15 (Laughter.)

16 CHAIRMAN CERQUEIRA: Thanks for your
17 tolerance of the Committee here, Bob.

18 MR. HICKEY: I'd like to introduce Mr. Paul
19 Lohaus, the Director of the Office of State and Tribal
20 Program, and Mr. James Myers from the same office.

21 MR. LOHAUS: Good morning.

22 CHAIRMAN CERQUEIRA: Welcome.

23 MR. LOHAUS: I welcome the opportunity to
24 meet with you.

25 Let me recognize Jim Myers. I understand

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 you wanted to talk about the National Materials Program
2 and current status and where we're going. Jim was co-
3 chair for the National Materials Program working group,
4 along with Kathy Allen, who at that time was chair for
5 the Organization of Agreement States.

6 But maybe by way of background just a couple
7 of introductory remarks. Part of the genesis for the
8 National Materials Program really comes out of the growth
9 in the number of agreement states. If you look at the
10 number of states that were projected, we're at 32 today.
11 We're projected to go to 35 by FY 2004, and the
12 proportion of licensees that the agreement states had
13 responsibility for, really they're going to have about 75
14 percent of the total number of licensees in the country.

15 And in recognition of that, what the
16 Commission did is directed the establishment of working
17 group to look at options in terms of how should we
18 function in the future relative to our program, and
19 that's where the term for the National Materials Program
20 comes from, relative to both NRC and the agreement
21 states, given this continued shift in the program with
22 the states having the larger proportion of licensees.

23 And the process that was used was the
24 working group was set up of NRC and agreement state
25 staff, and they worked for about a year and a half and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 developed a report which was provided to the Commission
2 in May of last year, and we brought with us copies of
3 that Commission paper.

4 You may have copies. If not, we brought
5 copies. So if you'd like you can take a copy with you.

6 CHAIRMAN CERQUEIRA: Yeah, it would be good
7 to give it out to the Commission.

8 MR. LOHAUS: And basically what the working
9 group did is examined a number of options, and they range
10 from some rather what I would term drastic changes in the
11 program whereby you would shift the program back to NRC
12 having complete responsibility for regulatory
13 jurisdiction over all licensees in all states to an
14 option where all states would take over that authority,
15 with the exception of a few categories of licensees where
16 at least by current law NRC would need to maintain
17 regulatory jurisdiction.

18 For example, federal facilities where
19 jurisdiction resides with the federal government, as
20 opposed to the state government.

21 There were a number of middle options, and
22 the option that the working group settled on and is
23 really their recommendation is what's called an alliance
24 option, and basically the alliance option is a program
25 structure that's very reflective of the current evolution

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of the program today.

2 In other words, what it reflects is a
3 sharing of regulatory responsibilities among the states
4 and NRC. There would be a process of using centers of
5 expertise, for example; a process of using working
6 groups, coalitions of technical staff among the agreement
7 states and NRC to help develop regulatory products that
8 are needed to support the program, and those products
9 could then be used by either NRC or the agreement states.

10 It sort of pushed the envelope on this
11 concept, but at the same time, that option is reflective
12 of current evolution of the program where there's a lot
13 of activity and a lot of sharing in utilization of
14 expertise within both the states and within NRC staff to
15 address common problems, to identify solutions to those
16 problems, and help, you know, basically bring the best
17 expertise and the best talent to addressing those
18 problems.

19 There's a couple of questions or big issues
20 when you look at this that we're going to be examining in
21 some follow-on work, and one of these questions is: will
22 the states be able to take on increased responsibility
23 and provide the resources that would be necessary under
24 this alliance type concept, you know, if we were to move
25 in that direction, and produce a product on schedule that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 could be used by the states and also by NRC?

2 And at the same time there's sort of a
3 question on the other side, and that is, you know, will
4 NRC be able to use a product that's developed by the
5 states and fold that into its regulatory program without
6 a tremendous amount of additional staff effort. In other
7 words, there would be some savings and reduction in the
8 FTE loading that NRC would experience in terms of
9 development of the regulatory infrastructure and
10 supporting products that it would need for its program.

11 So what we have under preparation today is
12 a second paper for consideration by the Commission, which
13 would identify what I would term some pilot programs to
14 provide further opportunity for the NRC and the state
15 staff to work together, to help provide some of the
16 demonstrations that are, I think, necessary to help
17 support the concepts and the thinking that's reflected in
18 the working group report and their concept of the
19 alliance program.

20 And some of these pilots could be very
21 simple. For example, developing a new guidance document
22 or taking an existing guidance document and maintaining
23 that document up to date, in other words, insuring that
24 it meets current practice, reflects current state of the
25 art, et cetera.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Other cases it may be that there may be a
2 rule area that's identified that's in need of attention.
3 That may be an item that could be addressed through a
4 working group and a rule package prepared that could be
5 used both by the States and by NRC to address that
6 particular rule area.

7 But we're looking at a number of
8 different --

9 DR. WILLIAMSON: I'm sorry. Could you make
10 clear what alliance is as a regulatory structure and how
11 it differs from the current overall regulatory structure
12 with respect to the domain of NRC, whether it's NARM or
13 byproduct material? It's not clear at all what you're
14 saying.

15 MR. LOHAUS: Well, I think some of the
16 points you mentioned are some of the issues that would
17 have to be addressed as a part of this program.
18 Presently, as you're aware, NRC does not have regulatory
19 jurisdiction over NARM materials.

20 The states do. This is an area that the
21 Commission did ask the staff to prepare some proposals,
22 which are with the Commission for consideration. But
23 this is an issue that, you know, when I spoke earlier
24 saying the alliance sort of represents the current
25 evolution of the program, but there are additional parts

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to that that would need to be addressed in the future.

2 And this could certainly be one of the areas
3 in terms of whether NRC should assert and maintain
4 regulatory jurisdiction over NARM as a part of the
5 alliance process for those states where we have
6 regulatory jurisdiction or whether we would continue with
7 the current situation. But I think those are some of the
8 issues.

9 What I might do is maybe ask Jim if he could
10 maybe talk through in more detail some of the thing.

11 CHAIRMAN CERQUEIRA: People are getting kind
12 of anxious and raising their hands, and I kind of hate to
13 defer questions.

14 MR. LOHAUS: Okay.

15 CHAIRMAN CERQUEIRA: So maybe we could let
16 people ask questions to the specific things that you've
17 identified so far.

18 MR. LOHAUS: Sure.

19 CHAIRMAN CERQUEIRA: I mean, how many of you
20 are aware of this ongoing process?

21 (Show of hands.)

22 CHAIRMAN CERQUEIRA: So really it was only
23 Ruth, and I think the rest of us are a little bit --

24 DR. NAG: In the dark.

25 CHAIRMAN CERQUEIRA: -- in the dark about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 this, and I think it would be important here --

2 MR. HICKEY: Excuse me. Mr. Lieto had
3 requested a presentation on this topic.

4 CHAIRMAN CERQUEIRA: Which I think is very
5 important. I mean, Ralph is asking all of the right
6 questions, you know. Just as a new member, I think he's
7 -- and I think this is very important and really impacts
8 on a lot of things we've done with the Part 35 revision.

9 But why don't we take questions now and then
10 we could -- so Dr. Nag.

11 DR. NAG: Yeah. How would the role of the
12 ACMUI play in this National Materials Program? We are
13 giving our input to the NRC. How would that impact the
14 National Materials Program?

15 And the second thing is how would this
16 National Materials Program help to insure that there is
17 some similarity between the different states. For
18 example, you know, the rule in one state may be quite
19 different from the rule in another state, and doctors go
20 from one state to the other, and you know, that makes
21 some problems.

22 MR. LOHAUS: I think both of the items you
23 raise are very good questions and very good issues and
24 are things that would need to be addressed and explored
25 as a part of future work.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Let me back up and make a very clear
2 statement. There is no preferred option that has been
3 identified at this point in time. The report of the
4 working group was provided to the Commission for
5 consideration, and we are preparing the second paper I
6 mentioned, but I want to make a point that, quote, the
7 alliance option which was the preferred option
8 recommended by the working group, that the agency and the
9 Commission has made no decision yet relative to a
10 preferred option.

11 But in terms of the Advisory Committee, I
12 think you raise a good point. The Advisory Committee
13 would certainly continue, in my judgment, in my view, to
14 advise the Commission as it has in the past, but if we
15 were to head more towards an alliance structure, there
16 may be additional advisory considerations that the
17 Committee could play in terms of the broader National
18 Materials Program alliance structure.

19 CHAIRMAN CERQUEIRA: So it hasn't really
20 been considered.

21 I guess one question I would ask you is it
22 seems a little bit self-serving that the NRC hires the
23 states to come up with a plan and basically the
24 conclusion is make no change at all.

25 If we go back to the Institute of Medicine

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 review, which the NRC commissioned and which was released
2 in what, '95 and '96, they clearly made the point that it
3 should all go to the states, which I guess if we look at
4 page 1 in the very back, description of options and
5 assumptions for resource estimates, it would really be
6 the independent state option.

7 Why was that not, you know -- I mean, based
8 on that report, they felt that that was the best option,
9 to basically minimize the federal regulations and put it
10 at the state level, which 95 percent of all the radiation
11 that's used, ionizing radiation, is state regulated.

12 MR. LOHAUS: What I might do in this case is
13 defer to Jim as co-chair for the working group. I mean,
14 they went through a lot of discussions, a lot of
15 deliberations, obtained a lot of feedback in, I think,
16 their report, and their recommendation in that report is
17 reflective of the views of the working group, which was
18 both NRC and agreement state staff, as well as the
19 various input that they received.

20 CHAIRMAN CERQUEIRA: What about the
21 stakeholders, the physicians? Were they involved in any
22 way or was their input sought?

23 MR. LOHAUS: Jim?

24 MR. MYERS: Yes. Dr. Cerqueira, good to see
25 you again.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Yes.

2 MR. MYERS: It's been a while.

3 Let me just kind of paint a little bit of
4 what the vision of this is, with the understanding that
5 the Commission has not made a decision about alliance
6 structure or any of the other structures that were
7 proposed.

8 The working group wrestled with, and I think
9 quite openly came to the table and sat down and said,
10 "Well, okay. What's wrong and what do we need to do to
11 fix it, given the scope of the SECY paper that the
12 Commission asked us to look at some things?"

13 The issue is, and I think that initially
14 almost everybody came to the table and said, "Well, heck,
15 you know. Maybe this whole thing just needs to be thrown
16 out and we'll start again."

17 But I think through the process of
18 discussions, of laying out some very good objectives for
19 the working group to achieve, to try to do it in a
20 rational fashion, what we really came up with is that
21 what we have today is a pretty good system. It's not
22 perfect, and there's maybe no expectation that it would
23 ever be perfect, but there's certainly some things that
24 we can do that would in the context of what the
25 Commission asked us to do, would be to improve the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 process and basically to seek more input and advice and
2 perhaps even using products that are developed by the
3 states to do, you know, certain things in medical or it
4 could be GLs or whatever, to use those kinds of things
5 and incorporating them more into a national program than
6 they are now.

7 And maybe what comes to mind is that -- I
8 don't know. Since everybody is here and didn't see this,
9 but the FDA approved a new drug called Zevulin today.
10 That's just out. That uses Indium-111 and it used
11 Yittrium-90, and it's basically a therapy drug.

12 But if we used this as an example, you know,
13 you can envision today that there would be like 33
14 different regulatory agencies that would approach how to
15 license or regulate this particular therapy drug, and
16 what we would say is that maybe we need to have, for lack
17 of better terms, more of the working group approach,
18 where we get somebody who has some expertise in this
19 maybe -- I'll say the State of Texas, for example, maybe
20 the State of Georgia or Rhode Island, whoever has worked
21 on this -- and some NRC folks together to come up with a
22 template or a concept of how to regulate this and what
23 would be required.

24 That would then be subsumed by the national
25 program, meaning all of those organizations. So we don't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 have to reinvent it 33 times. We would take something
2 that's good, modify it for the individual use of the
3 state or the NRC slightly, and then be able to use it
4 right away.

5 And that was the idea of trying to get more
6 input from the states and do more of that. Clearly, the
7 working group recognized that perhaps it's not totally
8 efficient to drop NRC out entirely, but clearly the role
9 seems to be diminishing, and you can look at the
10 different scenarios down here.

11 Even if you had no other NRC licenses except
12 those in the military and the VA and some others, it's
13 still a tremendous cost to the agency, but it doesn't
14 solve the questions that the Commission asked us to look
15 at, is what do we do now that we don't have the
16 expertise. How do we regulate medical if we don't have
17 any hospitals and we don't have that emerging technology
18 like Zevulin or stuff to deal with?

19 So that's kind of how it came about, and the
20 report is kind of lengthy, but there is an executive
21 summary to it, and this report here that we just handed
22 out, I think, also kind of characterizes a lot of that
23 thinking.

24 CHAIRMAN CERQUEIRA: Jeff?

25 DR. WILLIAMSON: Yeah, well, it sounds a lot

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 like the Institute of Medicine report in terms of the
2 layout of your options, and certainly that was a highly
3 controversial report and probably one reason it was
4 discarded by the Commission and not followed, was that
5 the regulated community fragmented in terms of what
6 option they supported.

7 This Committee extensively reviewed that
8 report and looked at the options, and you know, the 50
9 independent state regulatory associations, that was
10 rejected by this Committee out of concern that there
11 would be absolutely no uniformity in any of the basic
12 regulatory structures or training and experience
13 requirements and so on that would really hamper the
14 practice of medicine.

15 So, you know, I think that would remain a
16 concern probably of this group if we came up with it
17 again, is how can uniformity be preserved, given this
18 tendency for the states to become agreement states.

19 MR. MYERS: If I can respond to that, on
20 page 2 of the handout that we did, about the middle of
21 the page, there's some bullets there. These are
22 essentially kind of the evaluation or they are actually
23 the evaluation criteria that the working group used,
24 obviously, protecting health and safety, optimizing
25 resources of federal, state, professional, and industrial

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 organizations, at the same time, we need to account for
2 individual needs and abilities of agencies, promoting
3 consensus, promoting an exchange of information, and you
4 know, harmonizing regulatory approaches.

5 These were all factors that we looked at,
6 and this is the way it breaks out if you use a decision
7 matrix and use these as part of your evaluation criteria.
8 You end up with the concept of the alliance as being the
9 one that is the most favorable in terms of achieving
10 those some six or seven objectives.

11 And I think that addresses your issue about
12 fragmentation and other things. Clearly there has to be
13 a partnership, I think is what the working group was
14 saying; is that somehow it has to come together so that
15 you do talk, do share information, and you have good
16 information exchange and a number of other things, and
17 we're to have a harmonious program nationally.

18 MR. LOHAUS: You know, the question of
19 national harmony, I mean, we use the term compatibility.
20 That's in our statutes, but that's an issue that has been
21 with the agreement state program from its inception and
22 will continue to be with us in the future, and I think
23 that there was focus within the working group, and it's
24 reflected in the criteria that Jim mentioned on this
25 question, that you need to maintain a degree of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 flexibility so that individual programs can address
2 legislative direction and other aspects.

3 But at the same time, there needs to be a
4 degree of consistency and harmony so that there is not
5 disruption, there's not major differences between
6 individual states and those under NRC regulatory
7 jurisdiction.

8 And we've tried to address this in the
9 Commission's adequacy and compatibility policy and our
10 implementing procedures, but it will continue to be an
11 issue. There will not be complete uniformity and
12 agreement among all the states from my experience in the
13 program. You will see differences, but my goal, and I
14 think the goal of this agency is to insure that there is
15 a level of harmony and coherence and consistency within
16 the programs across the nation, which we accomplish
17 through our compatibility part of the program.

18 The two aspects are the adequacy component
19 and the compatibility component, and what I've seen on
20 the part of some of the working groups is that in sharing
21 in the process of developing the regulatory product,
22 irregardless of what it is, but there's greater agreement
23 on the product and greater agreement on wanting to move
24 forward and implement that product in a consistent
25 manner.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And that's part of the concept, I think,
2 that is reflected in the alliance concept, is that using
3 a working group process, you would hopefully end up with
4 a product where there is agreement and there isn't wide
5 variation in terms of how that product would be
6 implemented.

7 So there is good consistency, and the
8 regulated community has assurance that it's going to be
9 predictable, consistent, and understandable. And I think
10 that's a goal not only of our program, but I think of the
11 states as well.

12 But at the same time, from my experience you
13 will see some differences, and there's not going to be
14 complete consensus in all cases. And to me it's a
15 strength that we see in the program because given some of
16 the differences in view and given different approaches,
17 that considering those and reflecting those actually
18 results in a better product that's going to serve all of
19 us in a better way.

20 And that's one of the strengths that I see
21 in that program.

22 CHAIRMAN CERQUEIRA: Dr. Nag.

23 DR. NAG: Yeah. What would the policy be of
24 the Materials Program? Would it have authority over the
25 states and be, you know, more like a coordinating body

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 among the various groups?

2 MR. LOHAUS: Are you speaking with respect
3 to NRC or the alliance itself?

4 DR. NAG: The alliance.

5 MR. LOHAUS: See, the NRC, over oversight
6 responsibility in our oversight program would not change.
7 When you look at the alliance option, there's a very
8 clear role that NRC would continue with the integrated
9 materials performance evaluation program, the current
10 program we use for review of both the state and our
11 regional materials programs.

12 So NRC would continue with its oversight
13 program, and that responsibility would not change. So,
14 you know, if there are cases where there are both issues
15 with respect to the adequacy in a program and issues with
16 respect to compatibility, we would be able to address
17 those through our review program.

18 DR. NAG: Right, but is the National
19 Materials Program a separate entity, a separate body? If
20 it is, what is the authority between the National
21 Materials Program, the NRC, and the different states?

22 I'm somewhat confused. I might be --

23 MR. LOHAUS: Again, you raise to me a very
24 good issue with respect to the alliance, and I'm going to
25 ask Jim to also comment here, but part of what you do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 come away with when you do think about this is you think
2 of the alliance as a separate entity, and it may not be
3 a wholly identified separate entity as much as a
4 structure or process structure in which the NRC and the
5 states will function in the future.

6 And, on one hand, you could say, well, we're
7 going to have an alliance organization, and I've had
8 difficulty in my mind trying to understand if there was,
9 quote, an alliance organization. What is that? What's
10 it made up of? What does it do? Who's it responsible
11 for, et cetera?

12 But, on the other hand, I can also look at
13 it from the standpoint that it's a process relating to
14 how NRC and the states will interact and function in the
15 future, and as such it's not a clearly identifiable
16 entity.

17 But, Jim, I know you all wrestled with this,
18 and maybe you can help add some perspective on this.

19 CHAIRMAN CERQUEIRA: How is it different
20 than what we're doing now, I guess, is one question that
21 can be asked.

22 Jim?

23 MR. TERAQ: Yeah, this is a real, real tough
24 thing to kind of characterize, but it is more of a
25 process than a physical entity. That's for sure. It's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 a process that's made up of the different organizations,
2 and that would include ACMUI. It would include other
3 standard setting organizations. They are kind of plug
4 and play. As they need to come in and interface into the
5 alliance process or into a rulemaking process, we would
6 expect that that would happen.

7 I think what we see is what's different
8 about this is the fact that as the current system exists,
9 there are conflicts and there are stresses and there are
10 demands that are placed upon all of the states and on NRC
11 that are many times conflicting, and they consume a lot
12 of resources, either, you know, money or it could be
13 energy, a lot of different things.

14 And through the process of like the
15 conference where we have some committees that work and
16 those are well established, the OAS was another
17 organization the Commission asked us to integrate into
18 this working group; in looking at the whole thing, what
19 we saw was that, well, the process itself that we use
20 today really isn't terrible. It just isn't, but there
21 are some conflicts with it, and there certainly seems to
22 be a better way of doing business.

23 And how to do that would be perhaps to come
24 together. This is in theoretical space, is that at some
25 national meeting or it could even be a virtual meeting as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 far as we were concerned; is that you would establish
2 some national priorities, maybe getting some regulatory
3 guidance out, and how to regulate Zevulin, for example
4 would be a national priority at this point in time.

5 And we would bring together what we call
6 centers of expertise to work on that issue, and then they
7 would, again, share that with the alliance, and for
8 everybody to use versus individuals going out and doing
9 the work, which seemed to be counterproductive.

10 CHAIRMAN CERQUEIRA: I think we all
11 understand the concept and the potential for doing it,
12 but I guess just in terms of being pragmatic, I'm just
13 not quite certain what new entity or structure you're
14 going to create that would create this harmony,
15 compatibility.

16 We've had multiple discussions here amongst
17 the group just in terms of training and experience
18 requirements and how the difficulties we're going to have
19 once those get implemented and this three year lag
20 period.

21 But I think Ruth has had her hand up, Niki,
22 and then Jeff always has a question. So --

23 MS. MCBURNEY: Just coming from a stark
24 regulatory perspective, the way that I see this occurring
25 is it's going to have a greater role and responsibility

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 for the state, for the agreement states in that the
2 states are going to have to put forth more resources.

3 An example of that was that there were two
4 state people on the Part 35 working group, and they had
5 to commit a lot of time away from their regular jobs to
6 do that, but the states are willing to do that and also
7 a greater role in setting the priorities for rulemaking.

8
9 For example, several years ago the State of
10 Texas decided that the training of industrial
11 radiographers was a key priority, and we went ahead and
12 set up a certification program. And several years later
13 then the Nuclear Regulatory Commission adopted similar
14 regulations. So it is now a national program.

15 So the way I see this National Materials
16 Program working is that the states, along with the
17 Nuclear Regulatory Commission, would set some national
18 priorities for rules and procedures and so forth, and
19 then establish the working groups to work together to
20 come up with that so that everybody is not trying to
21 reinvent the wheel, that we're not having to commit a lot
22 of resources just to do it in our own state, that it can
23 be more of a national program.

24 CHAIRMAN CERQUEIRA: Again, I think the
25 concept is commendable, but just the structure is a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 little bit unclear.

2 Maybe, Niki, you were having a comment?

3 MS. HOBSON: Well, that's precisely my
4 question. Could you draw us an organization chart and
5 show how this thing is going to work?

6 DR. WILLIAMSON: Let me just express my
7 question, which is relevant. Could you describe the
8 potential statutory changes that would have to be made to
9 implement the alliance? Maybe that would help us
10 understand.

11 MR. LOHAUS: Okay. I'll answer the
12 questions in the order.

13 CHAIRMAN CERQUEIRA: In two minutes.

14 MR. LOHAUS: One is I don't think we can
15 provide an organization chart for the, quote, National
16 Materials Program or for the recommended alliance option
17 at this point in time because I don't think they're
18 sufficiently clearly defined.

19 But what we need is a recognition and a
20 sensitivity, and it's reflected in your comments and your
21 concerns in the issues you're raising. And you are
22 raising very good questions and very good issues, that as
23 we move forward, there needs to be a recognition that NRC
24 shouldered and really, you know, NRC licensees, given our
25 fee system, shouldered, and the lion's share of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 regulatory cost, if I can use that term, for maintaining
2 the infrastructure of supporting regulations and
3 standards.

4 And from an equity and fairness standpoint,
5 if you look at this from the standpoint of proportion of
6 licensees, a question is: given that the states are
7 regulating about 70 to 75 percent of the total licensees,
8 should they play a greater role and responsibility in the
9 resource costs for maintaining that infrastructure?

10 And along with that goes the responsibility
11 to maintain consistency and coherence, and that's the
12 issue that the Commission framed for the working group,
13 and that's the issue that is still there, that we're
14 continuing to wrestle with, and it's a National Materials
15 Program issue.

16 And you can look at different approaches on
17 how we might want to address that. You can look at
18 legislative issues. For example, one legislative issue
19 could very well be with respect to whether NRC should
20 assert broader regulatory jurisdiction over naturally
21 occurring in accelerator produced materials, for example,
22 or whether it should be limited to all accelerator
23 produce materials or just those that are used in medical
24 applications.

25 But I think, Jim, you may want to comment

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 here.

2 I think the sense of the working group was
3 that there were probably only two areas where legislation
4 might be required, and that really depended on where you
5 saw the National Materials Program headed.

6 One related to the regulatory jurisdiction
7 over norm, and the second related to the question of
8 whether jurisdiction over federal facilities, which is
9 sort of a reserved federal authority, whether there
10 should be some consideration of either changing that or
11 providing a mechanism where the states could pick up --

12 CHAIRMAN CERQUEIRA: So those are the two
13 areas, but maybe --

14 MR. LOHAUS: Jim, did you --

15 CHAIRMAN CERQUEIRA: I want to try to wrap
16 this up a little bit, maybe get a few questions from the
17 Committee, and then see if the Committee is going to
18 recommend some action on this.

19 Ralph, I want to thank you for bringing this
20 to our attention.

21 MR. LIETO: Well, you know, everybody is
22 trying to get a handle on, you know, physically what this
23 is, and I don't know if this would be an appropriate
24 analogy, and I would ask this to Jim.

25 Would this be sort of a concept that would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 be similar to CRCPD except you've got a federal? It's
2 sort of a federal type of a situation with the Conference
3 of --

4 CHAIRMAN CERQUEIRA: CRCPD?

5 MR. LIETO: CRCPD, excuse me. And --

6 CHAIRMAN CERQUEIRA: No, no, no. What does
7 it --

8 MR. LIETO: Conference of Radiation Control
9 Program Directors.

10 DR. NAG: What do they do?

11 MR. LIETO: Well, that's sort of a national
12 group of all the state radiation control program
13 directors that meet. I'm going to say it's more a
14 professional group rather than a regulatory group, but
15 they come out with national recommendations of state
16 regulations, and so forth.

17 And it sounds like this is sort of analogous
18 to that, except one of the partners in this group is the
19 federal agency, the NRC. And would that be an
20 appropriate analogy, taking into account that every
21 analogy has its weaknesses, but would that be some way so
22 that the Committee could get a handle on what this
23 working group is intended to try to develop?

24 MR. MYERS: I think it's what we were
25 envisioning as something that's Conference-like. Okay?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And the difference is that Conference has, for good
2 reasons, has its hands in a lot of different things, and
3 it's a very complex organization. What I think has to
4 happen with it is that the concept would have to be
5 broadened somewhat so that you get more of a national
6 regulatory perspective, again, involving all of the
7 federal players, whether it's FDA, NRC and others that
8 have an interest in radiation protection, to bring them
9 into this kind of a partnership or alliance concept
10 basically to kind of set out national priorities and then
11 to follow up on the accomplishment of those tasks
12 associated with the priorities.

13 We didn't envision that we would create
14 another NRC-like structure of some 3,000 people or so to
15 kind of oversee all of that, but it would be basically
16 made up of perhaps parties who had special expertise. It
17 could be volunteers on the part of the states or other
18 NRC employees to work on that at the direction of their
19 organizations, to kind of ride herd on that process at
20 least initially.

21 CHAIRMAN CERQUEIRA: I guess, you know, part
22 of the discomfort that I'm sort of sensing from the
23 Committee is that, you know, these are all very nice
24 concepts, abstract, organizational structures, but we
25 don't see enough of the framework on how to best

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 structure it.

2 And I guess, you know, I'd sort of like to
3 find out from the Committee. I mean, is this something
4 that we should have been involved in? Is this something
5 that we should be involved in in the future?

6 And certainly as a user, I guess the
7 question I would ask is how is this going to make my life
8 any different? Is it going to relieve all of this
9 regulatory burden that I experience down at Georgetown
10 every day?

11 If it does, I'm all for it. But if it
12 doesn't, you know, big government is great, but if it's
13 not going to help me, I'm not so sure.

14 So what's the sense of the Committee?
15 Should we have been involved?

16 MR. LIETO: Well, one reason I brought this
17 up is because it talked about stakeholder input.

18 CHAIRMAN CERQUEIRA: Right.

19 MR. LIETO: And it wasn't clear to me who
20 the stakeholders were, and it appears now it was just the
21 states.

22 CHAIRMAN CERQUEIRA: And the NRC.

23 DR. NAG: And the NRC.

24 PARTICIPANTS: No.

25 MR. LIETO: Well, I mean, they were not --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. WAGNER SCHWARZ: But the users are not?

2 MR. LOHAUS: I'd like to maybe separately
3 have Jim respond to the opportunity for stakeholder input
4 because there was a lot of opportunity.

5 CHAIRMAN CERQUEIRA: Sure. Can you describe
6 that perhaps, Jim?

7 MR. LOHAUS: Please, yes.

8 MR. MYERS: Yes. We are very concerned
9 about stakeholder input, and everything we did was
10 totally public. It was all announced. It was all there.

11 CHAIRMAN CERQUEIRA: Yet the Committee
12 didn't know about it, and we are representing
13 professional medical societies.

14 MR. MYERS: I would say that, you know, we
15 made sure that things were Internet available constantly.
16 We had a stakeholders meeting specifically in Arlington,
17 Texas in January of 2001.

18 CHAIRMAN CERQUEIRA: And who attended from
19 the medical community?

20 MR. MYERS: I don't have the list here, but
21 I can provide that to --

22 CHAIRMAN CERQUEIRA: Any organizations?

23 MR. MYERS: Oh, yes.

24 DR. NAG: Who are the stakeholders? You are
25 talking about stakeholders. Who are the stakeholders?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. MYERS: At that particular meeting, and
2 I'm sorry. I just didn't bring the notes on the meeting,
3 but basically we invited folks from Health Physics
4 Society. There was a gentleman from Texas who was with
5 the Texas Health Physics Society. There was others.

6 We even got people in low level waste
7 issues, you know. So that was quite a broad based thing.

8 MS. McBURNEY: I thought somebody was there
9 from the Society of Nuclear Medicine.

10 MR. MYERS: And we had some folks from the
11 Society of Nuclear Medicine and others there.
12 Regrettable --

13 CHAIRMAN CERQUEIRA: The therapeutic
14 community?

15 MR. LOHAUS: I believe ACR may have been
16 represented.

17 MR. MYERS: Yeah, ACR was there.

18 MS. WAGNER SCHWARZ: And ASTRO.

19 MR. MYERS: And ASTRO as well.

20 CHAIRMAN CERQUEIRA: I guess I'm just not
21 tuned in. I mean, Dr. Diamond, were you aware?

22 DR. DIAMOND: No one at ASTRO let me know
23 about it.

24 MR. LOHAUS: One thing. You know, being
25 sensitive to your point, Dr. Cerqueira, one thing we can

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 do in the future is meet with you at your regularly
2 scheduled meetings or periodically and give you an update
3 on where we are.

4 Again, another point maybe to try and put
5 this in perspective for you in terms of timing, I don't
6 see this happening immediately. This is going to be a
7 long process.

8 CHAIRMAN CERQUEIRA: No. Part 35, we've
9 been involved in what, Jeffrey? Fifteen?

10 DR. WILLIAMSON: Five years, six years.

11 CHAIRMAN CERQUEIRA: Yeah, and so I think,
12 again, this is the reason we're all here, is that we
13 represent stakeholders in the medical use, and we
14 certainly would like to find out about changes that are
15 going to affect this and would like to have input.

16 And perhaps that was provided, but certainly
17 the people at the table who were fairly involved were
18 unaware of it.

19 Maybe it was the fault of the societies for
20 failing to give us the information, and I don't think we
21 disagree with some of these approaches, but I think I've
22 learned to be a little bit more pragmatic about these
23 things, and I think that would be helpful.

24 What's the sense of the Committee? Is this
25 something we should be involved in and what role?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: Can I? I just want to expand
2 about the stakeholder issue.

3 CHAIRMAN CERQUEIRA: Yeah.

4 MR. LIETO: And when I found out about this.
5 I don't mean to portray this negatively, but one of the
6 things I wanted to bring to the Committee, because it
7 seemed to me to indicate this is a direction where the
8 NRC is going, which as an Advisory Committee obviously we
9 want to be at least sensitive to maybe some significant
10 changes in where the Commission plans on taking the
11 regulation of radioactive materials.

12 So that was one reason that I think we need
13 to be aware of because I think this alliance concept kind
14 of -- it's much different than what I think any of us had
15 thought NRC would be going in terms of the future.

16 And the other thing that came out at least
17 of this article on the summary of the working group was
18 that it pretty much said that the NRC needs to seek
19 authority to regulate NARM material, and that it seemed
20 to be sort of a linchpin in order to make this alliance
21 concept to go forth.

22 Now, maybe that's a strong term, "linchpin,"
23 but it seemed like it was very, very critical to making
24 this work with the states. I mean, I'm definitely in
25 favor of it personally, but I think, again, it was to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 make the Committee aware of where what's going on with
2 the Commission, that maybe we're not quite aware of on
3 the medical side, especially in light of PET.

4 You know, Sally was bringing up yesterday,
5 you know, it's really important that we need to have some
6 consistency in the regulation of radioactive materials
7 both, I think, on the NARM and the byproducts side.

8 MR. MYERS: If I could just make a quick
9 comment in there, the working group did not, and in fact,
10 the way the report is written, it's pretty clear we did
11 not say that the agency had to seek that authority to
12 regulate NARM materials and then to go to alliance.

13 Actually you could go through the alliance
14 process and seek the regulation. It's just that if the
15 agency would seek that and seek to regulate it, we
16 believe that you would have a more uniform program
17 because it would begin to kind of pull things together
18 that are kind of untidy out there from a regulatory
19 standpoint.

20 And as you know, NRC does not regulate that
21 stuff right now, and that's an issue.

22 CHAIRMAN CERQUEIRA: Yeah, that's obviously
23 an issue that's been present all along.

24 I'd like to try to wrap this up because
25 rather than an hour and a half for lunch, I'd like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 give us an hour, and we'd reconvene at quarter to one.

2 But, Ralph, did that address any other
3 comments?

4 Dr. Nag had one last.

5 DR. NAG: Yeah. As far as funding and who
6 is footing the bill for the extra bureaucracy? And is it
7 going to be from the licensee again? You know, we made
8 separate funding for the agreements, state licensing, and
9 then the NRC, and then a different program.

10 MR. MYERS: I would say that as envisioned
11 by the working group and absent the decision by the
12 Commission as to what option that they want to choose, we
13 did not see that there would be any additional cost in
14 doing this because it's part of kind of rechanneling some
15 of the resources that are already out there and making it
16 more efficient versus -- in other words, I wouldn't
17 envision you would get a bill from the alliance for their
18 services for the next year.

19 CHAIRMAN CERQUEIRA: Not directly perhaps,
20 but --

21 MR. MYERS: But it would be somehow folded
22 into existing processes and as the states do today. I
23 mean, they provide resource and so forth, and that's not
24 really --

25 CHAIRMAN CERQUEIRA: Yeah. If the state or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the federal government are doing it, it's better than the
2 stakeholders.

3 Sally, one last comment, and then I want the
4 Committee to give me some direction on where we should
5 go.

6 MS. WAGNER SCHWARZ: I actually do have a
7 question just about whether the NRC has actually made
8 progress or made steps to actually contact states to find
9 out those interested in giving over state regulated
10 materials to the NRC. Have they actually begun
11 discussing this with the states?

12 I did see something that was sent to the
13 State of Missouri. This is why I'm curious, and I wasn't
14 aware that it was a formal effort, but that something was
15 sent and asking about the interest of having the NRC take
16 over regulation of NARM. And I'm wondering if that was
17 done to all non-agreement states.

18 MR. LOHAUS: There were two things -- I'm
19 sorry. Go ahead, Ruth.

20 MS. McBURNEY: There have been resolutions
21 passed at the Organization of Agreement States meeting in
22 I believe the Conference of Radiation Control Program
23 Directors encouraging this legislation.

24 MR. LOHAUS: That's correct, and there were
25 two things that were done. One is the Chair of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Organization of Agreement States did do a I'll use the
2 term "informal survey" of the states, and when we were
3 developing the paper for the Commission in response to
4 their asking for some feedback from staff on this issue,
5 we did work with the Conference of Radiation Control
6 Program Directors to help identify whether there were
7 strong views among the different states one way or the
8 other.

9 So we had some sense of where the states are
10 when we reported back to the Commission. So that is the
11 genesis, I think, of this.

12 MS. WAGNER SCHWARZ: Were they favorable,
13 the majority?

14 MR. LOHAUS: Yes, they were, yes.

15 CHAIRMAN CERQUEIRA: All right. Jeff, maybe
16 you could ask your question afterwards because we should
17 break.

18 DR. WILLIAMSON: I just wanted to make a
19 comment.

20 CHAIRMAN CERQUEIRA: All right. One
21 comment.

22 DR. WILLIAMSON: My comment is I think I'm
23 rather concerned and alarmed at the thought of NRC
24 expanding its jurisdiction over additional materials
25 because it was not too long ago when NRC regulations

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 destroyed the economic viability of certain treatment
2 modalities.

3 And so for me personally, it would take a
4 lot of --

5 CHAIRMAN CERQUEIRA: Yeah, that's -- that's
6 --

7 DR. WILLIAMSON: -- convincing before I
8 would find that acceptable.

9 I think if the problem is paying for the
10 regulatory infrastructure that NRC provides for byproduct
11 materials, perhaps you should go back to Congress and ask
12 for a different funding mechanism so that it's paid for
13 out of the general revenues rather than penalizing the 18
14 non-agreement state licensees.

15 MR. LOHAUS: That's certainly an option, and
16 I believe that's -- Jim, correct me if I'm wrong --
17 that's recognized within the working group report.

18 CHAIRMAN CERQUEIRA: Right. Now that's
19 good.

20 Now, what are the wishes of the Committee?
21 I mean, I certainly got the sense that people feel that
22 this is an important development and there should be more
23 involvement, input from the Committee. Is that the
24 general consensus? I mean, anybody would disagree?

25 DR. NAG: I would support that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: And how do we do that,
2 John and Paul, Jim? I mean --

3 MR. LOHAUS: One thing --

4 CHAIRMAN CERQUEIRA: -- we haven't been
5 asked, you know, to come to the dance, but is there a
6 dance card? Can we sign up?

7 MR. LOHAUS: I mean, I guess one thing that
8 I can do is provide information to the Committee, you
9 know, for example, as we're doing today. Give you a
10 briefing and --

11 CHAIRMAN CERQUEIRA: That would be a good
12 start, and just, you know, even a full --

13 MR. LOHAUS: -- keep you up to date.

14 CHAIRMAN CERQUEIRA: Yeah.

15 MR. LOHAUS: And if there's areas that you
16 see are of concern or interest and you want to report out
17 on those areas, it gives you an opportunity to do that
18 early and have an opportunity to influence the outcome
19 and considerations.

20 CHAIRMAN CERQUEIRA: That would be a good
21 start, and I think just sort of a list of the
22 stakeholders who attended these meetings. Again, the
23 fact that a lot of us weren't aware of it, I mean, I
24 would just like to see if there was representation from
25 the cardiology community, from the radiation oncology

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 community. I think that would be important.

2 MR. LOHAUS: We could provide that to you,
3 sure.

4 CHAIRMAN CERQUEIRA: How can the Committee
5 get more involved in this?

6 DR. NAG: May I suggest --

7 CHAIRMAN CERQUEIRA: Sure.

8 DR. NAG: -- that you examine either by an
9 observer or if you want to nominate someone else.
10 Someone from ACMUI, whether an examiner or someone else,
11 be part of that working group or at least be an observer
12 in the working group.

13 MR. LOHAUS: The working group is sunsetted.
14 It completed its product. So the working group is
15 basically sunsetted. It no longer exists. The product
16 is completed, and as I said, what we're doing now is
17 working on a follow-on paper to address the --

18 CHAIRMAN CERQUEIRA: But is there a final
19 document that's gone to the Commission?

20 MR. LOHAUS: Yes, there is. We can provide
21 that to the Committee.

22 CHAIRMAN CERQUEIRA: Well, but the
23 recommendations weren't that clear, you know, in just the
24 cursory time that I've had to look at it in terms of
25 where to go. Maybe there's more in the --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LOHAUS: You will find no recommendation
2 in the Commission paper from the staff, but the
3 recommendation of the working group in their report was
4 the alliance option. That was the working group's
5 recommendation.

6 But I want to emphasize again these are
7 issues that are under consideration. There has been no
8 decision reached, and you're correct. That paper does
9 not have a recommendation there.

10 There are options that were provided for
11 consideration, and --

12 CHAIRMAN CERQUEIRA: Well, I think, you
13 know, the Commissioners said that they really value the
14 input of this Committee into these kind of decisions
15 makings, and I think here's a situation where, you know,
16 we weren't even asked to participate or be involved, and
17 so you know --

18 DR. NAG: We weren't even aware of it.

19 CHAIRMAN CERQUEIRA: Yeah. That's even more
20 distressing.

21 And so what are the wishes of the Committee?
22 So we can't be involved in this because it's been done.
23 I mean, Ralph, we should see the final report, but should
24 we make some recommendations to the Commissioners on
25 this?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: Well, I guess I'm going to kind
2 of ask John. I mean I take it that the working group's
3 sunset. The parties are still there, okay, and that
4 whatever, you're waiting to hear back from the
5 Commission. Is that what the next step is?

6 MR. LOHAUS: The paper is before the
7 Commission.

8 CHAIRMAN CERQUEIRA: Well, when did it go
9 into the Commission?

10 MR. LOHAUS: In May, but I want to make it
11 clear --

12 CHAIRMAN CERQUEIRA: In May?

13 MR. LOHAUS: In May of last year, but again,
14 there was no staff recommendation. There were items;
15 there were options that were provided for consideration,
16 and there's an expectation that the Commission has that
17 there will be additional material provided to them to
18 assist them in consideration of that paper and in
19 reaching a decision at the right point in time.

20 So it's under consideration. That's why I
21 want to emphasize these are issues that are under
22 consideration. There's not a hard decision that's been
23 reached, and they are issues that we're going to
24 collectively need to continue to wrestle with.

25 One thought I'll pass on for consideration.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 We can provide a copy of the report to you.

2 CHAIRMAN CERQUEIRA: Well, we agree that
3 that's critical to be done.

4 MR. LOHAUS: And maybe in looking at that
5 report if you see areas where you believe there would be
6 benefit and there are views that you'd like to provide to
7 the Commission, it's an opportunity to provided those.

8 DR. NAG: May I suggest that once you have
9 provided us the report, we look through it, make a
10 comment, and then send it to the Chairman, and then the
11 Chairman can compile a joint report from all of us and
12 send it to the Commission.

13 CHAIRMAN CERQUEIRA: I think that would be
14 the best way to do it. I'd also like to personally, you
15 know, contact the Commission and say that, you know, to
16 not be involved or informed is really not taking
17 advantage of the Committee and the time that we've put
18 into it.

19 You know, in a sense I feel, you know,
20 slighted. We're basically not -- you know, we have a
21 Committee. We all spend lots of time and effort in
22 coming to these meetings, and here's an issue, which is
23 probably as important as Part 35 revision, and we've
24 basically been left out of the loop.

25 MR. MYERS: If I could, Dr. Cerqueira.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Yes.

2 MR. MYERS: I would say this. I don't think
3 anybody on this Committee should feel slighted or
4 anything. We at the working group level really, I think,
5 spent a lot of time trying to make sure that we made
6 interested parties or folks, stakeholders, as we want to
7 call them, aware of this, and there were a huge number of
8 folks in different organizations that were contacted.

9 I will have to say, and as co-chair I will
10 take the hit for this, is that I don't really think that
11 we thought about ACMUI in that process. So if we -- if
12 anything was wrong, we didn't think about you all, and
13 the fact that although we know that you guys would have
14 some input and concerns and questions about it, it's just
15 thinking back on it is like I don't think that we, the
16 working group, really looked at that thing, and that's
17 important.

18 So what we'll do is we'll make sure that you
19 get a copy of the report, and as you know, the Commission
20 has not made a decision. The working group folks are
21 still there, but we're kind of like old baseball players,
22 I guess, or something. We're on the bench for a while,
23 whatever.

24 So if the Commission decides that it needs
25 more input, the Commission would have to decide that it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 would constitute the group, reconstitute the group, a new
2 group. You know, I can't --

3 CHAIRMAN CERQUEIRA: I think that would be
4 -- that should be done, but we'd still -- I think the
5 feeling of the Committee is we should still get the
6 report and get some comments.

7 MR. MYERS: Sure.

8 CHAIRMAN CERQUEIRA: So Jeff and then Niki.

9 DR. WILLIAMSON: yeah, I would make a motion
10 that the Chairman direct the ACMUI to review the report
11 and subsequently develop a position or consensus within
12 the Committee as to the wisdom of enlarging NRC's
13 jurisdiction.

14 MS. WAGNER SCHWARZ: I second that motion.

15 DR. WILLIAMSON: To include NARM.

16 CHAIRMAN CERQUEIRA: Okay. Discussion?

17 (No response.)

18 CHAIRMAN CERQUEIRA: The motion --

19 MR. HICKEY: Well, Mr. Chairman, could I
20 just clarify that? That's a resolution that does not
21 necessarily relate to this working group report directly.

22 CHAIRMAN CERQUEIRA: Right.

23 MR. HICKEY: It can be taken as a separate
24 issue.

25 DR. WILLIAMSON: But I think it's an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 important issue for us to consider --

2 MR. HICKEY: Okay.

3 DR. WILLIAMSON: -- and be aware of the pros
4 and cons. And there may be pros that I, for example, am
5 unaware of, and I think it's well for this Committee to
6 have a point of view --

7 CHAIRMAN CERQUEIRA: Right.

8 DR. WILLIAMSON: -- on this matter and be
9 prepared to communicate it to the Commission at the
10 appropriate time.

11 MS. WAGNER SCHWARZ: I agree. I think that
12 this is a significant --

13 DR. WILLIAMSON: So this is really very
14 serious.

15 DR. NAG: I think that we should, after we
16 have reviewed this report so that we have an idea what
17 the report --

18 DR. WILLIAMSON: That's what I just said.
19 I said that the Chairman -- I move that the Chairman
20 direct the Committee, the ACMUI, to review the final
21 report of this group and then develop at our next meeting
22 a consensus on the wisdom of enlarging NRC's
23 jurisdictional mandate to include NARM.

24 CHAIRMAN CERQUEIRA: Well, review the report
25 and make recommendations. You know, the wisdom to expand

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 may not be part of it. I'm not sure we can -- so I think
2 the recommendation to review and comment on the report is
3 probably, you know, the more appropriate.

4 Do we have a second on that?

5 DR. NAG: I would second the revised motion.

6 CHAIRMAN CERQUEIRA: Okay.

7 DR. NAG: And I would like to add a time
8 line, please. I mean, by what time? Are we going to
9 meet forever? Are we going to have a one month or you
10 know? Are you going to write the report within one week?
11 You know, some type of time line should be added.

12 CHAIRMAN CERQUEIRA: Well, how hard does the
13 Committee want to -- a month? A month? Jeff, a month?

14 Okay. A month, good. All right. That
15 sounds reasonable. So we had a second with the
16 amendments.

17 Any further discussion?

18 (No response.)

19 CHAIRMAN CERQUEIRA: All right. I move that
20 we vote.

21 MR. MYERS: I have one question --

22 CHAIRMAN CERQUEIRA: Yes.

23 MR. MYERS: -- just so we can cover this.
24 How many members are on the ACMUI now? Eight?

25 MR. HICKEY: Thirteen.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. MYERS: Thirteen? Okay. So I'm just
2 trying to figure out how many copies.

3 MR. HICKEY: We're not all here.

4 MR. MYERS: Okay. So we need at least 13
5 copies. Okay.

6 MR. LOHAUS: We'll try and get 13 copies to
7 you today.

8 CHAIRMAN CERQUEIRA: Well, if you can get
9 them today so that we can carry them home. How many
10 pounds is this, 30?

11 MR. LOHAUS: It's a two volume report. It's
12 maybe about, I'd say, a quarter to half an inch thick
13 total. Does that sound about right, John.

14 CHAIRMAN CERQUEIRA: All right.

15 MR. MYERS: It's probably about --

16 MR. LOHAUS: This is available
17 electronically also, Jim, on our Web site. So we can
18 give you the URL for it also.

19 CHAIRMAN CERQUEIRA: I'm not sure it's
20 critical to get it to the Committee today. I think we
21 should make it available, and I think Angela could
22 overnight it to people. If people want it
23 electronically, I think that would be the preferred
24 method.

25 But we have a motion that's been seconded

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and discussed, and I call for a vote on this. All in
2 favor?

3 (Chorus of ayes.?)

4 CHAIRMAN CERQUEIRA: And opposed?
5 Abstentions?

6 (No response.)

7 CHAIRMAN CERQUEIRA: None. Okay. So I make
8 the recommendation.

9 And how do people feel? Should I talk to
10 the Commissioner about that this Committee feels left
11 out, slighted?

12 MS. WAGNER SCHWARZ: Yes.

13 MS. HOBSON: I can hardly believe that a
14 major policy change like this has just sort of slipped
15 through with, you know, not very much public comment at
16 all, and I think that's really not a very desirable
17 thing.

18 And then I would also like to ask you: did
19 you invite any patient groups to participate? Because
20 patients are the ultimate stakeholders.

21 MR. LOHAUS: Jim?

22 MR. MYERS: I'm thinking. I think we did
23 ask, but I don't believe that we had anybody come that I
24 recollect. We did have some folks from some of the
25 public interest groups initially, but recognizing that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 medical is one part of this complex puzzle that we were
2 dealing with, I'd have to say initially no. I don't
3 think that there were anybody that were patient advocate
4 groups that were there.

5 Also recognize that this report was provided
6 to the Commission and thought we sought a lot of public
7 comment and stakeholder comment on it, and I think that
8 the working group did a really good job of trying to get
9 everybody involved, what happens is that once the
10 Commission makes a decision about whatever it wants to
11 do, that's probably more in the realm of policy, and
12 that's where more comment and more favorable things that
13 would be coming from the public would be put into this as
14 well.

15 And I think that --

16 CHAIRMAN CERQUEIRA: Right, but the problem
17 with that is once you've got a draft of something, you've
18 spent the time. It's much more work to undo something
19 that's been created than it is to be involved in initial
20 development and do it right.

21 And certainly without the input of, you
22 know, certain patient groups -- and again, I'd like to
23 see the involvement of the professional medical
24 community. I think it's important.

25 MR. LOHAUS: Yeah, I hear you. I hear you.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And we'll give you the listing of people that attended
2 the stakeholder meeting, and that was part of the reason
3 for holding that meeting, was to provide opportunity when
4 there was a product that could be reviewed to give folks
5 an opportunity to look at it and give the working group
6 some feedback, but we'll give you the list of people that
7 attended.

8 And we may not have had all the right people
9 there, but I think the intent and our goal was to involve
10 a cross-section of stakeholders.

11 CHAIRMAN CERQUEIRA: Well, we're not
12 questioning the intent or the product, but it's just more
13 of the process, and again, I'd like to thank Ralph for
14 putting it on the agenda, bringing it to our attention.

15 MR. LIETO: Thank me or blame me.

16 CHAIRMAN CERQUEIRA: Okay. Now, let's
17 everybody be back here by one o'clock. We don't want to
18 come back any earlier.

19 (Whereupon, at 12:04 p.m., the meeting was
20 recessed for lunch, to reconvene at 1:00 p.m., the same
21 day.)

22

23

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:04 p.m.)

CHAIRMAN CERQUEIRA: I hope everyone had a good lunch. Dr. Williamson was observed to be taking part in the dance lessons in the hallway there. He does a pretty mean swing, but not too good on the tango.

(Laughter.)

CHAIRMAN CERQUEIRA: Just kidding, Jeff.

And now we're back to Dr. Ayers.

DR. AYERS: Yeah, hoping to pick up where we left off. Maybe we've got all of the questions out of the way, but I doubt it.

(Laughter.)

DR. AYERS: As I said, partial recognition, and what we haven't gotten into is the process of responding to the Board's applications and going back and forth and working out together where the endpoint will be.

CHAIRMAN CERQUEIRA: When will that happen. You know, obviously you can't do it until the regulations get approved, but once they get published, will you be able to initiate the process so that by the time it becomes law you'll be able to --

DR. AYERS: I defer that to John.

MR. HICKEY: Yes, we would do that prior to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the effective date, but now the response has to reflect
2 the discussions we've had yesterday and the work that the
3 subcommittee and the staff are going to be doing as to
4 what solutions are there.

5 But the reviews have pretty much been
6 completed so that if you set aside the discussions
7 yesterday and today, we could go ahead and notify all of
8 the Boards the results of the review.

9 CHAIRMAN CERQUEIRA: What about the Boards
10 that aren't affected? You know, it looks like the AB&M,
11 the ACR, CBNC, and some of the other exams would --

12 DR. AYERS: All are affected except two.

13 CHAIRMAN CERQUEIRA: Okay, and you're going
14 to tell us which two.

15 DR. AYERS: Yeah.

16 MR. HICKEY: Well, one is at the Board of
17 Nuclear Medicine. They've already been notified.

18 DR. AYERS: That's correct, and the other
19 one is the CNBC; is that right?

20 CHAIRMAN CERQUEIRA: CBNC?

21 DR. AYERS: CBNC.

22 MR. HICKEY: Well, tell people what that
23 stands for.

24 CHAIRMAN CERQUEIRA: Certification --

25 DR. AYERS: Cardiologist -- oh.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Certification Board of
2 Nuclear Cardiology.

3 DR. AYERS: Yeah. In fact, they had to
4 manage informing the Board rather late, and compared to
5 others and actually incorporated all of the requirements
6 right into it. So it's really straightforward.

7 CHAIRMAN CERQUEIRA: I didn't mean to take
8 you off on a tangent there, Bob.

9 DR. AYERS: Okay. The next slide.

10 I think you're all aware of the problems
11 which are kind of reflective of many of the Boards with
12 the American Board of Health Physics, for example. They
13 don't have the specific requirements which are required
14 by the regulations.

15 Now, mind I'm not including any of the
16 discussions in the last couple of days, and if we do have
17 some rule changes, we'll have to all go back to the
18 starting point on this whole thing, but this is purely as
19 it relates to the existing draft of new 10 CFR, Part 35.

20 So they don't meet the one year full-time
21 radiation experience in medical applications, nor the
22 corresponding written preceptor statement.

23 Next slide.

24 CHAIRMAN CERQUEIRA: Well, Bob, can we go
25 back to that?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And I guess, you know, again, these
2 discussions I'm sure we --

3 DR. AYERS: Well, I will add at the end I
4 list all of these problems for discussion. I was just
5 pointing to individual --

6 CHAIRMAN CERQUEIRA: Okay. So the preceptor
7 statement, there's no way we can require that and then
8 the one year training?

9 DR. AYERS: I go through the individual
10 Boards --

11 CHAIRMAN CERQUEIRA: Sure, okay.

12 DR. AYERS: -- and then we go to the general
13 discussion and then relist all of the across the board
14 features --

15 CHAIRMAN CERQUEIRA: I apologize.

16 DR. AYERS: -- with Boards.

17 All right. The letter to the American Board
18 of Nuclear Medicine did say that we were planning to
19 grant NRC recognition for the modalities they requested,
20 except for the RSO under 3550(a) because, again, they
21 don't -- they have not presented evidence that they meet
22 the one year and the preceptor statement, although most
23 of the medical boards, they can become radiation safety
24 officers for their specific modality based on their
25 authorized user status, and that includes medical

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 physicist.

2 CHAIRMAN CERQUEIRA: Right.

3 DR. AYERS: What they can't do is qualify
4 for broad scope RSO big programs under A.

5 Next slide.

6 As I said, we just see no issues on this
7 one.

8 Next slide.

9 The only thing I guess I'll add as a comment
10 to that, they're only requesting 290 and the regulation
11 requires that the preceptor have 190 and 290 experience,
12 and I agreed with them in the draft letter that it would
13 seem pointless that they have 190 experience for their
14 preceptor since they're not authorizing that modality.

15 Here's the key point. For radiation safety
16 officer authorizations, a large number of the Boards,
17 essentially all of them or -- I'm sorry -- all that
18 asked, but a great number asked for recognition under the
19 full radiation safety officer qualifications under
20 3550(a), but none at this point has been able to document
21 they meet that one time or one year full-time medical
22 experience under supervision of a qualified radiation
23 safety officer, nor do either present evidence for the
24 preceptor statement that goes along with that.

25 MS. MCBURNEY: Bob, if the American Board of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Health Physics did change their requirements for
2 certification to include a preceptor statement and
3 documentation of experience --

4 DR. AYERS: Yeah, that's really coming up on
5 the next slide.

6 MS. MCBURNEY: Oh, okay.

7 DR. AYERS: Okay. But as I said, many of
8 the Board diplomates would qualify under 3550(c). In
9 fact, the only one that wouldn't would be that -- I don't
10 remember that acronym accurately, but that specialty
11 Board for Nuclear Medicine.

12 CHAIRMAN CERQUEIRA: CBNC or --

13 DR. AYERS: No

14 MR. LIETO: American Board of Science and
15 Nuclear Medicine?

16 DR. AYERS: American Board of Science and
17 Nuclear Medicine, that one, because they don't have any
18 corresponding authorized user status in any other
19 category, nor are they asking for one.

20 Next slide.

21 With the medical physics authorizations,
22 again, for both ABR and American Board of Medical
23 Physicists -- Physics, they have lack of, as we've talked
24 about many times, the Board requirements for the
25 specified training in all of the modalities and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 corresponding signed preceptor statement.

2 And we already talked about the partial
3 recognition, and this could apply to all Board, and in
4 the next slide, I think we get into the big generic
5 issue, I hope.

6 CHAIRMAN CERQUEIRA: Before we go on, Jeff,
7 do you have a question?

8 DR. AYERS: Yeah.

9 DR. WILLIAMSON: I recently reviewed the
10 eligibility requirements for ABR, American Board of
11 Medical Physics. They certainly do require signed
12 letters testifying to the competence. So I'm wondering
13 what is the --

14 DR. AYERS: That's the next slide.

15 DR. WILLIAMSON: -- legal deficiency of that
16 requirement compared to the --

17 DR. AYERS: Okay. I intend to talk -- I
18 believe the next slide has that.

19 DR. WILLIAMSON: Okay.

20 DR. AYERS: Yeah, the next slide, please.

21 The generic issue is, as I said, applicable
22 to all the Boards except the Board of Nuclear Medicine
23 and the Board of Nuclear Cardiology, is the absence of
24 the exactly specified signed preceptor statement or
25 statements in accordance with the new Part 35

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 requirements for the various Board certification
2 processes.

3 Now, ABR, for example, asks for a reference
4 letter for a physicist and a --

5 DR. WILLIAMSON: From a radiation
6 oncologist, I believe, too.

7 DR. AYERS: Well, in one they call it a
8 reference letter, and in the other one they call it
9 something else. The name escapes me. Sometime somewhat
10 similar.

11 The problem is -- and the Boards could
12 easily if they chose or maybe I shouldn't say "easily."
13 The Boards could -- one option would be to change their
14 procedure. The biggest blocking point from any of the
15 Boards is a signed preceptor statement. They have --

16 CHAIRMAN CERQUEIRA: Well, tell me --

17 DR. AYERS: -- requirements that are
18 similar, but not the same.

19 DR. WILLIAMSON: What's missing from the
20 ABR when they say letter of reference from a certified
21 physicist and a physician? What's wrong with that?

22 DR. AYERS: Two things that stick up
23 immediately is they don't say that they've supervised
24 them and they've been -- they're trained and qualified in
25 the specific numbered parts of the regulations.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And the second one is there's no requirement
2 that that letter, recommendation, reference -- I think
3 it's called recommendation in place of reference and
4 others -- there's no requirement on the part of the
5 Boards that those be from what we would deem a qualified
6 preceptor, that is, an authorized user that is authorized
7 for those modalities.

8 CHAIRMAN CERQUEIRA: Jeff, how difficult an
9 issue would that be to get that letter? I mean, is most
10 of the training done by authorized user or AUP or AMP?

11 DR. WILLIAMSON: I think largely that is so.
12 I think the major problem would be that the certificate
13 itself would have to be amended to specify HDR, gamma
14 stereotactic, and teletherapy. I think that is the big
15 blocking point, is that there is no mechanism by which,
16 you know, footnotes can be made to the diplomate
17 certificate indicating the different modalities.

18 You know, this letter is not something
19 they're going to be willing to share with you.

20 DR. AYERS: Well, it wouldn't be if they
21 chose to have some subset and say we require the
22 appropriate preceptor statement or this subset and that's
23 a partial part.

24 DR. WILLIAMSON: Yeah, but they don't do
25 that for any subset. They're don't do it for Cobalt --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. AYERS: I know that.

2 DR. WILLIAMSON: -- 60, HDR or gamma
3 stereotactic, and it's unlikely they will.

4 DR. AYERS: It's a little more
5 straightforward for the medical Boards, for ABR, for
6 radiation oncologists, for pharmacists. The same
7 problem; it's across the board with all of these Boards.
8 I keep forgetting.

9 None of the medical Boards that I've
10 reviewed have at this point presented any evidence to us
11 that they require and goes in the file for their Board
12 diplomate, the required certification.

13 The other alternative, of course, is
14 changing the requirements, which you've already presented
15 to the Commission.

16 The other alternative under the existing
17 regulation would be for the Boards to adjust the
18 requirement.

19 And some of the medical Boards may be a
20 little further away in that the letters they require are
21 from their clinical director who may or may not be active
22 or may or may not be what we would deem an authorized
23 user. I don't know. We've got to ask these questions.

24 CHAIRMAN CERQUEIRA: Ralph, you know, you're
25 not weighed down by all of the baggage of past

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 discussions. How do we get out of this and come up with
2 a way that --

3 (Laughter.)

4 MR. LIETO: What I see is what we're trying
5 to do is put a square peg into a round hole.

6 DR. AYERS: Exactly.

7 MR. LIETO: And I think --

8 CHAIRMAN CERQUEIRA: So how do we shave it?

9 MR. LIETO: It seems like the discussion
10 I've been hearing is how do we get the Boards to do this.
11 How do we get this to change? And I don't think that's
12 the way to go. Okay?

13 I was thinking at first, well, maybe there
14 should be sort of this form letter of recommendation that
15 says, you know, "I, Dr. So-and-so, attest to the fact
16 that Physicist XYZ meets the criteria for taking the
17 Boards because of his experience," and lists some of
18 these modalities, but these things are going to change
19 with time.

20 DR. AYERS: And certify that --

21 CHAIRMAN CERQUEIRA: That he's competent.

22 MR. LIETO: Well, the Board exam --

23 CHAIRMAN CERQUEIRA: That the person is
24 competent.

25 MR. LIETO: You know, passing the exam would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 establish his competency. So my feeling is that I think
2 any discussion of trying to get changes in the Boards or
3 applications to the Boards is going to be very lengthy,
4 time consuming, because they have to go through their
5 mechanisms of approval, and I don't really think in the
6 long term it's going to solve the problem. I think the
7 issue is, as we discussed this morning, is change in
8 rulemaking.

9 CHAIRMAN CERQUEIRA: The rulemaking.

10 MR. LIETO: I really think that's where we
11 have got to go.

12 CHAIRMAN CERQUEIRA: Yeah.

13 DR. AYERS: And that's why I said I'm
14 confining my remarks to not changing the rule. The rule
15 changes; the whole thing starts over. It's a whole new
16 ball game with regard to what I'm presenting.

17 CHAIRMAN CERQUEIRA: And, Richard, in terms
18 of the RSO, is that also the situation?

19 DR. VETTER: Yeah. For example, the
20 American Board of Health Physics certifies people in all
21 areas of health physics. If they changed their
22 certification process, they would need to have a
23 preceptor statement for everyone whether they're going to
24 be in medical or not.

25 I mean, it just doesn't work. Like Ralph

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 said, it's a square peg in a round hole or vice versa.
2 And they're not going to change it.

3 CHAIRMAN CERQUEIRA: No. In nuclear
4 medicine, I mean, you know, the preceptor statement
5 specifically lists the isotope and the number of hours
6 that people have had, and we've been using those
7 preceptor statements for the longest time. Isn't that
8 something that could be generalized?

9 DR. AYERS: Well, we've been using the
10 preceptor statements under the old rule for non-Board
11 certified individuals, physicians, medical physicists,
12 RSOs, and so forth. That's always been there.

13 What's new with new Part 35, and I think why
14 a lot of people missed that it was a change is that the
15 Boards are now being vetted against the training and
16 experience requirements in the second and sometimes third
17 parts of the rule.

18 And I don't know how the Boards that are
19 recognized now by us achieved that process. That was
20 before my time.

21 CHAIRMAN CERQUEIRA: And, Ralph, Jeff, and
22 Richard, the Boards have been approached and it's not
23 doable?

24 DR. VETTER: Well, I've talked with two
25 Boards, and it just doesn't fit their objective. They're

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 looking to certify the competency, the knowledge base,
2 and that really has nothing to do with where they got it.
3 It just doesn't fit for them.

4 CHAIRMAN CERQUEIRA: And it's not specific.
5 Again, for some of these things, for the agents.

6 DR. VETTER: Right.

7 DR. NAG: Yeah, I have a problem. Directly
8 in radiation oncology is that in the Board certification
9 it says you are now qualified to do radiation oncology on
10 the whole. I may never want to do a gamma knife, and if
11 you say you are going to require everyone to have that
12 knowledge, you're not going to have many people, you
13 know, passing the Board.

14 You know, they want to certify a general
15 overall knowledge. Now, you can use that knowledge, and
16 then if you're going to do gamma knife or some of these
17 special procedures, you can take some special training
18 for that.

19 But you cannot make that a requirement for
20 every radiation oncologist to know about gamma knife.

21 CHAIRMAN CERQUEIRA: But if we had an
22 interventional cardiologist, he would say, "Well, why
23 can't we take them and have them do a limited subset of
24 training and experience to be able to meet their
25 requirements, to sort of be the sole user?"

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. NAG: Yeah, but the problem is you need
2 an overall general knowledge, and then you need to
3 supplement that with specific knowledge. You can't just
4 say I want to have only the specific knowledge without
5 the general fundamental knowledge to back you up.

6 So if you do a separate requirement just for
7 gamma knife, it is not good because you can't just make,
8 you know, 200 hours at gamma knife without knowing the
9 rest of the general radiation basics.

10 DR. WILLIAMSON: There's another problem.
11 Even if the Boards adjusted their procedures so that
12 prospectively new candidates complied with these rules,
13 it's not retroactive. The problem would still exist that
14 the vast majority of Board certified physicians and
15 physicists could not meet these regulatory standards.

16 DR. AYERS: Well, I think the grandfathering
17 might be a large part, but --

18 CHAIRMAN CERQUEIRA: So is that possible
19 under the --

20 MS. MCBURNEY: Yeah, grandfathering.

21 DR. AYERS: That's my next slide, which has
22 some issues there, but I'll get to that.

23 CHAIRMAN CERQUEIRA: Why don't we go to the
24 next one? Are you done with this one?

25 DR. AYERS: Yeah, I think the problem is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 well identified. There are really three branches to
2 this, work to the existing Part 35, and most Boards won't
3 qualify and will have to come in under training and
4 experience; change the rule and get it where most people
5 are happy. I don't know if you can ever make everybody
6 happy.

7 CHAIRMAN CERQUEIRA: That's not our mission
8 here.

9 DR. AYERS: Okay. Let's go to the next
10 slide.

11 CHAIRMAN CERQUEIRA: But, again, we do have
12 this subcommittee that's going to look at this and come
13 up with some recommendations on how to resolve this.

14 DR. AYERS: And I guess one question you
15 raised was that, well, the Boards have responded to this.
16 Well, the letters haven't gone out yet. So our query to
17 them about this hasn't went out to them yet. So there
18 hasn't been any forma interchange between the Boards and
19 NRC until those letters go out.

20 Okay. On the grandfathering, I wasn't
21 prepared to talk about it last time, and I wasn't sure,
22 and I agreed that the language was a little ambiguous,
23 but the states in consideration are very precise. For
24 medical physicists, pharmacists, and RSOs, which is
25 really not relevant, it's mostly for medical physicists.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 What the statements in consideration very precisely say
2 is you will get what you have. If you're an authorized
3 teletherapy physicist, that's all you get. If you're
4 authorized for teletherapy and HDR, you get those.

5 You get what you have now. You don't get a
6 broad recognition.

7 DR. WILLIAMSON: Which undercuts the last
8 point that was made. So there is an issue with
9 grandfathering the previously boarded --

10 DR. NAG: What about authorized user, NRC
11 authorized user?

12 DR. AYERS: I'm sorry?

13 DR. NAG: Authorized user? I mean, are they
14 not grandfathered?

15 DR. AYERS: No, the authorized user is
16 35.57(b), which wasn't an issue. The language differs in
17 that a little, and it's much clearer. So this was the
18 issue item from last time.

19 DR. WILLIAMSON: Can the statements of
20 consideration be modified? Are they as unmodifiable as
21 the rule?

22 MR. HICKEY: The answer is yes, and that
23 will be within the scope of what the subcommittee and the
24 staff looks at. Certainly if the rule can be changed,
25 the statement of consideration can be changed.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. McBURNEY: But not for this printing.
2 It would be a new rulemaking and a new statement of
3 consideration, right?

4 MR. HICKEY: If the question is how quickly
5 can it be done, it's easier to change something that's
6 not a rule than it is to change a rule.

7 DR. AYERS: I think the Commission would
8 probably have to be on board on that, but don't hold me
9 to that.

10 MR. HICKEY: That's correct.

11 DR. AYERS: And you have presented your
12 views to the Commission, and that's outside of the scope
13 of what I'm talking about.

14 MR. LIETO: Bob, could you just refresh my
15 memory? What's 35.57(b)?

16 DR. AYERS: That's the grandfathering
17 clause. That means everybody that is currently listed as
18 an authorized user at the time the new Part 35 takes
19 effect will be grandfathered for the authorities that
20 they now have essentially.

21 MS. McBURNEY: I understand all the stuff
22 about the Board certification was in the proposed rule as
23 it is in the final, but not a whole lot changed.

24 DR. AYERS: I was not involved in the
25 rulemaking. So I can't -- if somebody else wants to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 speak to the history, I know it went through several
2 revisions because at one time there was consideration of
3 a written test on radiation safety, and where the changes
4 occurred along the path, I guess Marjorie is coming up to
5 the microphone. She's more knowledgeable of the history
6 of rule development than I am.

7 MS. MCBURNEY: And whether there were
8 comments about that or did people just sort of assume
9 that their Boards would be accepted?

10 DR. AYERS: I'll let Marjorie address the
11 question.

12 MS. ROTHSCHILD: Okay. Well, the proposed
13 rule published in August of 1998, the language that is
14 now at issue was virtually identical in the proposed
15 rule, and I can point you to that. Okay? It's 3550 --
16 if we're taking like authorized medical physicist as an
17 example, that proposed rule language was, "The licensee
18 shall require the authorized medical physicist to be an
19 individual who," and then under A it states, "is
20 certified by a specialty Board whose certification
21 process includes all of the training and experience
22 requirements in Paragraph B of this section and whose
23 certification has been approved by the Commission."

24 Now, that last phraseology there --

25 DR. AYERS: That's the same, yeah.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. ROTHSCHILD: -- may have been changed
2 slightly, just the last phrase, and there was a
3 provision, you know, in this proposed Rule 3551 for
4 passing an examination, but the language at issue, taking
5 this provision as an example was virtually the same in
6 the proposed rule published August '98.

7 And the kind of brief review I've had time
8 to do in terms of comments and responses in the
9 statements of consideration, I didn't see this precise
10 issue as raised by commenters or any of the professional
11 societies.

12 DR. AYERS: Yeah, I looked through that.
13 There were no comments on this issue that I could find in
14 my review through the package. The intent of this whole
15 thing was to take naming the Boards out of the regulation
16 where it prohibited us from adding or deleting new Boards
17 or Boards that changed without -- we'd be rulemaking to
18 add or delete the Board as it exists now in the old Part
19 35.

20 And I guess when you say we're going to
21 recognize Boards, you've got to put something in, and
22 this appears where the miss occurred, at least from the
23 perspective of the Committee here. You've got to put
24 something in that says this is what it takes to be
25 qualified to be recognized.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Now, the recognition criteria could be
2 different obviously than what they are if we're rewriting
3 the rule or if you went back listing them in the rule
4 itself, you again tie Board recognition to rulemaking
5 process in the future.

6 CHAIRMAN CERQUEIRA: All right. Jeff?

7 DR. WILLIAMSON: I think a couple of
8 comments have been made by the Commissioners and maybe
9 others on the staff -- I think Don Cool -- that there was
10 something that could be done in the implementation of
11 these regulations that would at least temporarily
12 ameliorate the consequences or mitigate the consequences
13 of this problem, and I'm wondering if John or Bob could
14 expand on this.

15 DR. AYERS: I'll defer to John.

16 MR. HICKEY: I don't think I can add
17 anything to what's been said. We agreed that --

18 DR. WILLIAMSON: I gathered that this was --
19 this is what I understood them to be implying, although
20 it wasn't made clear, that there was the possibility when
21 the regulations are implemented that basically a hold
22 could be put on some component, subcomponent of the
23 regulations if it turned out there was an unforeseen
24 difficulty in implementing them without postponing the
25 implementation of the rest of the new Part 35

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 requirements.

2 DR. AYERS: Yeah, I think that can be
3 considered. However the Commission, they haven't
4 addressed the issue of a fragmented effective date
5 directly, but they's stated that they don't want to
6 revise the rule in pieces.

7 So if there were a proposal to implement it
8 with different effective dates for this part, that would
9 be an issue, but I think that does need to be considered
10 nevertheless.

11 DR. WILLIAMSON: So that is a possibility.
12 That was my question.

13 MR. HICKEY: Everything is a possibility.

14 DR. AYERS: Yeah, I think most of what
15 you're talking about now is at the Commission level, and
16 it was great that everybody had a chance to bring these
17 issues to the attention of the Commission yesterday, and
18 now it's on the radar so to speak.

19 I can't predict what will happen.

20 CHAIRMAN CERQUEIRA: Okay. We have a
21 question from the audience.

22 MR. UFFELMAN: I'm Bill Uffelman, Society of
23 Nuclear Medicine, ACNP, but on behalf of the American
24 Board of Science and Nuclear Medicine.

25 With the six month delay or call it the six

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 month delayed effective date of the rule, those -- and
2 you made the comment somebody who is already an RSO is an
3 RSO and, you know, they're grandfathered. But somebody
4 who was previously an RSO, but is now working as an RSO
5 because they've changed jobs or whatever, can they go
6 back and be an RSO without going through the whole
7 rigmarole? That's question one.

8 Question two, those --

9 CHAIRMAN CERQUEIRA: Wait. Why don't we get
10 an answer to question one, and then we can --

11 DR. AYERS: Question one, I don't know. I
12 haven't looked at that issue.

13 CHAIRMAN CERQUEIRA: That was easy.

14 MR. UFFELMAN: Okay. Question two, ABS&M's
15 exam is given in June at our annual meeting in L.A. this
16 year. Those who pass the exam in June and become
17 diplomates of ABS&M, because they're in this window
18 between the March publication and September-October
19 effective date, what is their status, you know? Under
20 which rule are they applying for recognition of their
21 qualification?

22 DR. AYERS: Well, they're applying under the
23 current Part 35 until such time as the new rule becomes
24 effective.

25 MR. UFFELMAN: Okay. So that's different

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 than what you said last year. That's why I was checking.

2 MR. HICKEY: This is John Hickey. Let me
3 point out that they have to be listed on a license. It's
4 not good enough just to be certified as of the effective
5 date of the new rule.

6 MR. UFFELMAN: So they've got to have this
7 RSO job lined up for, you know --

8 MR. HICKEY: We said -- I agree I don't
9 offhand know the answer to the first question because the
10 rule says "identified." So I'd have to get an
11 interpretation as to whether that means currently
12 identified or previously or currently.

13 But the answer to the second question is you
14 have to be certified, and if you haven't been listed on
15 a license, you need to get listed on a license before the
16 effective date of the new rule.

17 DR. AYERS: Yeah, a job offer wouldn't do
18 it. I mean, you'd have to actually go through the
19 process and be listed on the license to be grandfathered.

20 CHAIRMAN CERQUEIRA: All right. Well, I
21 guess we overlooked a few things at different levels, and
22 I think we've identified the problem. We've spoken to
23 the Commissioners. We've established a subcommittee
24 that's going to look at it, and we kind of need to
25 address it possibly as a new rule.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 I guess the one question is that for the
2 Boards who have already applied and have been reviewed
3 and have met most of their criteria, I don't see any
4 reason that they should be held up. Is that the feeling
5 of the Committee?

6 There's no --

7 DR. AYERS: Well --

8 MR. HICKEY: Wait a minute. He's asking the
9 Committee.

10 DR. AYERS: I'm sorry.

11 MR. HICKEY: Sorry.

12 DR. WILLIAMSON: And these Boards, just to
13 refresh our memory are the nuclear medicine, two nuclear
14 medicine Boards, right?

15 MR. HICKEY: That's right.

16 CHAIRMAN CERQUEIRA: What about the ACR?

17 DR. NAG: ABR you mean.

18 CHAIRMAN CERQUEIRA: ABR. I'm sorry.

19 DR. AYERS: A preceptor issue, a preceptor
20 statement issue.

21 DR. WILLIAMSON: It's important to
22 recognize. It sounds like right now radiation oncology
23 certification is not going to make it for either the
24 brachytherapy, teletherapy, or the radiopharmaceuticals.
25 Only nuclear medicine certification.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. AYERS: The same applies to the
2 radiopharmacy and the medical physics and RSO. It's
3 essentially everything else.

4 DR. WILLIAMSON: So the scope of the
5 disaster widens.

6 CHAIRMAN CERQUEIRA: It's definitely a
7 problem.

8 Ralph?

9 MR. LIETO: I just wanted to make maybe a
10 comment regarding the grandfathering. You said you
11 weren't too sure about if somebody was not listed now,
12 but had been previously, would they be grandfathered. I
13 guess --

14 DR. AYERS: Yeah, and I don't know, and
15 there is some provisions in our current regulations that
16 gives a window of time in which you can --

17 MR. LIETO: My suggestion was going to be as
18 long as that meets the recentness of training requirement
19 --

20 DR. AYERS: That's the window.

21 MR. LIETO: -- that they be allowed to
22 grandfather.

23 DR. AYERS: Again, I don't know at this
24 point without --

25 MR. LIETO: Just a comment.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. NAG: One possible solution for the
2 short run, since we now have a separate meeting, until
3 the results of the subcommittee comes out -- that means
4 the new will not be implemented until the subcommittee
5 comes out.

6 CHAIRMAN CERQUEIRA: I don't think we can do
7 that procedurally. I mean, basically the Commission has
8 made the decision, I think, which was supported by the
9 Committee, you know, that they didn't want to fragment
10 the rule out, break it out in different ways, and I think
11 the option that has been given to us is basically
12 implement a rule and then come up with a new rulemaking,
13 which is part of the charge of this Committee.

14 But in the meantime I'm not sure it's in the
15 interest of the stakeholders. If some of the Boards
16 basically have been approve by this new standard, I think
17 it would make sense since they weren't affected as
18 directly by some of these other ones to basically let
19 them get approval.

20 DR. WILLIAMSON: Well, I think I concur with
21 our chairman. There seems to be no reason not to go
22 ahead and recognize the certifications of the two nuclear
23 medicine Boards. It sounds like if the fragmented date
24 of implementation strategy is used, it could be carefully
25 calibrated to avoid the 35, 200 and 100 modalities and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 focus on the 300, 400, and 600 modalities where the
2 problem occurs.

3 DR. AYERS: Well, I think the last two days
4 have introduced a reason. Now that the Board
5 certification process may be back on the table, and what
6 we're prepared to do now may not be valid tomorrow.

7 (Laughter.)

8 DR. WILLIAMSON: Well, that's a good point.

9 CHAIRMAN CERQUEIRA: All right, but the
10 decision on this is going to have to be made soon, very
11 soon, I mean, and if Congress gives approval to go ahead,
12 then I think the Commissioners are going to need to make
13 some decision on how to deal with this.

14 I didn't get the feeling from yesterday's
15 meeting that they had a solution for us. They're willing
16 to have us look at it, but there's no immediate
17 resolution that's been put forward by the Commission, by
18 this Committee, or by the NRC staff.

19 DR. AYERS: And I think if the rule goes
20 through as planned, we'll immediately get those letters
21 out. One of them is, in fact, granting recognition to
22 the second diagnostic Board, and we've accomplished what
23 you're asking for. It's just merely we're just waiting
24 until we know for sure which way to jump.

25 CHAIRMAN CERQUEIRA: Right.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. NAG: And I agree with having the two
2 Boards, you know, approved, but what is going to happen
3 with the other four or five Boards? Once implemented, I
4 mean, you know, what are the consequences of that?

5 CHAIRMAN CERQUEIRA: Well, the people that
6 are already out there, I mean, should it change? They
7 would be grandfathered, correct?

8 DR. NAG: No, but the new graduates are
9 coming out this year.

10 DR. VETTER: But they would be approved
11 under the -- filling out all of the forms of the
12 preceptor statement, training, and so forth.

13 DR. AYERS: And these letters are going
14 to --

15 CHAIRMAN CERQUEIRA: And the people who
16 would be most affected would be the people who are
17 starting training now; is that correct?

18 DR. NAG: No.

19 DR. AYERS: Well, the letters going to the
20 Boards are not denying recognition. It's asking
21 questions. What I'm getting from the Committee is we may
22 not get the right answers back, but it's not going out
23 and saying you're not qualified. It's saying we don't
24 see where you do A or B, and could you please advise us
25 how you do this?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Yeah, I think there was
2 precedent for some of this. I mean, when my predecessor
3 Barry Segal was here, there was quite a little
4 controversy for the people who didn't have Boards but
5 were trying to meet the requirements for authorized user
6 under training and experience as to whether there could
7 be two 500 hour blocks, whether they were simultaneous or
8 concurrent, and a vote was taken that, you know, if there
9 were issues, it could come to this Committee for review.

10 I think we maybe reviewed one or two, and
11 potentially this Committee could assume some of that
12 responsibility, but we're talking about large numbers now
13 if we're talking RSO.

14 DR. AYERS: Yeah, the issue of multiple 500
15 hour blocks was addressed in a letter from the Chairman.
16 I'm trying to remember the addressee right offhand, but
17 that we wouldn't -- for a radiation oncologist for a
18 number of different modalities, we wouldn't sum those 500
19 hour blocks. That was addressed in a response from the
20 Chairman.

21 CHAIRMAN CERQUEIRA: Well, we need to do
22 something, and I think it's going to be implemented, and
23 we need to initiate this process. It doesn't seem like
24 we've gotten any indication that the guidance documents
25 would deal with it effectively, and it seems like the new

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 rule may be the only way to do it.

2 And I guess the best thing would be to try
3 to get this started.

4 DR. AYERS: I think the problem is guidance
5 is intended to tell you or to provide information how to
6 comply with the rule not change the rule.

7 DR. WILLIAMSON: Well, that's correct, but
8 the guidance, you know, it would seem to me we've made
9 the recommendation as a Committee that the guidance
10 should bend over backwards within the confines of the
11 rule as written to preserve as much of the existing
12 recognition of Board certification as possible, and I
13 still think you should take that as your goal.

14 MR. HICKEY: Yes. From what our review has
15 indicated so far, it's clearly there is an issue with
16 medical physicists and RSOs. There may be more
17 flexibility to soften the impact with respect to the
18 authorized users.

19 DR. WILLIAMSON: Can you give us your draft
20 guidance on how to -- what would be required to establish
21 your screening criteria, so to speak, for establishing
22 compliance with the authorized medical physicist
23 provisions?

24 DR. AYERS: I can say all that I'm using now
25 is the rule. That's the guidance, and the corresponding

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 statements of consideration.

2 MR. HICKEY: We will do that. We're going
3 to put a priority on addressing this first issue of what
4 needs to be done to fix the rule, but we also will do
5 that.

6 We have a letter from I believe it's the
7 American -- from AAPM that has a proposal that we need to
8 respond to.

9 CHAIRMAN CERQUEIRA: All right. Niki.

10 MS. HOBSON: Well, this morning one of the
11 speakers referred to that there could possibly be a
12 transition period where there would be some
13 enforcement --

14 MS. McBURNEY: Discretion.

15 MS. HOBSON: -- discretion. Could that
16 apply in this instance?

17 And also, what is the absolute shortest time
18 that this rule could be amended? What is the absolute
19 shortest time?

20 MR. LIETO: Not amended, but rewritten.

21 CHAIRMAN CERQUEIRA: Not amended, but, well,
22 just a new rule dealing --

23 MS. HOBSON: The new rule, the new rule.

24 DR. NAG: IBS.

25 CHAIRMAN CERQUEIRA: John? Best case?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. HICKEY: I can't comment on that.

2 DR. NAG: IBS.

3 DR. AYERS: The only comment I'd have is
4 this is not an enforcement issue. It's a licensing issue
5 in a sense, an indirect licensing. It's kind of unusual.
6 We haven't been in this kind of space.

7 DR. DIAMOND: Bob, I actually disagree with
8 that. Dr. Frant earlier today was very clear, 100
9 percent crystal clear that there's going to be some
10 leeway with respect to how implementation is done,
11 interpretation, maybe windows for implementation and so
12 forth.

13 So please don't be as strict as you're
14 telling us.

15 DR. AYERS: Oh, no, it's just wording.
16 Implementation I have no disagreement with, but all I
17 just said is it is not an enforcement issue. It's
18 clearly an implementation issue. Ms. Hobson presented it
19 as an enforcement issue, and that it isn't.

20 Implementation, which she talked about, of
21 course it is.

22 CHAIRMAN CERQUEIRA: The sense that I'm
23 getting from the Committee is that, you know, we kind of
24 agreed that we were correct on the nuclear medicine
25 aspect of training and experience and Boards, and we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 should probably once the rule goes into effect implement
2 that in the sense of approval of the Boards that have
3 been reviewed and found to meet the criteria.

4 And I don't think -- that pretty much covers
5 all of the stakeholders for nuclear medicine, but then
6 we've got this other problem with, you know, potentially
7 the radiation oncologists authorized users, but
8 definitely with the radiation safety officers and the
9 medical physicists, and we haven't really come up with a
10 solution, and I think we kind of need to escalate this
11 to, you know, maybe have a -- we met with the
12 Commissioners yesterday. I think we were just kind of,
13 you know -- the full implications of this were made known
14 then.

15 You know, maybe we should try to talk to the
16 Commissioner again, talk to Commissioner Meserve to sort
17 of see what the options are. You know, maybe Richard on
18 behalf of the Committee and I could talk to him to see
19 what the solutions would be.

20 Is that a reasonable way to go forward on
21 this?

22 MR. LIETO: Well, I guess I'm a little
23 confused now. Where is the subcommittee that was charged
24 this morning fit into this?

25 CHAIRMAN CERQUEIRA: Well, the subcommittee

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 would basically do the leg work. The thing is there's a
2 whole bunch of unknowns. You know, how much can be
3 incorporated in guidance? How much could be incorporated
4 in grandfathering? Can we conceivably stagger the
5 implementation, which is something that the Commissioners
6 have said they did not want to do?

7 Nobody can give us a time line for the new
8 rulemaking, and you know, we kind of need to have that
9 information to see how we can basically solve it.

10 DR. WILLIAMSON: Well, I was going to
11 suggest maybe a motion that we could vote on, that the
12 ACMUI recommends that the staff petition the Commission
13 to stagger the dates of implementation of the training
14 and experience requirements to preserve the existing
15 training and experience requirements for radiation
16 oncologists, authorized medical physicists, nuclear
17 pharmacists, and radiation safety officers until such
18 time as a revised regulation can be implemented.

19 CHAIRMAN CERQUEIRA: Do we have a second on
20 that?

21 DR. NAG: I'll second the first place.

22 CHAIRMAN CERQUEIRA: I'm sorry?

23 DR. NAG: What you were asking in the first
24 place.

25 CHAIRMAN CERQUEIRA: Right, right.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. NAG: You know, I second that.

2 CHAIRMAN CERQUEIRA: Yes, so you second it.

3 DR. WILLIAMSON: I just think we need to
4 think outside of the box here a little bit, and that we
5 should not impose a very confusing and conflicting
6 transitional structure on the community if there is some
7 possibility of avoiding that, given that everybody --
8 there's a general consensus among the Commissioners, the
9 staff, and the regulated community that this needs to be
10 addressed by a rulemaking initiative.

11 So to me it only makes sense to avoid
12 imposing a very confusing and flawed system upon the
13 regulated community for a brief interval of time.

14 CHAIRMAN CERQUEIRA: And fully assuming some
15 responsibility ourselves for not having clearly
16 identified the problem that is --

17 DR. WILLIAMSON: Everybody screwed up on
18 this, and there's a lot of blame to be shared for why
19 we're in this position, but it only seems like the
20 rational thing to do.

21 CHAIRMAN CERQUEIRA: Ruth?

22 MS. McBURNEY: My only comment on that is
23 that I don't think it would be the proper mechanism for
24 the staff to petition the Commission; that we as a
25 Committee can make that recommendation.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Right.

2 MS. MCBURNEY: But I don't think putting
3 that responsibility on the staff to go to the Commission.

4 DR. WILLIAMSON: I would amend it then to
5 say that the ACMUI --

6 CHAIRMAN CERQUEIRA: Okay. That's
7 appropriate.

8 DR. WILLIAMSON: -- recommends to the
9 Commission and otherwise unchanged.

10 DR. AYERS: Marjorie, you were wanting
11 protocol input, is waiting.

12 MS. ROTHSCHILD: Well, actually not on this
13 particular motion. It was just Dr. Cerqueira's request
14 for some information on a time line for rulemaking. I
15 didn't mean to interrupt.

16 CHAIRMAN CERQUEIRA: No, no, no. If you've
17 got some information factually that's good.

18 MS. ROTHSCHILD: Oh, okay. I was going to
19 say generally with rulemaking under the Administrative
20 Procedure Act, you have to have notice and comment. In
21 other words, you give people notice as in a proposed
22 rule, what you're planning to do, and then there's an
23 opportunity for comment, which of course, is what
24 occurred in this rulemaking.

25 Now, the duration of that comment period,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 you know, it can be very short or it can be, you know,
2 very long.

3 I'm sorry?

4 MS. MCBURNEY: Is there a minimum? We in
5 the states have a minimum number of days --

6 CHAIRMAN CERQUEIRA: Comment period?

7 MS. MCBURNEY: -- for comment.

8 MS. ROTHSCHILD: Well, the thing is there
9 are other legal requirements, I guess, that figure into
10 the comment period. Typically we have to allow for a
11 minimum usually of 75 days, and so there are some other
12 -- besides the Administrative Procedure Act, there's some
13 other statutory requirements, but I know that, you know,
14 there have been comment periods in the past as short as
15 two weeks.

16 The problem is people don't generally
17 consider that. Usually what we get are requests for
18 extension of comment period times.

19 Now, as far as, you know, shorter
20 rulemakings, it's possible you can have immediately
21 effective final rules, but those, the agency is
22 subjecting itself to -- it becomes vulnerable in terms of
23 the legal challenge when you have an immediately
24 effective final rule.

25 There's also something called a direct final

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 rule, but my understanding is for that it has to be an
2 issue that's not controversial. I think based on all
3 this discussion we could not say that.

4 So I hope that's somewhat helpful in terms
5 of the rulemaking process and time periods.

6 DR. NAG: Do you have like a number out of
7 the hat? Would you say like one year, two years, five
8 years?

9 MS. ROTHSCHILD: Oh, for the duration of a
10 rulemaking?

11 DR. NAG: From now till when the new rule
12 becomes --

13 MS. ROTHSCHILD: I mean, it depends on how
14 long your comment period is.

15 DR. NAG: Minimum, minimum.

16 MS. ROTHSCHILD: Minimum?

17 DR. NAG: Overall from today.

18 MS. ROTHSCHILD: I can't make -- I mean I
19 can just speak to what rulemakings that I'm aware of, you
20 know, how much time has been consumed. Sometimes, you
21 know, because of, say, statutory requirements where we
22 have to act, you know, we can do start to finish in less
23 than a year, but that --

24 CHAIRMAN CERQUEIRA: Let me ask Richard and
25 Jeff and Ralph. Is this controversial? Do we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 anticipated that there will be --

2 MR. LIETO: That's a good question.

3 CHAIRMAN CERQUEIRA: -- groups --

4 MR. LIETO: My feeling is it appears from
5 the discussion here that everybody is on the same page.
6 I don't really think -- I think what should happen -- you
7 know, I think in all due respect to Jeff's motion, I
8 think we're a little premature.

9 I think, first of all, the rule hasn't been
10 published yet. Okay? And we know what the problem is.
11 So with the Committee already being charged, and I guess
12 I would ask if it's possible that they could come back
13 with some proposal 30 days, you know, 45 days from now,
14 and then turn it over to staff for the rulemaking
15 process.

16 I mean if we had that and it's not
17 controversial, isn't it possible we could have this all
18 done by the end of the year?

19 MS. ROTHSCHILD: You know, I can't make any
20 commitment. I just think the amount of discussion that
21 the subject of training and experience generates, that
22 that one aspect of direct final rule in this case I
23 doubt, you know, whether this rulemaking, you know, would
24 be appropriate for a direct final rule.

25 But you know, I'm just speaking now, you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 know, personally.

2 CHAIRMAN CERQUEIRA: Certainly based on my
3 experience with this rule, I mean, you've got a public
4 comment, drafts, publish the draft. People get to
5 respond. You've got to respond to the questions that
6 you've gotten, and it's got to be published again for
7 another public comment period. It's going to take a
8 while.

9 DR. AYERS: And there's the internal
10 process, too, which includes the Commission's approval
11 and the publication period.

12 CHAIRMAN CERQUEIRA: And OMB.

13 DR. AYERS: And OMB, yeah.

14 CHAIRMAN CERQUEIRA: Ruth.

15 MS. McBURNEY: Looking at the issues of the
16 attempts to try to get more uniformity of the
17 requirements throughout the country, I would prefer that
18 these rules go ahead and go into effect, and even if
19 people have to be authorized as authorized users and
20 medical physicists under the alternate training and
21 experience, in the meantime, before we can get these
22 other proposed rules because it may take up to two years
23 to do that.

24 In the meantime the states are going to have
25 to start working on compatibility rules and so forth, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to have that total lag on all the rules and especially on
2 the training experience trying to keep those more
3 equivalent, that would be problematic.

4 CHAIRMAN CERQUEIRA: I agree with that.

5 So we have a motion.

6 DR. WILLIAMSON: I'm not sure I understand
7 the point. It seems like that is going to happen if the
8 implementation dates are not modified in this staggered
9 way, the states are going to have to approve Part 35 as
10 it is now within three years, and then in another 18
11 months a new modification of the rule is going to come
12 along, and then they're going to have to start working on
13 that at the same time.

14 It seems to me it would make sense to leave
15 the part alone that everybody agrees needs to be changed,
16 implement the rest, and then when the final rule comes
17 out, then the state should start working on it.

18 CHAIRMAN CERQUEIRA: Ruth?

19 MS. McBURNEY: No, I think that by the time
20 the states get to the point of actually or many of the
21 states get to adopting compatible rules, we would have at
22 least a proposed change ready to go, and they could
23 enfold that into their proposed rules.

24 DR. WILLIAMSON: But what would happen is we
25 would propagate this error through the whole agreement

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 state system that would disenfranchise --

2 CHAIRMAN CERQUEIRA: Yeah, but the agreement
3 states had three years upon which to act, and during that
4 time they can operate under the ole rules and, you know,
5 even under the best case a lot of them will.

6 DR. WILLIAMSON: Well, they can't -- for
7 three years they can, but they're going to start
8 implementing the new rule, and some of them will
9 implement the new rule if it's implemented in toto, and
10 that is going to propagate to the other 32 states
11 potentially this error.

12 So I actually think the most rational thing
13 is to keep that part of the old system intact until a new
14 part can be thought out and implement the rest.

15 CHAIRMAN CERQUEIRA: Ruth.

16 MS. McBURNEY: But during that time if the
17 Committee's recommendations get adopted by the staff and
18 put forth as a proposed rule, there will be parallel
19 rulemaking or parallel rule development among the -- for
20 the suggested state regulations that will be out and
21 available to the states along with that in that time
22 frame.

23 DR. NAG: I think to be realistic it's going
24 to be at least two or three years. I mean, nothing
25 happens in one year. I mean as a minimum, all that we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 talked about realistically look at two or three years.

2 DR. WILLIAMSON: So I think if there's a
3 concern with nuclear medicine, since that's
4 uncontroversial, more or less, that could be exempted,
5 but I do think in the therapy area, why propagate this
6 error unnecessarily?

7 CHAIRMAN CERQUEIRA: Niki?

8 DR. AYERS: Well, I would point out it isn't
9 as simple as keeping the old training or Board
10 certification training experience requirement. If you
11 keep those, they will now refer to sections that no
12 longer exist.

13 MS. MCBURNEY: That's right.

14 DR. AYERS: You're going to create a real
15 problem.

16 CHAIRMAN CERQUEIRA: Niki.

17 MS. HOBSON: Yeah, I'm just wondering what
18 the practical impact on patients that this is going to
19 have. Now, I mean, just sort of visualize. You know,
20 we're stringing this out over two or three years. Well,
21 people are going to change jobs. They're going to die.
22 They're going to retire. Are we going to be left with
23 enough people out there to provide, you know, these
24 essential services?

25 I think that the holes will just get bigger

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and bigger, you know, unless we do something to kind of
2 plug the gap until we can get the new rule.

3 CHAIRMAN CERQUEIRA: Richard, and then let's
4 go back to Jeff's motion because if we're going to get
5 out of here on time, we'll have to.

6 DR. VETTER: In response to Niki's comment,
7 I think the greatest impact would be on a licensee who
8 needs to hire a new RSO, and that new RSO, if they aren't
9 an RSO on some other license, they have to become
10 approved as an RSO, become qualified under the new rules,
11 and if they're Board certified or not, they are going to
12 have to go through the process of filling out all of the
13 paper work and so forth.

14 So the licensee in effect would hire a new
15 RSO who cannot be approved on the license until they've
16 gone through that entire process. It's going to be a
17 problem for licensees.

18 DR. AYERS: Yea, I don't think it bars
19 people, but it's a process issue, and the alternate
20 process is more lengthy than --

21 CHAIRMAN CERQUEIRA: Jeff, could you restate
22 your motion?

23 DR. WILLIAMSON: Yeah. My motion was that
24 the ACMUI recommend to the Commission that the
25 implementation dates of new Part 35 be staggered so as to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 delay the implementation of training and experience
2 sections for authorized nuclear pharmacists, authorized
3 user/radiation oncologist, authorized medical physicist,
4 nd radiation safety officer until such time as a revised
5 rulemaking can be completed to rectify the problem.

6 CHAIRMAN CERQUEIRA: Now, I think some
7 people had some issues with that just in terms of, you
8 know, the staggered implementation.

9 DR. WILLIAMSON: Well, I think it's
10 important to -- you know, the message is come up with
11 some administrative strategy to try to retain the old
12 system until --

13 CHAIRMAN CERQUEIRA: So could we make --

14 DR. WILLIAMSON: -- the rule can be fixed
15 and --

16 CHAIRMAN CERQUEIRA: -- the motion sort of
17 more general rather than trying to give them a specific
18 solution for it?

19 DR. WILLIAMSON: Okay. I'll rephrase it
20 then. The ACMUI recommends that the Commission retain
21 the old training and experience requirements for
22 authorized nuclear pharmacist, authorized user of 35-600
23 materials, authorized medical physicist and radiation
24 safety officer until such time as a rulemaking initiative
25 can be implemented to rectify the problem of training and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 experience requirements.

2 CHAIRMAN CERQUEIRA: Can we get comments
3 from people that would have problems voting positive for
4 that?

5 MS. MCBURNEY: I think I still think that
6 you're going to have problems in doing that as Bob Ayers
7 mentioned, referencing parts that don't exist anymore.
8 The requirements for diagnostic authorized user are
9 actually going down, I believe, on the number --

10 MR. HICKEY: Yeah.

11 MS. MCBURNEY: -- of hours of training, and
12 you --

13 DR. WILLIAMSON: But that's excluded from
14 this.

15 MS. MCBURNEY: Let me finish.

16 And the -- no, it's not excluded.

17 DR. WILLIAMSON: I just excluded it in my
18 motion.

19 MS. MCBURNEY: I didn't hear that.

20 DR. WILLIAMSON: Well, I focused, just to
21 repeat it, for authorized nuclear pharmacist, authorized
22 medical physicist, authorized user in 35-600, and
23 radiation safety officer. That's the scope of my motion.

24 MS. MCBURNEY: And it's going to leave some
25 doubt and confusion among the states as to what rules

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 need to be implemented, and in making their rulemaking,
2 do they use the old criteria or the new criteria, and so
3 forth?

4 DR. VETTER: The NRC is going to do what
5 they have to do to implement the new rule. I would vote
6 in favor of this motion to send the message, and they're
7 going to do what they have to do.

8 DR. WILLIAMSON: I think the basic message
9 is think outside the box and see if you can come up with
10 some way and solve all of these administrative problems
11 that Ruth and Bob have mentioned.

12 CHAIRMAN CERQUEIRA: But if you make that
13 motion without putting in specifics and delaying the
14 implementation of portions of it, which I think are going
15 to be controversial, I think that will send them the
16 message.

17 And I think we also agree that maybe Richard
18 and I should call Commissioner Meserve and talk to him to
19 see what other options are available.

20 DR. WILLIAMSON: I think, you know, we're
21 not the legal experts. It's their job to figure out how
22 to do this.

23 CHAIRMAN CERQUEIRA: Right.

24 DR. AYERS: I would comment I think you're
25 addressing the wrong issue there with the training and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 experience requirement. It's the Board recognition
2 that's the issue, and if the Boards had to be vetted
3 against the existing requirements, I think they'd have
4 the same problem.

5 DR. WILLIAMSON: Well, that's correct, and
6 so that's why I said leave it. Right now the existing
7 training and experience requirements don't create that
8 dilemma. That's why I phrase the motion --

9 DR. AYERS: Nor do the new ones. It's the
10 recognition process that's the problem.

11 DR. WILLIAMSON: But the old regulations
12 don't require a recognition process. That's why the
13 dilemma is not raised. It's avoided by my motion.

14 CHAIRMAN CERQUEIRA: Well, the NRC and this
15 Committee because we had a lot of input into it.

16 So state your motion again, Jeff.

17 DR. WILLIAMSON: Okay. The ACMUI recommends
18 that the Commission retain the existing training and
19 experience requirements for authorized nuclear
20 pharmacist, authorized medical physicist, authorized user
21 of 35-600 modalities, and radiation safety officer until
22 such time as a rulemaking initiative can be completed to
23 rectify the problem of recognition of the Boards as
24 pathways for achieving this status.

25 CHAIRMAN CERQUEIRA: We should probably get

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 a second on this new motion.

2 DR. DIAMOND: I'll second that.

3 CHAIRMAN CERQUEIRA: Any further discussion,
4 which I hope -- okay. So we should vote.

5 All in favor of Jeff's motion?

6 Opposed?

7 Okay, and you abstain? Okay.

8 Yes.

9 MR. LIETO: Dr. Cerqueira, are you and Dick
10 still going to plan on conversing with the Chairman?

11 CHAIRMAN CERQUEIRA: I would leave that up
12 to the Committee. If the Committee feels that would be
13 appropriate and helpful, okay.

14 DR. WILLIAMSON: I think you should.

15 CHAIRMAN CERQUEIRA: Okay. Now okay. We
16 can do that.

17 All right. Bob, thank you.

18 All right, John. So I guess we've got
19 actually three items left. The update on the new IVB
20 devices undergoing current review; security of
21 radioactive materials by Cathy Haney.

22 Has Cathy been in the audience? She's been
23 her in all of this.

24 MR. HICKEY: Could I request that we have
25 Cathy Haney go next since she's on a tight schedule and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 --

2 CHAIRMAN CERQUEIRA: Sure.

3 MR. HICKEY: -- I'm going to be here for the
4 remainder of the meeting?

5 CHAIRMAN CERQUEIRA: Sure. FCSS, SSSB.
6 What does that stand for?

7 MS. HANEY: It stands for Fuel Cycle Safety
8 and Safeguards, and the Safety and Safeguard Support
9 Branch.

10 (Laughter.)

11 MS. HANEY: And then I can tell you about
12 the next tier down, which are the sections, but I think
13 that's probably good enough.

14 CHAIRMAN CERQUEIRA: Okay. Well, that's
15 god, Cathy. Welcome back.

16 MS. HANEY: It's a long way from the
17 Division of Industrial and Nuclear Material Safety.

18 PARTICIPANT: Actually, do you have an
19 overhead?

20 MS. HANEY: Yeah, and I think my
21 presentation will be a lot less controversial than the
22 last ten minutes that I just heard. So you all can sit
23 back and enjoy for a few minutes.

24 DR. WILLIAMSON: Sort of like old days, huh?

25 MS. HANEY: Sort of like old days, right.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: You've never been
2 controversial.

3 MS. HANEY: No, never, never. It was so
4 nice to be sitting on that side instead of up there where
5 John usually sits.

6 What I want to talk to you about today is
7 mostly this is just an informational presentation, and
8 it's maybe a little bit of a look into the future of
9 where the medical and the other materials licensees may
10 be in two to three years.

11 So this is I'm just kind of planting a seed,
12 and also just since you are representatives of NRC, if
13 people know, you know, that you're on the Advisory
14 Committee and they say, you know, "What's NRC doing about
15 security at the nuclear power plants?" it will give you
16 a little bit of -- a couple of tidbits of information so
17 that you all can answer that question.

18 I have a long list of things to talk about,
19 but it really will not take me that long. I just want to
20 point out what the NRC mission is, and you're so used to
21 hearing about safety aspects, as I was when I was in the
22 other division, and now that I'm in Fuel Cycle, it's all
23 of a sudden there is another side to NRC, and that's the
24 safeguard side. So we'll touch on that for a second.

25 Just review some of the security regulations

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and some of the aspects of a security program, and what
2 I'm going to really be talking about is coming from the
3 reactor world, but when you sit back and look at them,
4 they apply to all of your facilities when you look at
5 security and safeguards as an overall issue.

6 I'll tell you about what we did immediately
7 following September 11th, and what we've done, some long-
8 term actions, and then talk about where we're going from
9 there, and then just touch real briefly on what are the
10 implications for this Committee, and in two years what
11 will I be talking with you about, and I'll be back in the
12 controversial seat. So that's why I'm starting now.

13 So as far as the NRC mission goes, I think
14 everyone realizes that it's to protect the public and
15 promote, but once you get beyond that first line, people
16 are not as familiar with that second line, which is we
17 really do have a role in promoting the common defense and
18 security aspects of use of byproduct source and special
19 nuclear material. So it is much larger than just a
20 safety and worrying about public dose and occupational
21 dose.

22 If you look at the regulation of security
23 aspects, it's very similar to what you see with the
24 safety aspects. First, we're regulating through a
25 licensing. There is inspection and oversight.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Now, in your particular hospital settings or
2 university settings, about the only regulation that
3 you're going to look to is Part 20, Section 1802 that has
4 to do with security of material, which is a little short,
5 two or three liner in 10 CFR.

6 When you get into some of the larger
7 facilities, you're looking at whole sections of 10 CFR,
8 and I don't see you going there. So don't get panicked
9 thinking, "Okay. She's really setting me up for two
10 years." I'm really not.

11 But we occasionally do rulemaking in the
12 security area. If we were going to change regulations
13 with regards to -- I mean, if we were going to change our
14 posture about security of licensed material, we would be
15 looking to possibly rulemaking.

16 There is a lot of research that goes on in
17 this area, especially post 9/11. Our research in the
18 security aspect has also increased, as well as our
19 intergovernmental coordination.

20 I mean, we always in this area had a lot of
21 coordination with the FBI, with CIA as far as looking at
22 intelligence information that was coming through, but now
23 with the Office of Homeland Security, that's increased
24 drastically.

25 We have also reached out to a lot of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 other intelligence communities, working closely with. We
2 are talking about possibly putting some staff a couple of
3 hours a week down at the FBI building and long term maybe
4 even down at the CIA.

5 So we are looking at really doing some
6 outreach with the other government users, and what we're
7 looking at this is really from a national infrastructure
8 standpoint. The government as a whole is deciding what
9 area to put their resources into to protect. There needs
10 to be some hierarchy of identifying what are the key
11 infrastructures that need to be protected, and that's
12 really -- NRC is playing in that area. So I want you to
13 know that we are particularly involved in that.

14 If you're looking at a safeguards and
15 security program, there are a couple of key terms that
16 you need to look at, and I'm not going to go through all
17 of this in depth, but the first one that I want to
18 mention is design basis threat.

19 And the reason I want to mention this to you
20 is this is something that we will be considering relative
21 to larger material licensees, and basically what a design
22 basis threat is is identifying the key components that we
23 want a facility to protect against, and then once the NRC
24 would identify those, this is turned over to the
25 licensees, and then the licensees develop a security

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 protocol for doing it.

2 Typically it's a denial strategy, which is
3 basically keep the bad guys on the other side of the
4 fence. So it's something very simple.

5 We are doing a top to bottom review of our
6 security program, the safeguards program. I'll get into
7 that in a few more minutes, but one of the things that
8 we'll be looking at is the design basis threat and
9 whether what we currently have should be changed in light
10 of the heightened threat environment and also who should
11 the design basis threat apply to.

12 Right now it really only applies to reactors
13 and to our very large fuel cycle facilities. So it's a
14 very small population. But should certain aspects of
15 that design basis threat apply to a hospital, apply to a
16 university?

17 And if you're thinking, "Okay. That sounds
18 great, Cathy, but what does that mean real world?" you
19 know, when you take it down to the hospital setting, I
20 mean, maybe that's putting up some extra vehicle barriers
21 to keep like a truck from approaching the facility very
22 close. It's just looking at your physical layout to see
23 if there are any changes that would need to be made.

24 When you're looking at security programs,
25 it's really broken into three areas. One is physical

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 security. Second is personnel security, and then
2 information security.

3 There's been a lot recently on the Internet
4 about the information security, and this has to do with
5 vulnerability of access to modems and your communications
6 systems, and I'm sure individuals at your facilities are
7 really looking at this already, but again, it does go
8 beyond just a nuclear environment when you get into the
9 information security.

10 And then we talked a little bit about the
11 NRC oversight program already, that it is in a way
12 similar to what you're familiar with.

13 And the last item is security levels, which
14 is probably something that you have not heard before
15 mostly because it hasn't applied. And again, I'm not
16 sure that I would if I was going to crystal ball it say
17 that it would apply to you, but let me tell you a little
18 bit about them.

19 Right now NRC has three security levels.
20 Immediately following the terrorist attacks, we went to
21 our highest security level for our licensees, which is a
22 Level 3, and this has the licensees increase security at
23 their site and make changes to really all of their
24 physical security, their background checks on personnel,
25 as well as their information security.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 There's an effort underway at the government
2 level to take all of the different threat levels or
3 security levels that each agency has and go to some type
4 of uniform level. This is an effort that's underway
5 under the Office of Homeland Security. And as a result
6 of that, you know, when one agency says we're at one
7 level, the other agencies are at similar levels.

8 So there will be more to come on that. It's
9 just in the initial stages at this point, but just be
10 aware that there are different security levels that NRC
11 does have now for some of its facilities.

12 I think what I'm going to do is skip over
13 the next couple of slides so that I can keep you on
14 schedule here. I've been responsible for keeping you
15 late before. So I don't want to be responsible today.

16 Let me tell you what NRC did immediately
17 following the attacks. The first thing is we activated
18 our Emergency Operations Center, and that was activated
19 within a couple of minutes, and we went to 24 hour
20 staffing on that particular area.

21 We had our executive team, which is a
22 representative from each one of the offices in NRC, like
23 the Office of Nuclear Material Safety and Safeguards;
24 Marty was there, which is our Director; Office of Nuclear
25 Reactor Regulation had their office director there; and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the Chairman of the NRC was also there. And we staffed
2 that for 24 hours.

3 Our first step was to issue a threat
4 advisory, which took all of our licensees to their
5 highest security level, and then subsequently we've
6 issued updates to those threat advisories. I think all
7 total we've probably issued in the 20 to 30 type of range
8 of advisories, and for various reasons.

9 If we saw a change in the threat
10 environment, we would inform licensees or if there were
11 certain actions we wanted licensees to take, we would
12 issue an advisory. And most of the advisories went to
13 the power reactors.

14 There were some -- I think there was one
15 advisory that went to all materials licensees. There
16 were some where we went to just the large material
17 licensees, those with emergency plans. But these were
18 typically the licensees that already had a very formal
19 security program in place where we thought that they
20 should make some changes in that particular item.

21 If with the larger licensees we did contact
22 them and discuss what actions they had taken in response
23 to the advisories, we maintained constant coverage of
24 monitoring the intelligence traffic to see if there was
25 anything changing that we needed to know about and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 whether we needed to increase or decrease security at our
2 sites, if there was a specific threat against any of our
3 reactors.

4 We also coordinated with the states, and we
5 did have someone down at the FBI's what's referred to as
6 SIOC, which is the Strategic and Information Operations
7 Center. And then I'm sure when you came in today you saw
8 a different security system than you had previously seen
9 here. So, I mean, even in house we increased our
10 security.

11 Post 9/11, and this is where we start to
12 look at where will we be going from here, and you guys,
13 some effects on your particular licensees. We were
14 looking at augmenting licensee's capabilities, and this
15 is recognizing that pre-9/11 there was a certain threat
16 environment that our licensees were expected to protect
17 against, but then post 9/11, we did want them to increase
18 that security.

19 So we're taking it up a notch or two or
20 three or four, depending upon who you ask, but we are
21 increasing licensee security requirements to what the
22 Commission believes is prudent in light of the current
23 threat environment.

24 We also have coordinated federal assets with
25 other government agencies. Two are noted up there. One

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 is the Coast Guard and the Combat Air Patrol. Depending
2 upon what action we were taking, if it was gathering
3 information from these other agencies or providing
4 information from our sites to these other agencies, we
5 were doing significant outreach to the other federal
6 agencies.

7 I've mentioned that we are doing a top to
8 bottom review of the safeguards program, and this is
9 something that is very much -- most of the work will be
10 done in fiscal year '02. There is some that extends out
11 into '03, and then there's a very little bit that goes
12 into '04, but the thought is that the majority of the
13 work will be done this year and next year.

14 There are a couple of things that we're
15 looking at, is looking at that design basis threat to
16 decide if any changes need to be made to that. We're
17 looking at vulnerability assessments at the sites where
18 we're actually going out to some sites or having
19 contractors go out to sites and look at the particular
20 sites and look for what are the vulnerabilities, and
21 given the increased threat environment, do adversaries
22 have better access to those sites typically referred to
23 as critical target areas? And are there any -- we have
24 not gotten down at this point to looking at your small
25 hospitals. The majority of the work is in the reactor

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 area in the fuel cycle arena.

2 We may be looking down into some of the
3 large irradiators, and again, the focus is on risk. What
4 risks do the specific facilities pose, recognizing that
5 from the standpoint of the medical facilities, you've
6 been complying with 20.1801, looking at security of
7 material all along. So with the hope that you would just
8 keep doing what you're doing and consider any of the
9 increased threat environment if there is anything that
10 you would need to make changes.

11 There may be possibilities for legislative
12 changes in this particular area. There are several
13 Congressmen that are very interested in what NRC does.
14 So it's possible long term you could see some changes in
15 that area.

16 Also, there will be some changes, I believe,
17 in the interagency coordination aspects, again, just
18 trying to work together. We're all trying to work
19 together as one federal government to come up with a
20 position that would be uniform between the different
21 government agencies.

22 As far as what's going on in the threat
23 world, because if you listen to CNN, you hear a lot about
24 it, hopefully we'd like to hear about it before it hits
25 CNN, and that usually works.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 There's one case where I was driving home
2 from work and heard something on CNN. It was like when
3 I left work everything was fine, and an hour later what
4 am I hearing on the public radio?

5 Once 9/11 hit, we asked all of the sites to
6 report suspicious activities to us, and to be quite
7 honest, we had hundreds of reports in, and some of them
8 were fly-overs where you'd have small planes flying over
9 the reactor sites at very low levels, caused some concern
10 because there really was no reason for the planes to be
11 down that low.

12 You know, when you go back and look at them,
13 you know, they could not track where the airplane came
14 from. So it makes you wonder as to what's going on.

15 A lot of strange people. It's amazing the
16 number of people that feel it necessary to take pictures
17 of nuclear power plants.

18 (Laughter.)

19 MS. HANEY: So now those people have found
20 it into our database of the number of incidents in that
21 particular area.

22 When we got an unusual case, it was
23 typically reported to local FBI, and local FBI would go
24 out and investigate it if it was something that was
25 deemed crossed a threshold of this seems awful strange;

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 maybe we should look at it.

2 And obviously, there were some differences
3 on some of the risks that were posed. I think there was
4 one case where we had someone being interviewed by local
5 FBI that was just two tourists that happened to want to
6 be taking a picture of the lake and then on the other --
7 they didn't realize that on the other side of the lake
8 was the nuclear power plant. So there were, you know,
9 things like that.

10 But in some of the fly-overs, it led you to
11 be a little bit more concerned about what was going on.

12 All right. Flip this one.

13 Okay. Surveillance and planning, and the
14 reason that we looked into this particular area was that,
15 you know, it's obvious that the September 11th attacks
16 did not just occur, and there have been multi-year
17 surveillance going on, and this is why it's important in
18 your facilities to -- you know, the constant attention
19 that you do pay to security because if something is going
20 to happen, it's usually not just, you know, I decided to
21 do something wrong today. It's something that someone
22 may have been thinking about for a while.

23 And looking at different systems that you
24 can have in place with regards to this surveillance
25 information collection, just sensitizing people in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 departments to be aware of any unusual activities.

2 Your security system challenges, I mean, you
3 have security systems in the hospitals for reasons beyond
4 the radioactive materials, but again, making sure that in
5 your particular departments that you are involved in
6 decisions made with regard to this security because it
7 does have implications for the radioactive material.

8 This insider infiltration sounds awful
9 serious in the area where you are, in the reactor areas,
10 the fuel cycle facilities. It is a big concern, but to
11 bring this down into, you know, the world of the
12 university and the hospital, this is the misuse of the
13 radioactive material where you're, you know, putting in
14 someone else's food or something like that.

15 I mean, we've had incidences over the year.
16 so it really does apply, and I think what I'm trying to
17 say is, well, you know, most of this program, security
18 and safeguards program is set for the power plants and
19 the fuel cycle facilities. It really does have
20 implications into the university setting and the hospital
21 setting.

22 Okay, and then the last one is really what
23 are the possible implications for the material licensees.
24 What will I be back here talking to you about in two
25 years?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And these are my crystal ball, I guess, if
2 you want to refer to it that way. One is the
3 vulnerability analyses.

4 As I said, right now we're really not
5 focused down into the university or into the hospital
6 setting, your small community hospital setting.

7 It's possible that long term that we do
8 start looking a little bit closer at what are the
9 vulnerabilities at the hospitals, and when we would
10 approach it from a hospital setting, we'd start with the
11 higher risk sources as compared to your community
12 hospital that's only doing 35, 100, and 35, 200.

13 There may be some statements that come out
14 from NRC with regards to increasing security at your
15 sites. We have proposed what we've called interim
16 compensatory measures for the larger licensees, and it's
17 possible that long term that we may be proposing some
18 security measures that would be at hospitals.

19 Again, you're not on the top of the list
20 right now, but long term, you know, we would be looking
21 at these areas.

22 And then as we do go on and make changes in
23 our safeguards and security regulations, there may be
24 some of those changes that would affect your facilities,
25 and that would be something that we would be coming back

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to talk to you about.

2 So as I said, these are long-term changes.
3 Obviously when we are doing this top to bottom review of
4 the safeguards and security programs, we're thinking of
5 all licensees. So you're not lost; you're not forgotten.

6 We are using a risk approach, the larger
7 licensees, higher risk licensees first, but recognizing
8 that some of the changes that come out of those programs
9 could have implications to the medical setting.

10 So that is the quick overview of the safety
11 and safeguards and what NRC has done post 9/11. I'd be
12 happy to answer any questions, just not about Part 35.

13 (Laughter.)

14 MS. HANEY: I had to get that in, Jeff.

15 DR. VETTER: We kind of laughed when you
16 mentioned people taking pictures of nuclear power plants,
17 but we've had people taking picture of our oxygen supply
18 at our hospital, of our own nuclear -- not nuclear. I'm
19 sorry -- our own power plant. We have two, one for our
20 clinic, one for our hospital. And so we're getting a
21 little bit -- some of these have been investigated by the
22 local law enforcement, and you know, it's innocent enough
23 just like you've mentioned. Nevertheless, you can't help
24 but get a little bit paranoid.

25 And then because of my own naivete, I've

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 learned today that the location of where we store our
2 brachytherapy sources and our nuclear medicine generators
3 and all of that is on ADAMS. It's there for the world to
4 see, and I didn't know that because our information
5 security is so tight I can't get to ADAMS. I can't get
6 through the firewall. I can get E-mail, you know, and
7 all of that. You can get out, but when it comes time to
8 getting back in, our firewall is so secure I haven't been
9 able to go up to ADAMS.

10 I'm going to work on an alternate pathway,
11 but what I'm really getting at is I hope I'm not the most
12 naive RSO in the world. I would submit that most RSOs
13 don't know that the location for the storage of their
14 radioactive materials is on ADAMS.

15 If they did know, they might think a little
16 differently about the security of their area. And in
17 fact, if I knew that in my last license reapplication,
18 broad scope license application, which we turned in in
19 December, I might not have furnished room diagrams. I
20 would have challenged the NRC to have Enforcement or
21 Licensing come out and look at it rather than give you a
22 room diagram showing the location.

23 I'm just a little concerned about that, and
24 the challenge I would have for you is, or the NRC,
25 whomever, is to notify radiation safety officers that, in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 fact, all of this information is on ADAMS in case they
2 didn't know about it, and you know, they may want to
3 heighten their own awareness of security issues because
4 of that.

5 MS. HANEY: Well, I think that's a good
6 point. Early on NRC took down its Web site completely.

7 DR. VETTER: But they didn't take down
8 ADAMS, did they?

9 MS. HANEY: Well, there were a couple of
10 days where it was down. Everything was down. You
11 couldn't access anything on NRC because of just some
12 concerns about what information was on there.

13 Bit by bit the Web site has gone back up,
14 but I think you're correct about the ADAMS issue, and
15 that would be one thing. I will take that challenge, and
16 I guess as you're interacting with your associates, you
17 know, also to make them aware because that's a good way
18 of getting the word out, sometimes better than what NRC
19 is doing.

20 And I think it is good to think about what
21 information you are sending into NRC, and it's time to
22 question it because, you know, information that we didn't
23 used to worry about pre 9/11 coming into the agency, and
24 then the aspect of NRC trying to share the information
25 with the public, to be open. Things have changed, and I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 think you raise a very valid point.

2 MS. WAGNER SCHWARZ: Cathy, is there some
3 way that that portion of the information can be withdrawn
4 and not -- I mean, because of security reasons, not made
5 available?

6 MS. HANEY: We can look into it. I would
7 say it certainly is a valid concern. There are ways that
8 you can take information out of ADAMS, such as that.

9 So I mean, I'll take that as an action item
10 for John.

11 (Laughter.)

12 MS. HANEY: John's over there saying you
13 like that. You just vote me on that one.

14 But I think it's something that we probably
15 should look into and consider.

16 CHAIRMAN CERQUEIRA: David.

17 DR. DIAMOND: Cathy, thank you very much.
18 If memory serves, I think I'm the one that suggested that
19 we have this little briefing, and I found it very, very
20 informative.

21 I would like to echo what Dick said, which
22 is that certainly we're not the highest risk licensees,
23 but at some point it would be useful to send out some
24 general memorandum to the hospital based licensees just
25 to gently remind them regarding the importance of these

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 issues.

2 My question is without giving us any
3 information which would make you uncomfortable, just
4 stemming from some discussions we had earlier today with
5 Dr. Frant, has there been any concern in the government
6 of prior credible threats about folks, bad folks, trying
7 to avoid these very high risk targets and starting to
8 look into these dirty bomb issues or dispersal of
9 radioactive materials, such as Iridium-92 or cobalt?

10 Can you tell us if that's been a credible
11 concern or is it just our paranoia reaching down?

12 MS. HANEY: Well, I guess for as much as I
13 can say, I guess there is a concern obviously looking at
14 the Washington Post and the Washington Times. There have
15 been numerous articles about dirty bombs, and I'm sure in
16 your local newspapers you've seen some, and there's been
17 some reporting.

18 So I think it's fair to say that it is a
19 concern and something that people are looking at. Beyond
20 that I'm not sure I can give you much more information on
21 that.

22 CHAIRMAN CERQUEIRA: Ruth.

23 MS. McBURNEY: Getting back to Richard's
24 comments and the fact that license information is on
25 ADAMS, in our state once we send out our security

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 advisories to our major licensees, we had some calls from
2 one of the major manufacturers there in the state who was
3 concerned that the location of their radioactive material
4 was available under open records.

5 We don't have that same information on our
6 Web site, but I did assure him that we are looking at
7 whoever. We take the names and so forth of people who
8 come in to look at files and have been a little more
9 aware of who's looking at what in that case.

10 CHAIRMAN CERQUEIRA: Richard.

11 DR. VETTER: Cathy, I wanted to also thank
12 you for being here. This has been very, very
13 enlightening. You said you didn't have much to offer
14 hospitals relative to vulnerabilities, but of course, the
15 obvious one is the room exists; the storage facilities
16 exist. Hopefully they've all got the door locked.

17 But we're from, especially in the hospital
18 environment, from a value system that we find it very
19 difficult to think like a terrorist, and so if in your
20 studies of this issue, if you have come up with
21 vulnerabilities that could, in fact, be applied to a
22 hospital environment, I think it would be really
23 worthwhile to share that with us.

24 MS. HANEY: And I think that's the long-term
25 intent that we would be doing that. Obviously if we had

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 reason to believe that there was a threat against a
2 hospital, we would make the hospital aware of it, and it
3 would not be a delay, you know, factor.

4 What our tendency has been, we have the
5 routine review of the intelligence traffic, and if a
6 facility by name were to come across or even by category,
7 we would notify that category.

8 But beyond that, you're right. As we
9 identify vulnerabilities at different sites, there are
10 some items that are common to the hospital setting, and
11 we would certainly share that with you.

12 And what we are looking at also is going
13 beyond. Obviously our focus is the radiation aspect of
14 the material, but at some of our sites, there are certain
15 chemical hazards that NRC does get into the oversight
16 with because it is inherent to the processing of the
17 radioactive material.

18 So we are looking even broader than just the
19 radioactive material aspect.

20 CHAIRMAN CERQUEIRA: Other questions for
21 Cathy?

22 If not, I'd like to thank her for coming
23 back to the ACMUI.

24 MS. HANEY: You're welcome. It's always a
25 delight. I like coming back here.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: We miss you.

2 MS. HANEY: I miss you guys, too. I really
3 -- and I wanted to come to the Commission meeting
4 yesterday. I had it on my calendar, and I couldn't get
5 down there. So I felt better because I thought I'd get
6 to come down and say hi today. So I'll see you all when
7 you come back.

8 DR. DIAMOND: Maybe we can get you back for
9 the next round of rulemaking.

10 MS. HANEY: I don't know.

11 (Laughter.)

12 MS. HANEY: Is that what I want? You need
13 me back? Okay. Well, they'll just transfer me down the
14 hallway. Actually all I am is around the hallway. So
15 they'll send me back around. So whatever I can do,
16 please let me know, and take care.

17 CHAIRMAN CERQUEIRA: Again, thank you.

18 We have several items on the agenda. People
19 wanted to try to end by three o'clock. So we may try to
20 keep some of these brief rather than in detail, but
21 obviously if there's need for discussion we'll do so.

22 John, do you want to update us on the new
23 IVB devices?

24 MR. HICKEY: Yes. I will be brief.

25 First of all, I want to say that in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 licensing and providing guidance on IVB, intravascular
2 brachytherapy devices, the Committee has provided
3 invaluable advice and suggestions, and our approach has
4 reflected that advice, and we think it has held up very
5 well.

6 A couple of areas, for example, was in one
7 of the questions was use of the procedures in ways that
8 were not specifically reviewed by FDA when FDA granted
9 approval of the devices.

10 Another example is the physical presence
11 issue and who should be physically present during the
12 procedure. We think the approach we've used has held up
13 well. We've gotten some questions clarifying, you know,
14 do you really mean an authorized user is actually
15 supervising the use of the material, and we would say,
16 yes, we really do mean that.

17 But we think the approach has held up very
18 well and will continue to hold up for things that may
19 come in the future. I don't think we're going to have to
20 come back to the Committee for some things that we, you
21 know, didn't anticipate in these initial approaches,
22 although, you know, you never know what we may need to
23 come back to the Committee for.

24 As far as future devices, there are a couple
25 it's our understanding are in trials, but we don't think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they will raise new issues. They still will use solid
2 material is my understanding. It might be a coded
3 (phonetic) source rather than a sealed source, but the
4 technology I don't think will pose any new issues that we
5 haven't discussed, but if they do, we can come back to
6 the committee.

7 There has been talk of -- I shouldn't say
8 just talk. There have been proposals and prototypes of
9 liquids and gas, but I think those are farther away, in
10 our sense, but that is always a possibility. I don't
11 think they will raise issues that aren't covered by the
12 existing guidance and positions we've taken.

13 So that's basically a summary. I think so
14 far we have a success story on IVB.

15 CHAIRMAN CERQUEIRA: We have a number of
16 approved devices. How many new devices are currently
17 under FDA review?

18 MR. HICKEY: Well, one is a coded material,
19 but it's still basically a sealed source. Another is a
20 high dose rate type source that could be used in large
21 vessels, using a sealed source.

22 There have been other discussions of liquids
23 and gas, but I think a lot of those have been dropped,
24 but there may be other ones out there that I'm just not
25 aware of because they're farther down the road. They're

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 farther on the way.

2 DR. DIAMOND: I was just going to clarify
3 the point. One is a wire foil which is radioactive. So
4 a kind of variation on the theme of a solid source.

5 The second one is an extant source design in
6 which the delivery system is modified in a very clever
7 way so as to change the depth dose characteristics.
8 That's the one that's addressing the larger vessels.

9 DR. NAG: I'd be interested in that. I
10 would like to just make a couple of comments, if I can
11 have the line.

12 Now, I think when intravascular
13 brachytherapy came in, it was but in a separate technical
14 emerging technology because brachytherapy was used as a
15 basis for intervention in developing for cancer and
16 required different consideration, and they used different
17 technology.

18 But I think we have to reexamine those
19 issues because it's true that brachytherapy is normally
20 used for treatment of cancer, but brachytherapy has been
21 used for many years for prevention of non-cancer things
22 like halite (phonetic), iridium, and they have the same
23 radiation safety requirement as that for cancer
24 brachytherapy.

25 So, you know, the first argument about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 placing brachytherapy in a separate category, you know,
2 doesn't hold.

3 Through the medical consideration for
4 interventional brachytherapy is different from
5 brachytherapy at other sites, but here are medical
6 considerations at individual sites, like brain. When we
7 started doing brain, we had entirely different
8 considerations. When we went to prostate, we had
9 different considerations. Eye had different
10 considerations, and the specialists from these various
11 sites worked in conjunction with the authorized user to
12 implant radioactive source at these sites.

13 So how is that different from a cardiologist
14 working in a vessel, working with an authorized user? If
15 the radiation safety issues in interventional
16 brachytherapy are different from the regular
17 brachytherapy for cancer, the same regulation should
18 apply. So why have a separate category for
19 interventional brachytherapy and a separate emerging
20 under 1,000?

21 The other thing is interventional
22 brachytherapy uses separate technology from cancer
23 brachytherapy. Again, that's not true because for each
24 type of interventional brachytherapy you have in
25 conventional brachytherapy and will give you some

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 examples.

2 And the radiation safety issues --

3 CHAIRMAN CERQUEIRA: Subir, again, I don't
4 mean to -- this was sort of added to the agenda, and just
5 for the sake of time --

6 DR. NAG: I just have my recommendation for
7 that.

8 CHAIRMAN CERQUEIRA: Okay.

9 DR. NAG: And therefore, I think -- but
10 these are important -- my recommendation is to eliminate
11 the special consideration of intravascular brachytherapy
12 as an emerging technology and place equally
13 interventional brachytherapy in the corresponding
14 brachytherapy category, and all the radiation safety
15 regulatory requirements as needed for other brachytherapy
16 procedures should apply for interventional brachytherapy
17 and that will give you these examples.

18 Under the guidelines you have remote HDR,
19 the Cordis, the same as your manual iridium. Novoste is
20 the same as your strontium eye brachytherapy. A new
21 liquid Radiance is the same as your gliacyte which is
22 being used for brain tumors.

23 And the other thing is many of these new
24 technologies that are being developed for brachytherapy
25 for interventional brachytherapy is also being applied

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 for cancer brachytherapy, like the beta HDR development
2 guidance is being multiplied and used for intraluminal
3 HDR for biliary and esophagus. The check developed for
4 interventional brachytherapy has been used for bronchial
5 radiation.

6 So it doesn't make any sense to have a
7 different regulatory guideline for interventional
8 brachytherapy when you are using the same equipment and
9 the same category for brachytherapy elsewhere.

10 And again, you are having an unintended
11 consequence when you substitute the "or" or the "and"
12 because now you can have interventional brachytherapy
13 performed by the cardiologist with the authorized user or
14 the physicist.

15 So basically what you did is that it
16 required a signature of your user without their
17 involvement in many cases, and therefore, you can
18 potentially compromise radiation safety.

19 I don't want to go into all the details, but
20 you can have similar examples at almost every site, and
21 I believe this issue has to be reexamined.

22 CHAIRMAN CERQUEIRA: Well, I guess in a
23 sense by putting it into the emerging category was to
24 sort of delay it, and I think we're getting to the point
25 where some of these things are out there and, you know,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 as we know, there is a lot of work going on between the
2 intravascular -- the people doing intravascular
3 brachytherapy, the oncologists and the cardiologists.

4 You know, again, I'm not sure that this is
5 a time for us to take action on this, you know. The
6 rules, we had a lot of discussion and put it into the
7 1,000 category. I think the Commission recognizes that
8 there are issues related to, you know, safety as well as
9 who's doing it, and I think the fact that they've
10 appointed an interventional cardiologist to the Committee
11 sort of recognizes that, and I think there's preparation
12 to do this.

13 DR. NAG: Right, but the thing is if you're
14 having a different rule and you are using the same
15 brachytherapy for interventional and you have a separate
16 rule when you're using it for other brachytherapy, that
17 doesn't make sense. It has to follow.z

18 CHAIRMAN CERQUEIRA: Jeff?

19 DR. WILLIAMSON: Well, I actually think that
20 there's a contradiction in what you're present. To argue
21 that the Novoste and the Cordis system be treated as
22 manual brachytherapy sources, as you do, and actually
23 reduce the regulatory burden because there is no NRC
24 requirement that either a physicist or physician be
25 present when the sources are put into the patient.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So you know, there certainly are standards
2 of practice in radiation oncology that are independent of
3 what NRC says. But if the best Cordis system were
4 treated strictly as manual brachytherapy, there would be
5 no requirement of physical presence whatsoever in the
6 operating room. So now there is.

7 So you know, to say, you know, your two
8 wishes are inconsistent -- to say there should be an
9 "and," physicist and authorized user and should be
10 treated as a 3400 is a contradiction.

11 DR. NAG: Then you're going out for the HDR.
12 For HDR you have the N, and in an HDR application, then
13 you need both. You need an HD -- for HDR application for
14 cancer, you need the physicist and the authorized user,
15 but when you have an HDR interventional brachytherapy,
16 you don't need both.

17 DR. WILLIAMSON: But that's not what you
18 said. You said that the Cordis should be treated as a
19 35-400.

20 DR. NAG: No.

21 CHAIRMAN CERQUEIRA: I would kind of leave
22 it up to the Committee. Do you want to continue the
23 discussion? I mean this was sort of an added item to the
24 agenda. We agreed that because of flights we would try
25 to basically get out of here in the next 20 minutes.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 You know, I think this is a legitimate
2 question that needs to be addressed. I think the
3 Committee and the Commissioners --

4 DR. NAG: This is what I wanted to bring
5 forward.

6 CHAIRMAN CERQUEIRA: -- have made a process
7 in place and I think will come to it.

8 David?

9 DR. DIAMOND: Yeah, I don't think we need to
10 discuss this further right now. I would convey to the
11 Committee, however, a sense that VBT or vascular
12 brachytherapy really heretofore has been a success story.

13 If you go back now two and three years when
14 this first came out, if you remember the discussions we
15 had about real horror stories about people using this
16 inappropriately, off label, it going crazy, people
17 getting hurt, public fears.

18 I think that we really need to congratulate
19 ourselves once in a while and say, you know, we kept a
20 handle on this for a while, and then starting about a
21 year ago, we said things look like they're going well.
22 People are practicing good, safe medicine. We took some
23 of the brakes off. We said, "Don't be too overly
24 prescriptive with respect to off-label use."

25 Since that's gone through to my knowledge,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 as one of the largest operators of this technology in the
2 country, people have continued to use it with very good,
3 judicious intent. Dr. Triparenini is probably even a
4 more higher volume user than I, and he would, I would
5 hope, share the same feelings.

6 People really have with this multiple
7 disciplinary approach, really have been very, very good
8 at protecting the public and preventing bad things from
9 happening. So once in a while we do need to give
10 ourselves a little pat on the back.

11 CHAIRMAN CERQUEIRA: I think we deserve it
12 after yesterday and today's discussions on our failure
13 with certain guidelines.

14 Well, this is very informative, and
15 obviously this issue will come back, and I think we'll
16 definitely get it on the agenda.

17 Thank you, Subir.

18 We should move along on the agenda, I guess.
19 Joe DeCicco on the mixed doses.

20 MR. DeCICCO: Both sides so I can remember
21 who I am.

22 This is going to be very brief. I don't
23 even have a presentation per se. I don't have any slides
24 or anything because all I wanted to do was update you and
25 let you know that we're still discussing and working on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 mixed dose, the mixed dose issue.

2 And in your handout there is just a brief
3 summary of how we've addressed the issue since the last
4 meeting, as a matter of fact, in October.

5 What we have done is taken the existing
6 regulations and kind of looked at it with a fresh eye and
7 maybe redefined the box that we're supposed to be
8 thinking in and used the footnote in the weighting factor
9 table in Part 20 that basically allows the agency to use
10 other weighting factors other than one for external dose.

11 So that with either a case-by-case
12 evaluation or guidance that would be issued by the
13 agency, some other method other than deep dose equivalent
14 could be used for determining the external exposure.

15 In your package you have a regulatory issues
16 summary, and a regulatory issues summary is similar to an
17 information notice that you might be more familiar with,
18 but the regulatory issues summary focuses on a regulation
19 and either a different interpretation that has been done
20 in the past or to allow for a new interpretation of a
21 policy position or a relief in burden.

22 And I think the regulatory issues summary
23 that you have in your package kind of addresses the issue
24 for fluoroscopy when using a protective apron.

25 The regulatory issues summary has been

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 distributed to the state regulatory agencies for comment.
2 It was issued to the states on January 24th, and they
3 were given 45 days for comment.

4 It is pre-decisional, which means it's not
5 out there for everybody, but the regulatory agencies can
6 look at it and address any comments to either me or to
7 the agency at the Web site that the states have access
8 to.

9 And the comment period for this regulatory
10 issues summary draft is March 14th. Hopefully by the end
11 of March or very close to that date, we should have this
12 regulatory issues summary issued and out to licensees so
13 that they can use this guidance that addresses the issue
14 of that mixed exposure when using fluoroscopy and the
15 lead apron and also being exposed to NRC licensed
16 sources.

17 So that's about it. That's all I wanted to
18 do is make you aware of. If you have any comments,
19 please provide them to me or any other method that you
20 say.

21 Yes, sir.

22 CHAIRMAN CERQUEIRA: Richard.

23 DR. VETTER: So how is the license -- if an
24 interventional cardiologist is involved in fluoro, of
25 course, like in most of the exposure there and doing IVB,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 how is the licensee to distinguish what exposure came
2 from the brachytherapy source versus the X-ray source?

3 MR. DeCICCO: That's a very difficult
4 technical issue, and it's not addressed in the regulatory
5 issues summary per se because we didn't want to try to
6 address all of the issues.

7 However, the staff has actually looked at
8 that issue, and I don't want to state too much because I
9 don't state policy, but from a technical point of view,
10 the evaluation done when evaluating the X-ray exposure is
11 probably as close to the true dose than any other method
12 used, and I think that particular issue will be addressed
13 after this RIS comes out because that's a much smaller
14 community than, say, the fluoroscopist also doing nuclear
15 medicine.

16 There's probably fewer physicians doing both
17 IVB and fluoroscopy as opposed to physicians being
18 exposed to both source and non-source at separate times.

19 DR. VETTER: Okay. I understand that, and
20 that does make sense. I mean, for the nuclear
21 cardiologist who's also doing intervention, you can have
22 two badges and you can sort it out easily.

23 CHAIRMAN CERQUEIRA: That easy, but for the
24 IVB.

25 Ralph?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: Boy, I've got a number of
2 things. One, I think this type of guidance affects
3 basically almost totally medical users, and I think that
4 something like this, which I want to say I think it's a
5 very good document; I applaud the summary information and
6 so forth.

7 I've got just a couple of comments on it
8 myself, but I think the point that was brought up about
9 addressing the situation of the person who has like the
10 cardiologist or the radiologist who does nuclear medicine
11 and a lot of fluoroscopy I really think has to be
12 addressed in this.

13 I think to take it at one time and then come
14 back later and revisit it I really think is sort of a
15 disservice to this document. I really think that there's
16 a real need for this, and I think the guidance that a lot
17 of RSOs and medical physicists that sort of struggle with
18 this is out there.

19 You know, one thing may be for consideration
20 is the fact that you don't have to badge a worker who is
21 not likely to get ten percent of the dose limit or you
22 know that a cardiologist is not likely to get ten percent
23 of his dose from intravascular brachytherapy. In fact,
24 you could almost say that with certainty.

25 And I can say also it's very likely that a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 radiologist who does fluoroscopy is not likely to exceed
2 ten percent of his does from his nuclear medicine
3 activities. It's very hard to get exposed from behind
4 that alternator.

5 And so I would say that as maybe a
6 suggestion for guidance in this document is that using
7 this guidance and assigning doses for external and
8 internal for NRC licensees would be applicable to those
9 situations where the licensee can document that it is
10 very unlikely, that it's not likely that the worker is
11 going to exceed ten percent from his licensed NRC
12 activities.

13 And I guess I had one question. Your Item
14 No. 4 on page 3, you said that any alternative method
15 that is used incorporating the license must be
16 incorporated in the licensee's procedures and program.

17 It almost makes it sound like it's a license
18 condition. Do you understand where I'm kind of going
19 with this? And that it has to be instituted prior to the
20 exposure for which an alternative method has been
21 applied, and I'm just trying to understand why that went
22 in there.

23 MR. DeCICCO: Yeah. Not to go into too much
24 detail because of time and since it was pre-decisional,
25 I think what we were trying to avoid is this is going to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 be a prospective application of the accepted -- the
2 guidance. We didn't want people to go back to previous
3 exposure or past years and say, "Oh, well, that exposure
4 really wasn't that. Now we can reevaluate it."

5 We didn't want people to go back. We just
6 want this to be a prospective.

7 It being a requirement to be documented,
8 that was put in there primarily to avoid people flopping
9 from one procedure to another to fit their needs. We
10 wanted it to be a prospective application, and therefore,
11 you use that application as long as you feel that that's
12 appropriate prospectively.

13 You don't say, "Oh, well, let me reevaluate
14 this after the fact." And that's why that particular
15 phrase was put in there.

16 MR. LIETO: Okay.

17 MR. DeCICCO: It was to avoid that flip-
18 flopping or going back to previous exposure.

19 MR. LIETO: Okay. I thought that was kind
20 of handled in number five already, and I just --

21 MR. DeCICCO: Maybe it was; maybe it was.
22 Okay. We'll take a look at that. Thank you.

23 CHAIRMAN CERQUEIRA: So, Ralph, how do you
24 suggest we go? I mean, so this is basically a draft
25 form, and has it gone out to any of the stakeholders?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. DeCICCO: It's gone out to state
2 regulatory agencies for their comment, and the comment
3 period is up until March 14th, and then we'll --

4 CHAIRMAN CERQUEIRA: But what about -- I
5 mean, has a cardiologist had a chance to look at this to
6 give you some feedback?

7 MR. DeCICCO: Not licensees, not non-
8 regulatory agencies because it's a pre-decisional.

9 CHAIRMAN CERQUEIRA: Right.

10 MR. DeCICCO: Pre-decisional.

11 CHAIRMAN CERQUEIRA: Would it be worthwhile
12 getting their input as well as, you know, the health
13 physicist community?

14 MR. LIETO: I was just going to say I think
15 it would be interesting to see what, you know, like the
16 Health Physics Society might have to say about this or,
17 you know, have some input from some of the scientific
18 groups, but I'm not quite sure. When you say it's pre-
19 decisional, I don't know if there's some type of
20 restriction in the distribution of the information from
21 a I don't want to say security standpoint, but --

22 MR. DeCICCO: Well, it's not security, but
23 it's a matter of procedure.

24 MR. LIETO: Okay.

25 MR. BROWN: Yeah, this is Fred Brown.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 This document was shared with you for your
2 comments as professionals in the field, as contract
3 employees of the NRC, and we would appreciate your input,
4 and hopefully it will serve as the type of input that
5 you've proposed, but the Administrative process for this
6 document and the time frame for it basically restrict us
7 to sharing it with you at this point, and we hope to have
8 it out soon.

9 DR. VETTER: So how do we get our comments
10 back to you?

11 CHAIRMAN CERQUEIRA: Back to you, yes.

12 MR. BROWN: Either through Angela or
13 directly by E-mail.

14 CHAIRMAN CERQUEIRA: And what time line do
15 we have on getting the comments back?

16 MR. DeCICCO: Well, the comment period is
17 officially open until March 14th, and until it's signed,
18 you know, I'll take comments up until I can get the final
19 version.

20 CHAIRMAN CERQUEIRA: Yeah, I gather it's a
21 situation where we're -- this sort of has an impact on
22 certainly the users, the stakeholders being the medical
23 community, and it would have been good to have gotten
24 this ahead of time.

25 So I think all of the people that are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 basically representing some of these regulated
2 communities should give input.

3 And can we get specific information where to
4 send the input? How do we contact --

5 MR. DeCICCO: On the last page of the RIS
6 which is the next to the last page of the document, is my
7 E-mail address, my phone number, where you can send
8 comments.

9 CHAIRMAN CERQUEIRA: Okay.

10 MR. DeCICCO: Or to Angela.

11 CHAIRMAN CERQUEIRA: Okay. All right. Do
12 we need any follow-up on this?

13 I mean we should get -- Ralph, don't you
14 think we should get some follow-up as to how this is
15 going to eventually come out?

16 MR. LIETO: I think it would definitely be
17 welcomed, especially by the Committee, and there is --
18 yeah.

19 CHAIRMAN CERQUEIRA: So should we make it an
20 action item that, you know, at the next meeting we get
21 some follow-up either from Joe or from the NRC staff as
22 to what's happened with this and some time line of when
23 it's going to be implemented as well?

24 Okay. Well, thank you very much, and we'll
25 -- yes?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: Joe, is there like a time line
2 that you guys are under in terms of having this all
3 complete? I mean, it sounds like there might be some
4 deadline.

5 MR. DeCICCO: Right now my time line is to
6 try to get this thing signed out some time around the end
7 of March, the beginning of April, and that was basically
8 a Commission request on getting this issued.

9 MR. BROWN: Once it's issued, it will be in
10 effect, and it should reflect the discussion that we had
11 at the last meeting with you about how this issue should
12 be handled.

13 So although you haven't seen the draft, when
14 you look at it, it should reflect your comments to me.

15 MR. DeCICCO: Yeah, I don't think you're
16 going to see any surprises. It's just a matter of
17 putting officially in black and white guidance that the
18 Agency will -- guidance that is put out by the Agency for
19 the licensees.

20 We didn't recreate the wheel. We just kind
21 of looked at the wheel a different way.

22 MS. McBURNEY: I would note that we have
23 adopted the similar rules to the suggested state
24 regulations, and it's working well. We've had them in
25 place for several years.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. LIETO: The only area I foresee issues
2 are in non-agreement states --

3 MS. McBURNEY: Right.

4 MR. LIETO: -- that may not be as
5 progressive as the State of Texas.

6 MS. McBURNEY: I understand.

7 CHAIRMAN CERQUEIRA: Okay. Thank you very
8 much.

9 MR. DeCICCO: Thank you.

10 CHAIRMAN CERQUEIRA: We should move along
11 here, and if we just basically skip down on page 2 of the
12 agenda, I think we've covered the first two items that we
13 were supposed to cover age the break.

14 The ACMUI vacancies, there's a sheet that
15 was distributed by Angela to the Committee, and we're
16 actually in fairly good shape in the sense that we've got
17 two appointees, and it says, you know, 2001, and yet
18 we're into 2002 and we still don't have those people on
19 board.

20 And I think, John, the feeling of the
21 discussion we had earlier is that the sooner we get these
22 people on board, the better.

23 MR. HICKEY: Yeah, we agree.

24 CHAIRMAN CERQUEIRA: And I guess just sort
25 of looking ahead, 2003 we have a whole slew of people who

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 are eligible for reappointment, and we should, you know,
2 basically send requests to these people.

3 And I guess now is the appointment made by
4 the NRC? Do we normally go back to the societies that
5 recommended these people? How are reappointments
6 handled?

7 MR. Hickey: No, the reappointments can be
8 handled internally with the Committee and the Commission
9 if the appointees are still willing to continue to serve.

10 CHAIRMAN CERQUEIRA: So how soon can we
11 reappoint people so that we, in case somebody decides not
12 to continue on the Committee, we can --

13 MR. HICKEY: Well, late -- I'm sorry.

14 CHAIRMAN CERQUEIRA: No.

15 MR. HICKEY: Late in the calendar year prior
16 to the appointment date, I think we would check with the
17 appointees and then confirm their reappointment early in
18 that year.

19 CHAIRMAN CERQUEIRA: But when would they go
20 off on 2003? Would it be the fall of 2003 that they go
21 off?

22 MR. HICKEY: Well, we didn't put months
23 here. We'd have to check on that, but I would say six
24 months ahead of time would be plenty.

25 CHAIRMAN CERQUEIRA: Well, I would say, you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 know, if we know that people are coming up, we should
2 request if they want to continue, and then make it
3 available for them to be reappointed, and if they say no,
4 then I think we need to initiate the process.

5 MR. HICKEY: Yes. Well, certainly if a
6 member knows they don't want to be reappointed, they
7 should advise the Commission staff immediately. I mean,
8 you know, as soon as they --

9 CHAIRMAN CERQUEIRA: Well, they may not
10 actually know the reappointment date. So I'd make a
11 recommendation that, you know, we basically send out
12 letters to these five people. That's a huge chunk of the
13 Committee that basically goes off on 2003, asking them if
14 they wish to, you know, be reappointed, in which case we
15 can initiate the process, and that would identify, you
16 know, clearly identify people who don't plan to come
17 back.

18 Is that a reasonable?

19 DR. NAG: I think on the reappointment the
20 problem is only if they don't want to be reappointed.

21 CHAIRMAN CERQUEIRA: Right.

22 DR. NAG: Therefore, you need about one
23 year.

24 CHAIRMAN CERQUEIRA: At least a year.

25 DR. NAG: Now, if all of these people said

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they wanted to be reappointed, there's no problem.

2 CHAIRMAN CERQUEIRA: Right.

3 DR. NAG: But if they are not, then there is
4 a problem. In fact, I'm even wondering. The ones in
5 2004, if they are spring 2004, we should start thinking
6 about them because there are one, two -- there are two
7 people who are going to be rotating off, three.

8 CHAIRMAN CERQUEIRA: Yeah. No, I think
9 that's very, very true.

10 So maybe what you're saying is the first
11 action item is that the reappointees for 2003 should be
12 contacted regarding their desirability to continue on the
13 Committee, and for the people who are going to rotate off
14 on 2004 we should initiate the process for soliciting
15 names and nominations. Does that sound like an action
16 item from the Committee?

17 DR. NAG: I think so

18 CHAIRMAN CERQUEIRA: Ralph?

19 MR. LIETO: I think it's just a consensus to
20 the staff and go from there.

21 CHAIRMAN CERQUEIRA: Yeah.

22 DR. WILLIAMSON: I think so.

23 MR. LIETO: It's something you've already
24 got in the hopper anyhow, I imagine.

25 MR. HICKEY: That's fine. It just seems to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 me it's a little early now to solicit appointees for
2 2004. I would have to look at how long it has taken in
3 the past.

4 CHAIRMAN CERQUEIRA: Right.

5 MR. HICKEY: I think you're going to find
6 this cardiology position is going to be filled within
7 about three or four months of the Commission stating that
8 they wanted someone appointed.

9 CHAIRMAN CERQUEIRA: No, no. Well, that's
10 good, and that's -- but, again, we've kind of -- I think
11 the Committee has been pushing to try to get this done,
12 and so does anybody object to requesting that the NRC
13 staff take those actions?

14 PARTICIPANT: It's a good idea.

15 CHAIRMAN CERQUEIRA: Sounds like reasonable
16 to do.

17 Okay. So maybe we could have that as a
18 follow-up item for the next Committee meeting.

19 Okay. So that sort of takes care of the
20 vacancies and reappointments and people who rotate off.
21 I just have to hold onto 2004, right?

22 And then follow-up discussion, ACMUI
23 recommendations regarding interpretation of 10 CFR 35.57.
24 John?

25 MR. HICKEY: We've already been through

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that. We don't have to have anymore discussion on that.

2 CHAIRMAN CERQUEIRA: That's right. Okay.

3 Meeting summary. Oops. We goofed upon the
4 RSOs and the authorized medical physicist, and we need to
5 take action fairly quickly to try to remedy that. I
6 think that's clearly the one thing that's come out of
7 these two days. I think we've identified a subcommittee
8 to deal with it.

9 And Richard and I will contact Commissioner
10 Meserve to sort of see what action we can get on it.

11 MS. WILLIAMSON: Will the subcommittee
12 members then just be contacted by E-mail?

13 CHAIRMAN CERQUEIRA: I think that would be
14 the best way to do it, and Angela can provide the
15 support, but once you get sort of a group mailing for the
16 Committee, I think it would be reasonable to, you know,
17 do whatever you feel is appropriate and, you know,
18 perhaps copy me and John and Angela on the E-mails would
19 be the best way to go forward on this.

20 Next meeting. We traditionally have been
21 meeting twice unless there were like urgent needs. We
22 meet in the sort of, you know, late winter, early spring
23 and then in the fall. So the next meeting would probably
24 be some time in October or November.

25 Does anybody feel we need to meet any

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 sooner?

2 We have a lot of unresolved issues. You
3 know, we still don't know if Part 35 revision is going to
4 be signed into law. If it is signed into law, then we
5 still have to deal with all of the issues related to the
6 RSOs and the authorized medical physicist and the
7 radiation oncologist.

8 MS. HOBSON: How will we handle the
9 recommendations of the subcommittee on the new
10 rulemaking?

11 CHAIRMAN CERQUEIRA: I think it will be
12 distributed to the Committee members by E-mail to get
13 their input.

14 Can we have -- now, is the Committee allowed
15 to have conference calls and what are the rules for that?

16 MR. HICKEY: Yes. I would suggest, given
17 where we are, that we would plan on handling some things
18 by conference call or E-mail, in some cases hard copy
19 express mail if it's not amenable to E-mail, and then if
20 you could plan on having the fall meeting as a whole.

21 It may be appropriate to have a subcommittee
22 meeting or you were suggesting you may meet with the
23 Chairman or a subgroup could --

24 CHAIRMAN CERQUEIRA: Well, at least have a
25 discussion.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. MYERS: -- work with the Chairman or
2 call, have a telecon. with the Chairman.

3 CHAIRMAN CERQUEIRA: Yeah, I think that
4 would be preferable.

5 MR. HICKEY: I think the fact that this is
6 going to be done in bits and pieces, it will be more
7 effective and, in fact, will have to be done to a large
8 degree by E-mail and telephones anyway because you can
9 only do so much in a two day meeting anyway.

10 CHAIRMAN CERQUEIRA: Right. Now, in terms
11 of telephone conference calls, what are the requirements?
12 I mean, do they have to be public? Can they just be the
13 -- since it is not the whole Committee but a
14 subcommittee, do we need to have notice? Do we need to
15 make it open?

16 MR. HICKEY: As far as I know, if it's not
17 the whole committee, it does not need to be public. I
18 could check that with the -- there's not time to do it
19 right now, but I could check that with the attorney.

20 CHAIRMAN CERQUEIRA: I think it would be
21 important to get that because a lot can be done on
22 conference calls, and you know, we have no problems with
23 it being open, but I just want to make certain that if
24 that's a requirement that we allow that to happen.

25 Richard?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. VETTER: I wouldn't guess that would be
2 a problem because the subcommittee will simply be working
3 up a recommendation.

4 CHAIRMAN CERQUEIRA: Right.

5 DR. VETTER: We can't take any action.
6 We'll simply be writing a recommendation.

7 MS. MCBURNEY: Right.

8 DR. NAG: I would suggest that most of what
9 I hear like we would set a date or a tentative date when
10 we are not available and when we may be available.
11 Otherwise somebody --

12 MR. HICKEY: Yeah, my recollection is there
13 are certain weeks in November that are bad because of
14 conferences.

15 CHAIRMAN CERQUEIRA: The cardiology meeting,
16 yes.

17 DR. DIAMOND: And in October is our society
18 meeting.

19 MR. HICKEY: Yeah, there's certain weeks
20 that we need to block out.

21 DR. WILLIAMSON: May we need to avoid.

22 CHAIRMAN CERQUEIRA: That's the end of
23 November usually.

24 DR. WILLIAMSON: And ASTRO us usually what,
25 end of October?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

DR. NAG: Okay.

MS. McBURNEY: October.

DR. NAG: The ASTRO is October 6th through 10.

MS. McBURNEY: There's also the Organization of Agreement States, which will probably take not only me, but also several of the NRC staff.

DR. NAG: The RSNA, the first week of December. So some time in late October or early November is a possibility.

MR. HICKEY: I think we found in the past late October or early November is the window of opportunity.

CHAIRMAN CERQUEIRA: Right.

MS. McBURNEY: Right, Halloween.

CHAIRMAN CERQUEIRA: Well, what about the last week of October?

And what days of the week usually work best for us, John?

And we're not going to meet with the Commissioners this time. So it's just a matter of --

DR. DIAMOND: If we do a one day meeting, we had a successful go-round last time by holding it on a Monday, if I recall.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. MCBURNEY: That was great.

2 CHAIRMAN CERQUEIRA: So you want to go
3 for --

4 MR. HICKEY: That's more up to the
5 Committee. If something goes wrong over the weekend, you
6 know, there's always the possibility that you're going to
7 have a hard time starting up, but I know a lot of you
8 like having the Monday meetings.

9 MS. HOBSON: Except for the East from the
10 West Coast.

11 CHAIRMAN CERQUEIRA: So October 28th?

12 MS. HOBSON: That means I have to travel on
13 Sunday.

14 MR. HICKEY: Talk to the Committee.

15 DR. NAG: I mean, if we have it the first
16 week of October, you know, middle, the 14th, 21 or 28
17 October. October 28th is also -- oh, no, that's fine.

18 CHAIRMAN CERQUEIRA: October 28th?

19 MR. HICKEY: The 28th looks good, yeah.

20 MS. HOBSON: Yes.

21 CHAIRMAN CERQUEIRA: All right. So October
22 28th.

23 MR. HICKEY: So we would all have to travel
24 on Sunday, Niki.

25 DR. NAG: Right.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. HOBSON: Oh, these people that live
2 close by, they just hop on a commuter.

3 MR. HICKEY: There's only one that lives
4 that close.

5 CHAIRMAN CERQUEIRA: There's only one.

6 DR. WILLIAMSON: You don't think under the
7 circumstances of having the possibility of a new rule we
8 really should think in terms of a day and a half or two
9 days? Almost always our meetings have been two days if
10 you view it historically, and we've, generally speaking,
11 filled those two days. It's been hard to get through the
12 agenda.

13 DR. NAG: Yeah, the thing is if you're
14 having it one day with all of the new requirements, most
15 of us have to leave by three or 3:30 anyway. You know,
16 that way you're ending up with three quarters of a day.
17 So you might as well make it for one and a half days.

18 CHAIRMAN CERQUEIRA: The 28th and 29th?

19 DR. WILLIAMSON: Yeah, a compromise might be
20 to do it Monday afternoon and all day Tuesday so that
21 then we have --

22 DR. NAG: Yeah, but then you lose the whole
23 Monday morning because no one flies that morning.

24 DR. WILLIAMSON: Some people could fly in in
25 the morning.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. NAG: Then other people have to fly in
2 the previous night.

3 DR. WILLIAMSON: Yeah, that's right.

4 CHAIRMAN CERQUEIRA: I think Monday and half
5 a day Tuesday is --

6 PARTICIPANTS: Yes.

7 MR. LIETO: I don't know if you want an
8 action item.

9 MR. HICKEY: We will reserve this room all
10 day Monday and Tuesday and schedule the meeting. If,
11 upon closer, you know, to the time to the meeting it
12 becomes apparent that the agenda doesn't support that, it
13 can always be reduced, but I know you all want to block
14 your calendars.

15 CHAIRMAN CERQUEIRA: I think we should, you
16 know, Monday and half a day Tuesday.

17 MS. WAGNER SCHWARZ: Yes.

18 CHAIRMAN CERQUEIRA: The other thing we need
19 to talk about is just getting the agenda for the
20 Committee meeting, you know. This time we had the
21 briefing with the Commissioners, and that got done on a
22 fairly late basis. I would really like to get, you know,
23 to get the agenda so that we're here doing something
24 that's, you know, dealing with issues that are coming up
25 and trying to get as much background material out to the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Committee ahead of time as possible so that, you know,
2 our time is better spent here.

3 MR. HICKEY: We will do a better job of
4 getting you the background material.

5 CHAIRMAN CERQUEIRA: Yeah.

6 MR. HICKEY: And we'll work together to have
7 a good agenda, but part of that depends on what you
8 propose and how many members are interested in a given
9 topic.

10 CHAIRMAN CERQUEIRA: I'd say that by
11 September 15th, which is about a month and a half before
12 the Committee meeting, that we have a draft agenda at
13 least together to identify the issues that have come up.

14 So some of these informative things are
15 fairly nice, but if we have other pressing business, I
16 mean, we could make those briefer, get some of the
17 material out ahead of time.

18 DR. WILLIAMSON: I would suggest, too, that
19 the staff be more proactive in, you know, reviewing the
20 activities of the agency and bringing items forward to
21 the agenda for us to consider, like this group that's
22 doing the national materials safety exercise.

23 You know, it so happened Ralph was aware of
24 that, but the rest of us weren't and, you know, we have
25 limited insight into the operations of the Commission.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So I think a lot of burden falls on you --

2 MR. HICKEY: Yes.

3 DR. WILLIAMSON: -- to at least identify for
4 us the possibilities, issues to consider on the --

5 MR. HICKEY: Yes. We should have done a
6 better job on that. Frankly, we were distracted by the
7 legislation, throwing Part 35 out.

8 CHAIRMAN CERQUEIRA: So what was your point
9 about the follow-up?

10 MS. WAGNER SCHWARZ: On the regulatory
11 guide, the guidance that's coming out, there are meetings
12 that are planned, and how about feedback?

13 MR. LIETO: I was just going to say the same
14 thing, that they're going to have public meetings in
15 April, was it?

16 MS. WAGNER SCHWARZ: Yes, April 23rd and
17 fourth.

18 MR. LIETO: And I don't know if there's
19 going to be the need for us to get back together, not
20 maybe physically, but either via telephone or some other
21 means to follow up on this --

22 MR. HICKEY: That's true.

23 MR. LIETO: -- maybe a couple of times.

24 MS. WAGNER SCHWARZ: Yes.

25 MR. LIETO: So I guess maybe just an FYI to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 be prepared, I guess, is the best thing I can suggest
2 right now.

3 MS. WAGNER SCHWARZ: It seems like it might
4 be a reasonable thing that at least we talk by telephone.

5 DR. WILLIAMSON: I think so.

6 MR. LIETO: I would imagine if the
7 publication of the rule is delayed, then the April
8 meetings could get pushed back to May. Would that be
9 true?

10 MR. HICKEY: I mean, anything could happen
11 if publication of the rule is delayed. But we will do a
12 better job of communicating with you by E-mail as to what
13 is going on and what's coming up, and then you can get a
14 better feel of what your response should be, you know,
15 how you want to participate in that.

16 MS. WAGNER SCHWARZ: I have one more
17 suggestion. What about agenda items? Do you want to
18 give us a date now that you would like agenda items sent
19 to you?

20 CHAIRMAN CERQUEIRA: Yes.

21 MS. WAGNER SCHWARZ: So that we at least
22 have it on the calendar for --

23 CHAIRMAN CERQUEIRA: I said April. I'm
24 sorry. September 15th, but let's see what day of the
25 week that is.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. WAGNER SCHWARZ: That's a Sunday.

2 CHAIRMAN CERQUEIRA: Well, how about Friday,
3 September 20th?

4 MR. LIETO: A month?

5 CHAIRMAN CERQUEIRA: Yeah. Or do you want
6 to go for like Friday, the 13th?

7 MR. HICKEY: Well, Mr. Chairman, if I could
8 comment, I think we need a preliminary call earlier than
9 that.

10 MS. WAGNER SCHWARZ: Okay.

11 MR. HICKEY: Because once the agenda is set,
12 we prepare the background material to send out. So we
13 need more time to anticipate what the items are going to
14 be and what material needs to be prepared.

15 CHAIRMAN CERQUEIRA: September 6th? So
16 Friday, September 6th is the deadline for having items
17 for the agenda submitted.

18 DR. VETTER: And will the staff be sending
19 us a letter?

20 CHAIRMAN CERQUEIRA: A reminder.

21 DR. VETTER: Soliciting that or --

22 MR. HICKEY: Yes. Yeah, we go to the
23 Chairman and "cc" the other members.

24 CHAIRMAN CERQUEIRA: Yeah, and maybe send
25 that out --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. HICKEY: And we may send you --

2 MS. WAGNER SCHWARZ: That could come out
3 from Angela even.

4 MR. HICKEY: We may send you more than one
5 note, you know. "Start thinking," you know, and then the
6 next note is "the deadline is."

7 DR. WILLIAMSON: I think we have taken the
8 position already, haven't we at this meeting, that we
9 want to review the regulatory guide when the next draft
10 is available? And so there needs to be between now and
11 whenever that happens provision made to have at least a
12 virtual meeting over that.

13 CHAIRMAN CERQUEIRA: Right, and we actually
14 had wanted to get some input into it, but the Committee
15 is basically sitting idle. Well, not the -- the working
16 group for the states thing, which I guess is --

17 DR. NAG: Well, that's national material.

18 DR. WILLIAMSON: This is Volume 9 of 15.56
19 that I'm talking about.

20 MS. MCBURNEY: Right.

21 CHAIRMAN CERQUEIRA: That's a more immediate
22 need, right?

23 DR. WILLIAMSON: We've taken the position
24 that we want to be involved. It's not an "if." I'm
25 responding to John. I think that's already taken care

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of. So we need to get a copy of that as soon as is
2 possible, and then arrangements made to have a forum for
3 consolidating a review.

4 And I would think that at least a conference
5 call among interested parties would be wise.

6 DR. NAG: I only want to remind the staff to
7 make a list of all of these action items that we came up
8 with.

9 MR. HICKEY: Yes.

10 DR. NAG: Even though you may not have their
11 solution, at least send what the action items are so that
12 we will remember.

13 MR. HICKEY: Yes, we will do that.

14 CHAIRMAN CERQUEIRA: And I think that should
15 go out as soon as we get it to people so people have an
16 idea to see what was on the -- you know, what was
17 discussed and what needs to be done.

18 DR. NAG: Yeah. That would also be
19 something like a reminder of some of the things we may
20 have to do with our societies.

21 CHAIRMAN CERQUEIRA: Right, right.

22 MS. WAGNER SCHWARZ: So minutes of the
23 meeting, is that kind of what you're thinking?

24 DR. NAG: Not the whole minutes. That
25 becomes too long.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. WAGNER SCHWARZ: Right.

2 DR. NAG: What are the action items.

3 CHAIRMAN CERQUEIRA: The action items, you
4 know, which could be pulled out, and clearly we
5 identified them in the transcripts. Whatever -- John,
6 what do you think is the best way to get that out?
7 They're not official minutes. They're just sort of
8 action items.

9 MR. HICKEY: Well, I think we can E-mail it.
10 Tim has been trying to, in addition to the whole meeting
11 being transcribed, Tim has been trying to catch the
12 action items, and I've got them here, too. So I think
13 that --

14 CHAIRMAN CERQUEIRA: And I think we all made
15 a --

16 MR. HICKEY: -- can be done as an advanced
17 E-mail that will be reflected in the official minutes.

18 CHAIRMAN CERQUEIRA: Good. Any other
19 business?

20 (No response.)

21 CHAIRMAN CERQUEIRA: If not, I'd like to
22 thank the Committee and the NRC support staff for getting
23 us out on time and identifying all of the issues we need
24 to deal with.

25 Thank you.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 (Whereupon, at 3:20 p.m., the Advisory
2 Committee meeting was concluded.)
3
4
5
6
7
8
9
10
11
12
13
14

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701