

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses
of Isotopes: OPEN SESSION

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Tuesday, May 20, 2003

Work Order No.: NRC-916

Pages 1-263

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

(202) 234-4433

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

+ + + + +

OPEN SESSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

+ + + + +

TUESDAY,

MAY 20, 2003

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Advisory Committee met at the Nuclear
Regulatory Commission, Two White Flint North, Room
T2B3, 11545 Rockville Pike, at 1:00 p.m., Dr. Manuel
Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D., Chairman

JEFFREY A. BRINKER, M.D., Member

DAVID A. DIAMOND, M.D., Member

DOUGLAS F. EGGLI, M.D., Member

NEKITA HOBSON, Member

RALPH P. LIETO, Member

LEON S. MALMUD, M.D., Member

RUTH McBURNEY, Member

NEAL R. GROSS

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

1 COMMITTEE MEMBERS: (CONT.)

2 SUBIR NAG, M.D., Member

3 SALLY WAGNER SHWARZ, Member

4 RICHARD J. VETTER, Ph.D., Member

5 ALSO PRESENT:

6 THOMAS ESSIG, Designated Federal Official, NRC/NMSS

7 ROGER BROSEUS, Ph.D. NRC/NMSS

8 RYAN T. COLES, U.S. GENERAL ACCOUNTING OFFICE

9 WILLIAM HENDEE, M.D., American Board of Radiology

10 DONNA-BETH HOWE, Ph.D. NRC/NMSS

11 MICHAEL T. MARKLEY, NRC/NMSS

12 CHARLES I. MILLER, Ph.D. NRC/IMNS

13 LINDA PSYK, NRC/NMSS

14 JEFFRY SIEGEL, Ph.D., Society of Nuclear Medicine

15 ANTHONY TSE, Ph.D. NRC/NMSS

16 ANGELA WILLIAMSON, NRC/NMSS

17 RONALD ZELAC, Ph.D. NRC/NMSS

18

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

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

A-G-E-N-D-A

Opening Remarks - Mr. Essig 4

SNM Licensing Guide 6

GAO's Review of Domestic Regulation of
Nuclear Material 11

Training, Education, Certification, New Part 35 . 23

ACMUI Teleconferencing 58

T&E Rulemaking, Status and Discussion 63

Sealed Source Model Numbers 92

National Materials Program Pilot Project . . . 115

Content and Status of the Direct Final Rule . . 130

HHS Database Regulatory Actions 135

Written Directives for Brachytherapy 152

Downloading Part 35 from the NRC Webpage . . . 162

Society of Nuclear Medicine's Suggested 163

Guidance for Therapy Applications
Discussion 171

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

(1:04 p.m.)

MR. ESSIG: As designated federal official for this meeting I'm pleased to welcome you to Rockville for the public meeting of the ACMUI.

My name is Thomas Essig, I'm Branch Chief of the Materials Safety and Inspection Branch, and have been designated as the federal official for this Advisory Committee, in accordance with 10CFR part 7.11.

This is an announced meeting of the Committee, it is being held with the rules and regulations of the Federal Advisory Committee Act, and the Nuclear Regulatory Commission.

The meeting was announced in the March 24th, 2003 edition of the Federal Register. The function of the Committee is to advise the Staff on issues and questions that arise during the medical use of by-product material.

The Committee provides counsel to the Staff, but does not determine or direct the actual decisions of the Staff, or the Commission. The NRC solicits the views of the committee, and values them very much.

I request that, whenever possible, we try

NEAL R. GROSS

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

1 to reach a consensus on the various issues that we
2 will discuss today, but I also value minority or
3 dissenting opinions. If you have such opinions please
4 allow them to be read into the record.

5 As part of the preparation for this
6 meeting I have reviewed the agenda for the members and
7 employment interest based on the very general nature
8 of the discussion that we are going to have today.

9 I have not identified any items that would
10 pose a conflict. Therefore I see no need for an
11 individual member of the Committee to recuse
12 themselves from the discussion.

13 However, if during the course of our
14 business, you determine that you have some conflict,
15 please state it for the record and recuse yourself
16 from that particular aspect of the discussion.

17 At this point I would like to introduce
18 the members that are here today. Dr. Manuel
19 Cerqueira, nuclear cardiologist, who is Chair of the
20 Committee; Dr. Douglas Eggli, nuclear medicine, member
21 of the Committee.

22 Dr. Leon Malmud, health care
23 administrator, member of the Committee; Nekita Hobson,
24 patient advocate; Ms. Ruth McBurney, state
25 representative, member of the Committee; David A.

NEAL R. GROSS

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

1 Diamond, M.D., radiation oncologist, member of the
2 Committee.

3 Dr. Subir Nag, radiation oncologist,
4 member of the Committee; Sally Schwarz, nuclear
5 pharmacist, member of the Committee; Dr. Richard
6 Vetter, radiation safety officer, member of the
7 Committee; and Dr. Jeffrey Williamson, therapy
8 physicist, member of the Committee.

9 That concludes my opening remarks, Mr.
10 Chairman.

11 CHAIRMAN CERQUEIRA: Thank you very much.
12 We also have the next item, which is the Society of
13 Nuclear Medicine Licensing Guide.

14 MR. ESSIG: Yes. One thing I would like
15 to mention, initially, that the agenda item perhaps
16 mischaracterizes the guide, itself. It is not titled
17 a licensing guide, per se, it is simply a guide for
18 the medical use of byproduct material in diagnostic
19 settings.

20 We had, during the course of the, I just
21 want to say a few remarks about the genesis of this
22 guide. During the course of revising NUREG 1556,
23 volume 9, we were, we received some comments from the
24 Society of Nuclear Medicine that basically they felt
25 that the NUREG that we had drafted at that time was

NEAL R. GROSS

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

1 much too detailed.

2 And we had completed the earlier draft
3 prior to the Part 35 rulemaking, but then it kind of
4 lost ownership and was put on the shelf for a while.
5 So then we were challenged, as October of 2002
6 approached, when the Rule Part 35 would become final,
7 and so we pulled the old Volume 9 of NUREG 1556 off
8 the shelf and put it out for comment.

9 And we held two meetings on that in the
10 NRC auditorium, one on therapeutic, and one on
11 diagnostic aspects. And what emerged from that was
12 that the SNM came to us and felt that they could
13 produce something than we had in the Volume 9 for
14 diagnostic applications.

15 And so we invited them to proceed, and we
16 met several times over the course of the production of
17 the guidance document, and polished the language in
18 it. And then the ultimate question became, well how
19 will we promulgate the document and put it in general
20 use?

21 And so what we ended up doing is entering
22 into a licensing agreement with the Society of Nuclear
23 Medicine, and basically bought the rights to
24 distribute the document on our website, at no charge
25 to the user community.

NEAL R. GROSS

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

1 We announced this in a regulatory issue
2 summary 2002-23, dated November 27th, 2002, and we
3 specifically stated, in the regulatory information
4 summary, and I would quote from that, the SNM's Guide
5 for Diagnostic Nuclear Medicine provides information
6 that may be useful to nuclear medicine professionals
7 in understanding the applicability of NRC requirements
8 to the use of byproduct material in diagnostic
9 settings, and provides measures that practitioners may
10 use to facilitate the implementation of the revised
11 rule.

12 The information provided in the document
13 is not a substitute for NRC regulations. Licensees
14 are required to comply with all applicable parts of
15 Title 10 of the Code of Federal Regulations, unquote.

16 So that was just a, like all of the
17 guidance documents that we have, they do not contain
18 regulatory requirements, they are a method, or an
19 accepted way of implementing that portion of the
20 regulations that they address.

21 And so the diagnostic guidance document
22 would be an adjunct to the NUREG 1556 Volume 9. And,
23 really, that is all I wanted to say about that guide.
24 I think we just may be clarifying a couple of points.

25 CHAIRMAN CERQUEIRA: Just for

NEAL R. GROSS

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

1 clarification, so this is different than your
2 traditional guidance documents that are released?

3 MR. ESSIG: It is not, in a sense it is
4 not precedent setting, in that we have other, on other
5 parts of our regulative community, we do have, where
6 we've engaged with stakeholder organizations, where
7 they have felt that they could write some more user-
8 friendly guidance, if you will.

9 In fact, we are encouraged to do that.
10 There is an Act called the National Technology
11 Transfer and Advancement Act of 1995, that requires
12 federal agencies to use consensus standards, whenever
13 possible.

14 And so that we would -- we are encouraged
15 to engage on issues like this. And if we could find
16 that as an acceptable method of implementing that part
17 of the regulations, and then we would just --

18 CHAIRMAN CERQUEIRA: No, I'm very
19 supportive of it. The only question is that if the
20 regulated community follows all the guidelines, and
21 then they are not in compliance with the NRC, you
22 know, if they follow official NRC guidelines they
23 probably would have something to quote, or stand on,
24 at the time of defending their actions.

25 Do these SNM guidelines have the same

NEAL R. GROSS

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

1 weight, recognition?

2 MR. ESSIG: Well, we -- I believe we
3 recognize that in the regulatory issue summary, that
4 we said they were an acceptable method of implementing
5 that part of the NRC regulation.

6 So, yes, it doesn't -- I mean, they don't
7 look like a regulation guide or a NUREG, and they have
8 a different cover on them, and that sort of thing.
9 But we, nonetheless, reviewed them and found them
10 acceptable for implementing that part of the Rule that
11 relates to diagnostic practices.

12 CHAIRMAN CERQUEIRA: Any questions?

13 MEMBER LIETO: Tom, then would it be
14 accurate to say that this was a joint effort of the
15 NRC and the SNM, in promulgating guidance?

16 MR. ESSIG: I wasn't intimately involved
17 with it. But it was my understanding, we had several
18 meetings. And whether that really, I guess you could
19 call it a joint effort. I mean, if you have one
20 meeting then it's probably not joint.

21 But as you get up to several meetings, and
22 fine tuning the language of the document, yes, I would
23 say it is a joint -- you could call it a joint
24 document.

25 CHAIRMAN CERQUEIRA: Any other questions?

NEAL R. GROSS

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

1 Great.

2 So the next item, then, is the Update
3 GAO's Review of Domestic Regulation of Nuclear
4 Material. And Ryan T. Coles, and the GAO's office.

5 MR. ESSIG: You may recall, Mr. Coles was
6 here at our last meeting, and he is here to update us
7 regarding the GAO audit.

8 MR. COLES: Good afternoon, Mr. Chairman,
9 Members of the Committee, NRC Staff. I appreciate the
10 opportunity to come and speak to you today. My name
11 is Ryan T. Coles, I'm a senior nuclear analyst with
12 the United States General Accounting Office.

13 And today I just want to give you a brief
14 update on some of our work. Unfortunately the timing
15 of this meeting is somewhat inopportune, because we
16 are in the process of wrapping up our work on
17 regulation of nuclear materials in the United States.

18 So there isn't a whole lot that I can tell
19 you in terms of our findings, but I can talk to you
20 about three things today. First of all, I can give you
21 a status report on our three separate efforts looking
22 at materials regulation and security.

23 Second, I can describe some about our
24 objectives, scope and methodology, of looking at the
25 domestic regulation of nuclear material. And, third,

NEAL R. GROSS

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

1 to the extent that we have time, I can update you on
2 the findings of the one report that we have released,
3 thus far, on the Department of Energy's outside source
4 recovery program.

5 As you may recall from our previous
6 meeting, we have three ongoing efforts looking at
7 nuclear materials regulation in the United States.
8 The first report, which was issued in April, and it
9 was just issued to the public a couple of weeks ago,
10 was looking, specifically, at the Department of
11 Energy's outside source recovery program.

12 For those of you who are not aware, this
13 program is DOE's effort to collect unwanted, and
14 unused, greater than Class C sealed sources that are
15 present in the United States, primarily from academic
16 licensees, although there are some medical licensees,
17 as well, that have these sources.

18 Materials we are dealing with are
19 primarily transuranics and high concentration
20 strontium, cesium, cobalt sources. We, weeks ago,
21 got some press coverage, got some coverage from the
22 Department of Energy, and I can discuss that in a few
23 moments, if we have time.

24 The second report that we have been
25 conducting has been looking at international efforts

NEAL R. GROSS

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

1 to control sealed sources. And this has been
2 primarily looking at the Department of Energy's and
3 NRC's international efforts with the International
4 Atomic Agency, with the Russian Federation.

5 Some of the conferences, meetings, and
6 efforts that have been ongoing to control potential
7 sources of radiological dispersion device materials.
8 That report has just been issued to our requester,
9 which is Senator Akaka, and should be released,
10 publicly, within the next three weeks.

11 Finally, the sort of the capstone report
12 of our efforts has been looking at the domestic
13 regulation of nuclear materials. That report is
14 scheduled to be issued to our requester on July 3rd.

15 It, likely, will be released to the public
16 shortly afterwards, three, four weeks afterwards, I
17 would say, so I think we are looking at the end of
18 July, early August, before we issue that report.

19 We have just finished a first draft, we
20 are about to give NRC their first opportunity to take
21 a look at some of our findings, to provide us with any
22 technical comments, and as we proceed through the next
23 couple of three weeks, I think more and more
24 information will be coming out, and we should be just
25 about finished with our report.

NEAL R. GROSS

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

1 Unfortunately I can't really share our
2 conclusions and recommendations with you, at this
3 point, because we haven't given NRC the opportunity to
4 look at, and that is one of our standards, is that
5 affected agencies have the opportunity to comment
6 before the report is released publicly, or to our
7 requester.

8 But I can talk to you a little bit about
9 the work that we have conducted. This has been a very
10 extensive review, and from the beginning we knew that
11 we were biting off a lot, and decided, and over the
12 course of our review we have proceeded to sort of
13 change the scope of the review, to narrow down the
14 focus to what our clients on the Hill were
15 particularly interested in.

16 We've tried to take it from an educational
17 review point, that is to try to teach our clients,
18 teach the lawmakers, how radioactive materials are
19 regulated in the United States. And also to narrow in
20 and focus on specific security concerns.

21 We have been asking what is the scope of
22 the use of radioactive materials in the United States,
23 specifically what is the known number of licensees,
24 how many sources are being used, what are the typical
25 uses of radioactive materials in the United States.

NEAL R. GROSS

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

1 We have also been wanting to know
2 incidents related to the use of those materials, lost,
3 stolen, or abandoned sources, misadministrations,
4 malfunctioning devices, those types of things that are
5 required, on the part of the licensee community, to
6 report to their agreement state, or NRC regulators.

7 We have also been looking at the
8 effectiveness of federal and state controls over
9 sealed source material. And, finally, what efforts
10 have been initiated, or considered, since September
11 11th, to safeguard radiological material.

12 And to answer these questions we
13 distributed surveys to all 32 agreement states, the 18
14 non-agreement states, Puerto Rico, the District of
15 Columbia, and officials in NRC's four regional
16 offices.

17 We focused the survey to obtain
18 information about each state's radiation control
19 program, specific and general licensing activities,
20 enforcement actions, the effectiveness of the controls
21 over sealed sources, their program evaluation
22 processes, and transportation of sealed sources, and
23 also the impact of September 11th on their regulatory
24 programs.

25 We distributed the survey in February of

NEAL R. GROSS

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

1 2003. We received responses from 29 of 32 agreement
2 states, and 11 of 18 non-agreement states. We also
3 received a survey from Puerto Rico, and from all four
4 NRC regional offices.

5 We did not receive responses from three
6 agreement states, Arizona, New Hampshire, and Maine.
7 We also did not receive responses from the non-
8 agreement states of Alaska, Connecticut, Minnesota,
9 Missouri, Pennsylvania, South Dakota, and Wyoming. We
10 also did not receive a survey from the District of
11 Columbia.

12 In addition to our survey efforts we
13 visited and interviewed a number of officials at the
14 state and local level, and also licensees. We visited
15 the following states during our review, and these
16 states were chosen based upon the size of their
17 programs, the numbers of licensees, and the uses of
18 materials within those states.

19 We visited Illinois, Maryland, New Jersey,
20 North Carolina, Pennsylvania, Rhode Island, South
21 Carolina, and Utah. We also interviewed officials
22 from Massachusetts, Nevada, New York, and Ohio.

23 In each of these states we visited a
24 selection of radioactive materials licensees
25 representing a variety of uses. We tried to get a

NEAL R. GROSS

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

1 sample of uses in the academic, research, medical, and
2 industrial communities, and visited a total of -- we
3 visited three decommissioning and decontamination
4 sites, two low level radioactive waste facilities, two
5 moisture density gauge manufacturers, a selection of
6 industrial radiographers, medical licensees,
7 specifically several hospitals.

8 We visited several large irradiator
9 facilities, well logging licensees, nuclear
10 pharmacies, and several academic licensees.

11 The purpose of our visits was to discuss
12 with them the effectiveness of the current regulatory
13 framework and, also, to observe first-hand physical
14 security measures that are being undertaken at these
15 facilities.

16 We also had extensive discussions with a
17 variety of NRC staff offices, including nuclear
18 materials safety and safeguards, nuclear security and
19 incident response, and the office of state and tribal
20 programs.

21 We also involved the organization of
22 agreement states, and the conference of radiation
23 control program directors.

24 As I said, in addition to NRC we also
25 interviewed officials from other federal agencies,

NEAL R. GROSS

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

1 including the Department of Transportation, the
2 Environmental Protection Agency, the Federal Emergency
3 Management Agency, and the Department of Justice, and
4 the Department of Energy.

5 As I said, we are in the process of
6 completing our work, and we are completing a draft
7 report for NRC's review, and expect our work to be
8 completed within the next month.

9 We are probably running a little short on
10 time, but I do want to say that our first report on
11 DOE's outside source recovery program has received
12 some attention in the media, and with the Department
13 of Energy.

14 Basically we found that the Department of
15 Energy is not giving the problem of collecting greater
16 than class C sources sufficient attention. The
17 program within the Department of Energy is not at a
18 high enough priority.

19 The Department of Energy does not believe
20 that the environmental management, the office of
21 environmental management, that this is their
22 appropriate mission to be conducting, to be going out
23 and collecting greater than Class C material, and in
24 the nearly 20 years since DOE was required to provide
25 for permanent disposal of greater than Class C

NEAL R. GROSS

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

1 material, the agency has made no progress towards
2 coming up with eventual disposition.

3 The Department of Energy responded to our
4 report and stated that we had made several errors.
5 First they stated that we had not given enough credit
6 to the Department of Energy, and the Nuclear
7 Regulatory Commission, in the work that they have been
8 doing to categorize the sealed sources of greatest
9 concern.

10 We disagree with DOE. We do mention the
11 working group report. However, at the time our report
12 was published, this working group report was, A, still
13 draft; and B, classified as for official use only, so
14 we could not discuss it in a public forum.

15 It is interesting that DOE released the
16 report in response to our report. So we will address
17 that report in much more detail in the domestic job
18 that is coming up in the next month or so.

19 DOE also criticized us for not giving them
20 enough credit for sources they have already picked up.
21 On the contrary, we did note that they picked up over
22 5,000 sources since the program's initiation, and they
23 have been doing a good job.

24 It is simply that their future commitment
25 is questionable. And, finally, they criticized us for

NEAL R. GROSS

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

1 not interviewing any policy executives during the
2 course of our review.

3 We don't understand this criticism. We
4 met, on several occasions, with numerous policy
5 executives at the Department of Energy, including
6 three meetings with the Deputy Assistant Secretary,
7 three attempted meetings with the Assistant Secretary,
8 two of which she canceled, and one that we finally
9 attended, but we didn't get any substantive
10 information at.

11 And it is also an interesting remark that
12 they make, that we didn't meet with any policy
13 executives. Is DOE saying that the policy executives
14 are going to give us a different story than program
15 management officials?

16 Because, to me, that indicates a larger
17 problem than simply -- it indicates a disconnect in
18 communications. If program management isn't giving us
19 the same information as policy executives, then it
20 sounds like there are communications problems within
21 the Department of Energy.

22 I would be happy to answer any questions
23 that I can, and I apologize for not being able to be
24 more specific on our findings, but I will try to
25 answer whatever I can.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Questions for Mr.
2 Coles?

3 MEMBER DIAMOND: Mr. Coles, thanks for
4 coming back, it is nice to see you again.

5 Earlier today Mr. Cox, in a closed door
6 session, spoke to us about some of the compensatory
7 measures that NRC is working on, and the Committee as
8 a whole was very pleased to see that a lot of logic
9 and common sense was being applied as far as the
10 selection of sources and threshold limits in
11 developing these measures.

12 It is very hard for us to comment on what
13 you are doing with regard to the regulation of
14 domestic sources, because we haven't seen your report,
15 you haven't sent it to your client, yet.

16 But the concern that I have is that this
17 report will, obviously, be the framework for possible
18 legislation. And my caution would be that it is very,
19 very important, that our legislators get information
20 that not only is accurate, but also has a lot of
21 common sense.

22 Because we have the real potential for
23 developing legislation which could, really, adversely
24 impact the practice of medicine, if we are not smart,
25 on threshold limits, some care in the regulation, if

NEAL R. GROSS

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

1 it is desired, into the field of norm.

2 So that is my only comment, or concern, to
3 you to pass on.

4 MR. COLES: I appreciate that comment, and
5 I think I'm not giving away anything in terms of our
6 conclusions and recommendations, by saying that it is
7 vitally important, in any discussion of additional
8 security be placed on this material, that that
9 additional security be balanced with the beneficial
10 applications of this material.

11 NRC and the appropriate agencies need to
12 take great effort in determining exactly what the
13 greatest risk materials are, and those security
14 efforts that are already being placed upon them, so
15 that we do not place additional burdensome regulations
16 on materials that have beneficial uses.

17 We are doing our best to tell our clients
18 on the Hill that we can't take a broad brush approach
19 to security, that we have to be very specific in
20 regulating to the best sense possible those materials
21 of the greatest concern, without discouraging their
22 beneficial use in medical, industrial, and research
23 practices.

24 CHAIRMAN CERQUEIRA: Any other questions
25 for Mr. Coles? Thank you very much for your

NEAL R. GROSS

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

1 presentation, we look forward to your next report with
2 some real data.

3 MR. COLES: Thank you, Mr. Chairman, I
4 appreciate it.

5 CHAIRMAN CERQUEIRA: The next item is
6 training, education, board certification, and the new
7 Part 35. Dr. William Hendee, President of the
8 American Board of Radiology will be presenting.

9 Welcome, Dr. Hendee.

10 DR. HENDEE: Thank you very much, thank
11 you, Mr. Chairman. And thank you to each of the
12 members here of ACMUI for allowing the American Board
13 of Radiology to make comments regarding the training
14 and experience requirements, as denoted at the present
15 time, in the revisions of Part 35.

16 We appreciate, very much, the opportunity
17 to be here. I am the President of the American Board
18 of Radiology, my name is William Hendee, or Bill
19 Hendee.

20 I'm also Senior Associate Dean and Vice
21 President of the Medical College of Wisconsin, and
22 Dean of the Graduate School of Biomedical Sciences,
23 there.

24 I'm a Board certified health physicist by
25 the American Board of Health Physics, and also a board

NEAL R. GROSS

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

1 certified medical physicist by the American Board of
2 Radiology. I have been a member of the Board, now, of
3 radiology for about ten years. I'm the current
4 president, I'm a former member of the American Board
5 of Health Physics, as well, and a former examiner for
6 ABHP.

7 The comments that I'm going to make today
8 relate to the training and experience requirements as
9 laid out at the present time, in the proposed
10 rulemaking for revisions of Part 35, and there are
11 basically four issues that I want to bring up for
12 discussion.

13 But I want to tell you, first, that
14 members of different boards, certification boards, met
15 this morning with members of the NRC staff, and we had
16 an excellent, open, and frank discussion on several
17 issues, including those which I will bring up this
18 afternoon.

19 And I want to bring special attention to
20 the three people that were sitting around the table
21 with us, from the NRC, because of their openness and
22 willingness to listen to our concerns and questions,
23 and to work with us towards solutions.

24 And those are Roger Broseus, Patricia
25 Holohan, and Sandra Wastler. So thank you all very

NEAL R. GROSS

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

1 much for allowing us. And I think, in fact, we came
2 to some resolution of many of the issues that we hope
3 the Council here will also agree with.

4 So there are four issues. I would like to
5 raise each of these issues and see if there are any
6 questions for me on each issue, before we go forward
7 to the next.

8 And the first issue is the issue of
9 default pathways to NRC recognition and board
10 certification. Board certification, by a recognized
11 specialty board, is proposed as a pathway to
12 demonstration of adequate knowledge, to be recognized
13 by the Nuclear Regulatory Commission.

14 As an authorized medical physicist,
15 authorized user, authorized nuclear pharmacist, or as
16 a radiation safety officer, you have that in the
17 proposed rulemaking.

18 And then you have, in the proposed
19 rulemaking, an alternate pathway to NRC recognition
20 through the process of individuals attaining specific
21 numbers of hours of didactic instruction and
22 supervised practical training.

23 The proposed rulemaking, however, is vague
24 on whether the specific number of hours of didactic
25 instruction, and supervised practical training, must

NEAL R. GROSS

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

1 be explicitly required by a specialty board before the
2 NRC will acknowledge board certification as a pathway
3 to recognition, as one of the four categories,
4 authorized medical physicist, etcetera.

5 Now, it has been the presumption of the
6 American Board of Radiology that the NRC wishes to
7 consider board certification by a recognized specialty
8 board as a true default pathway to service, as an
9 authorized medical physicist, radiation safety
10 officer, authorized user, or authorized nuclear
11 pharmacist.

12 We presume, but it is difficult to tell,
13 from the proposed rulemaking, that the default pathway
14 of board certification is not viewed by the NRC as
15 simply an assurance that candidates meet the very
16 specific hours of didactic instruction and supervised
17 practical training considered essential by the NRC.

18 Because if you were to take that approach,
19 then, essentially the default pathway of board
20 certification is no more than perfunctory and is a
21 redundant process in the proposed rulemaking.

22 So here is what we recommend. The ABR
23 recommends that the NRC not be prescriptive in its
24 recognition of specialty boards. The ABR recommends,
25 instead, that well established specialty boards, such

NEAL R. GROSS

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

1 as the American Board of Radiology, be recognized as
2 a default pathway to service in any of the categories
3 that recognition will be appropriate.

4 While at the same time allowing the board
5 to define the education and training experience most
6 appropriate to the safe and effective delivery of
7 quality care to patients.

8 Now, we had an excellent discussion on
9 this point this morning. And in that discussion we
10 described the board certification process, which is
11 composed of three different elements.

12 One is there are education, training, and
13 experience requirements to sit for board
14 certification. Once you've attained those
15 qualifications, and you are admitted into the board
16 process, you go through a rigorous examination
17 process, which is composed of written examinations by
18 the American Board of Radiology, followed by an oral
19 examination in your particular specialty.

20 Those examinations cover, they are
21 certainly not limited to, but they cover radiation
22 safety, the aspects of radiation safety pertinent to
23 the particular specialties.

24 And we examine in those areas. And, in
25 fact, one can make the case that examination in

NEAL R. GROSS

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

1 radiation safety, and radiation protection, is a much
2 more effective way of determining the mastery of a
3 body of knowledge, than is simply hours of training
4 and experience.

5 I think we have reached consensus on this,
6 this morning. And that is that a certification board
7 could apply for dean status, as a default pathway,
8 could describe the areas it examines in, those areas
9 would be consistent with the areas that are required
10 by the NRC for recognition.

11 And if, in fact, the examination covers
12 those areas, and if the board requires mastery of that
13 body of knowledge, then that board will be recognized
14 as a default pathway, without having to state,
15 explicitly, an explicit number of hours of training
16 and experience.

17 We are very comfortable with that, and we
18 hope that you all will be comfortable with it as well.
19 Now, let me stop there, and see if there is any
20 question in that particular area.

21 CHAIRMAN CERQUEIRA: Jeffrey?

22 MEMBER WILLIAMSON: I was just looking at
23 our proposal that came back from the Commissioners,
24 you know, with some minor modifications. And our
25 intent was, and my understanding of what came back,

NEAL R. GROSS

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

1 does not require a specific number of hours for any of
2 the boards.

3 DR. HENDEE: And I'm very happy with that
4 response. It is part -- part of my reason for being
5 here is to clarify issues of uncertainty that I think
6 need to be clarified, and need to be clarified in the
7 final report of this Commission, and in the final
8 rulemakings, not confusion or ambiguity in what is and
9 is not required.

10 So I'm very pleased with that response.

11 CHAIRMAN CERQUEIRA: I guess one question
12 that came up during the discussions is that you take
13 a board like the ABR, which covers an extensive body
14 of clinical, technical, basic science information.
15 And, theoretically, somebody could pass the board, but
16 could have failed all the questions related to
17 radiation safety.

18 So what assurance is there that a
19 candidate who passes the board has met knowledge
20 criteria in the areas of radiation safety?

21 DR. HENDEE: Well, in several cases the
22 written examination focuses on different areas. Let
23 me give you an example.

24 CHAIRMAN CERQUEIRA: Sure.

25 DR. HENDEE: In examining candidates in

NEAL R. GROSS

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

1 various certification areas of radiological physics,
2 for example, the candidates take an oral examination.
3 That oral examination consists of questions in five
4 different areas.

5 One of those areas is in radiation
6 protection and safety. You must pass that oral
7 examination. You can't -- you cannot do poorly on
8 that exam, and have doing well on other parts of the
9 exam compensate.

10 CHAIRMAN CERQUEIRA: And that consists of
11 30, 40 questions, that are documented, or --

12 DR. HENDEE: Well, this is the oral
13 examination. So in the oral examination you typically
14 have about five minutes, in each of five different
15 areas, per examiner. And there are five examiners
16 examining in that area.

17 And so you ask five questions per
18 examiner, you ask one question by each of five
19 examiners. But that question is an open-ended
20 question which then leads to a lot of discussion. So
21 you cover the ground pretty well by the time you are
22 through.

23 And then in the written examination there
24 are multiple questions on radiation protection safety.

25 MR. NAG: I would like to ask --

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Yes, Richard? Go
2 ahead.

3 MEMBER VETTER: I just wanted to
4 underscore, for you, and the Committee and the general
5 audience, that when the subcommittee began to draft
6 its recommendations, one of its positions was that, in
7 fact, that it felt that passing an exam was, much
8 better demonstrated that an individual had the
9 competency, than sitting for a certain number of
10 hours.

11 So it was never the intent that a board
12 would be qualified on a prescriptive number of hours.
13 It was passing that exam. I'm sorry, not just passing
14 that exam, it is a whole certification process.

15 DR. HENDEE: But, thank you again. I
16 mean, you are confirming what our belief was, but it
17 needs to be explicitly stated, so that everyone
18 understands this.

19 MR. NAG: The American Board of Radiology
20 has a very extensive curriculum on radiation safety.
21 What would you say to another board who wishes to
22 apply for the exemption, but may have a lot more
23 limited radiation safety curriculum, if we don't say
24 there must be X number of hours in the curriculum?

25 The American Board of Ophthalmology says,

NEAL R. GROSS

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

1 well we have done one, but we have radiation safety in
2 our curriculum that for anyone who has passed the
3 American Board of Ophthalmology will be an authorized
4 user, or can be an authorized user.

5 How would you deal with that situation?
6 It may be hypothetical, or it may not.

7 DR. HENDEE: I think it is clear, in
8 reading through the alternate pathways to the default
9 pathway to board certification, if I read the other
10 ways that you can become certified, I think it is
11 clear what is expected, in terms of a body of
12 knowledge.

13 I think you can surmise what is expected
14 in terms of a body of knowledge, from reading those
15 alternate criteria, not so much the number of hours,
16 but the areas to be covered, and what you would
17 expect.

18 And I think that a board that was applying
19 for dean status, as a default pathway, would be
20 expected to have a method to examine and test, and
21 evaluate, a candidate's mastery of knowledge in those
22 areas.

23 So I think, in fact, the basic information
24 is there in the proposed rulemaking that would allow
25 you to decide whether a particular board was providing

NEAL R. GROSS

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

1 adequate, had an adequate expectation of mastery of
2 radiation safety or not. I think you could do that.

3 CHAIRMAN CERQUEIRA: Jeffrey, you had a
4 question?

5 MEMBER WILLIAMSON: No.

6 CHAIRMAN CERQUEIRA: That is unusual.

7 MEMBER WILLIAMSON: Well, anyway, there
8 was an effort -- I'm going to ask one.

9 In each of the categories authorized
10 nuclear pharmacist, medical physicist, and so forth,
11 we made an effort to define broad criteria for what
12 constituted an acceptable, you know, in the case of
13 the medical physicist it told an appropriate masters
14 and doctor's degree, have two years full time
15 practical training and/or supervised experience in
16 radiation oncology physics, some requirements that it
17 has to be in a clinical radiation oncology facility,
18 pass an examination which assesses knowledge and
19 competence in clinical radiation oncology, safety,
20 calibration, etcetera, etcetera, listing --

21 Is that an acceptably broad specification
22 of the body of knowledge that, you know, any eligible
23 board would have to asses? And in particular the
24 American Board of Radiology?

25 DR. HENDEE: I think so. When we looked

NEAL R. GROSS

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

1 through that list we said, well we test, we evaluate
2 candidate's mastery of this body of knowledge in this
3 areas, we could meet this requirement, so long as we
4 are not held to some specific number of hours of
5 training and experience.

6 I hear you saying that wasn't your intent.
7 I just have to tell you that when reading the proposed
8 rulemaking it is a little bit hard to know exactly
9 what is intended in order to determine whether a board
10 will meet those, will be accepted or not. And you are
11 clarifying that now.

12 CHAIRMAN CERQUEIRA: David?

13 MEMBER DIAMOND: Dr. Hendee, what we were
14 trying to -- since Dick, and Jeff, and I, were the
15 ones who wrote most of this fun stuff, again, what we
16 are trying to do is give the specialty boards this
17 latitude and, really, reinforce you, support you as
18 the default pathway, and only in the circumstances
19 where an individual would need, for some reason, to
20 follow an alternate pathway, in that particular
21 instance be very, very prescriptive.

22 So when I listen to you, and when I review
23 the proposal, I really don't think there is any true
24 friction going on. I understand that you are -- that
25 there may be a little confusion, but we really tried

NEAL R. GROSS

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

1 to insert that operator OR in there, to be very, very
2 clear, that only in that alternate pathway would we
3 have those very prescriptive guidelines come into
4 effect.

5 DR. HENDEE: Mr. Chairman, I'm perfectly
6 satisfied with this response. I think it is very
7 helpful to get this clarification. And I think I can
8 go back and assure the Board of Radiology, and I think
9 other specialty boards as well, that we understand,
10 now, how to go about this process, and we appreciate
11 the latitude that you have given us.

12 CHAIRMAN CERQUEIRA: Good.

13 DR. HENDEE: And I do want to move to
14 another issue.

15 CHAIRMAN CERQUEIRA: I suggest we go on to
16 the next issue, because we have about 15 minutes left.

17 DR. HENDEE: This is a fairly, I think a
18 fairly simple issue. And that is that oftentimes
19 individuals, now looking at individuals and their
20 qualifications, oftentimes an individual acquires the
21 training and experience to serve as an authorized
22 user.

23 This is particularly true with physicians,
24 while the physician is in a residency, or a fellowship
25 program, that is accredited through the accreditation

NEAL R. GROSS

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

1 council, the graduate medical education review by the
2 residents review committee, and all those kinds of
3 things.

4 In those situations the person in the
5 institution that is most responsible for assuring the
6 training of residents or fellows, is the program
7 director. And we would recommend that for individuals
8 who receive their radiation experience, and radiation
9 training, while in an accredited residency, or
10 fellowship program, that the person best suited to
11 attest to that training is the program director.

12 For individuals who did not receive their
13 training and experience in an accredited program,
14 certainly the authorized user would be the person you
15 would go to. But in the case of accredited programs,
16 the individual most responsible for assuring that the
17 training actually occurred the way that it was stated
18 to, supposed to have occurred, is the program
19 director.

20 And we would recommend that that be the
21 person that provide the attestation statement in those
22 situations.

23 CHAIRMAN CERQUEIRA: Do you have any
24 questions on that point, or --

25 MR. NAG: Should it be the training, that

NEAL R. GROSS

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

1 the principal and the authorized user, or should it be
2 an -- for example, there may be a friction between the
3 authorized user and the program director.

4 You know, the program director may not
5 like, for whatever reason, a resident. And I will not
6 certify you, while the authorized user, how do you
7 deal with conflicts like that?

8 DR. HENDEE: It is our impression that the
9 attestation statement is provided by one individual,
10 and in those situations the person that is responsible
11 for assuring the educational experience meets the
12 standards of the residency review committee, and the
13 AGCME, is the program director.

14 And so I would feel much more comfortable
15 that the program director would attest to the
16 training, rather than an authorized user, especially
17 when there is a conflict like that.

18 CHAIRMAN CERQUEIRA: Jeff?

19 MEMBER WILLIAMSON: Your statement, or
20 your description basically replacing the program
21 director with preceptor, was exactly the intent of the
22 subcommittee when we drafted the regulation.

23 DR. HENDEE: Replacing the authorized user
24 with the program director?

25 MEMBER WILLIAMSON: Precisely, or a

NEAL R. GROSS

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

1 preceptor. But, you know, what has happened is the
2 Commissioners had their go at this and they,
3 basically, have ruled that we have to put the
4 preceptor now, who I presume is somebody mentioned on
5 an NRC or agreement state license, back in as the
6 signatory.

7 So I think we are going to learn, later
8 today, the consequences of that. But, you know, that
9 was -- I'm not sure, at this point, what we can do
10 about that.

11 DR. HENDEE: Our advice to you, from the
12 profession and from the Board of Radiology is, the
13 program director would be a more appropriate
14 individual to sign off. But I do understand that we
15 all respond to people who have authority. So that is
16 just our advice.

17 MEMBER DIAMOND: I would just like to echo
18 Jeff's comments. Again, if you look through all the
19 drafts, every single draft that we wrote included the
20 language for the residency program director and as the
21 powers that be, when you get to the proposed rule, it
22 was replaced.

23 So we did our best, we agree with you.

24 DR. HENDEE: Okay, thank you. I will move
25 on to the third point.

NEAL R. GROSS

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

1 This is also, maybe, a somewhat complex
2 point. But I think we certainly reached consensus on
3 this, this morning. And that is the issue of
4 certification examinations as a measure of competency.

5 Because in various aspects of the
6 rulemaking, even though I think you took out the issue
7 of verifying competency by the preceptor, I'm not sure
8 about that, you can comment on that.

9 Here is what the American Board of
10 Radiology recommends. The American Board of Radiology
11 recommends that references to examination as an
12 evaluation of competence, in reference to specialty
13 board certification, be removed from any and all
14 sections of the proposed revisions to Part 35.

15 Specialty boards evaluate education,
16 training, experience, and mastery of a body of
17 knowledge, and its potential applications in a
18 clinical setting. That is what we evaluate, that is
19 what we test.

20 Specialty Boards, including the American
21 Board of Radiology, do not evaluate the competence, or
22 diligence, of individuals conducting technical or
23 medical procedures in a clinical setting, we don't do
24 that.

25 We have had long discussions about this,

NEAL R. GROSS

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

1 at the board level, and we have concluded that we do
2 not evaluate, or test, for competence. We test for
3 mastery of a body of knowledge, and its applications.

4 In fact, here is the mission statement of
5 the American Board of Radiology, and the mission of
6 the American Board of Radiology is to serve the
7 public, and the medical profession, by certifying that
8 its diplomates have acquired, demonstrated, and
9 maintained a requisite standard of knowledge, skill
10 and understanding essential to the practice of
11 radiology, radiation, oncology medical physics.

12 Nowhere in there is the word competence.
13 And we would only recommend that in this rulemaking,
14 as you revise it once again, you take out the
15 evaluation of competence anywhere that the boards are
16 referred to.

17 And you might think about whether or not
18 that is something that you can really, also, evaluate
19 or not. Mastery of a body of knowledge is one thing,
20 attesting to competence takes a one on one oversight
21 of the individual in a clinical study, over time. The
22 boards don't do that. I suspect the NRC would have a
23 hard time doing it as well.

24 MEMBER DIAMOND: Bill, this is another
25 subject that we spent a lot of time thinking about.

NEAL R. GROSS

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

1 In today's hyper-litigious world, no one really wants
2 to be the one stating whether an individual is
3 competent in the subject, or not.

4 We had a tremendous number of individuals
5 telling us that they, as program directors, did not
6 feel comfortable being the ones signing a statement
7 attesting to competence, they did not want that
8 liability.

9 And they all said to us, it is the boards,
10 the boards are the ones that are supposed to go and
11 help prove to us that these individuals were
12 competent, so take us out of the loop for an
13 attestation of competence, we will be happy to go and
14 sign off that they fulfilled the requirements of the
15 program, but put that in there for the boards, which
16 is exactly what we did.

17 And now, of course, you are making the
18 point that you are testing on a body of knowledge, but
19 are not capable of attesting to an individual's body
20 of knowledge and competency in the subject as a whole.

21 So we are left in a very difficult
22 predicament here, members of the Committee, we have
23 been through this quite a bit. I welcome any other
24 thoughts.

25 CHAIRMAN CERQUEIRA: Any comments?

NEAL R. GROSS

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

1 MEMBER DIAMOND: Where does the buck stop?

2 DR. HENDEE: You define competence in
3 terms of what it is that you are evaluating.

4 MEMBER VETTER: Well, just briefly, the
5 issue we struggled over was whether or not a preceptor
6 needed to certify that the individual was competent.
7 And we chose not to put that in our recommendation,
8 but that has been added in.

9 What you are raising is an additional
10 point relative to the certification process, where
11 these -- these are just draft rules, where it says,
12 assesses knowledge and competence, that is where David
13 -- somehow we were encouraged to build competency into
14 this process.

15 So that is how those words ended up there,
16 that is what we recommended, because we were not
17 recommending that the preceptors sign for competence.
18 So now we end up with both of them.

19 DR. HENDEE: If you define competence as
20 mastery of a body of knowledge, and its potential
21 applications in a clinical setting, that is what the
22 board evaluates.

23 But if you define competence in some other
24 way which requires some kind of, you know, on-site
25 over time evaluation of the practice of the

NEAL R. GROSS

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

1 individual, we don't evaluate that.

2 MEMBER WILLIAMSON: You require letters of
3 recommendation for candidates to sit for the board.
4 Those letters of recommendation request the evaluators
5 to give the opinion of the individual's competence in
6 the training environment.

7 You presume, you know, that these people
8 have had --

9 DR. HENDEE: We do ask whether or not --
10 I don't remember exactly how it is worded, but we do
11 ask whether or not the person who is signing off are
12 attesting to the individual's eligibility to sit for
13 the exam.

14 Whether or not that person feels as though
15 the person is qualified to sit for the exam. But we
16 don't ask if the person is competent to practice. I
17 mean, we have avoided this after long, long
18 discussions, we have decided that we can't evaluate
19 competence.

20 And it sounds like you all are starting
21 down the same road of having the same discussion.

22 MEMBER VETTER: I was just going to
23 mention, I'm fairly certain that the American Board of
24 Health Physics is the same way, it asks someone to
25 asses whether or not the individual is qualified to

NEAL R. GROSS

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

1 sit for the exam.

2 CHAIRMAN CERQUEIRA: Dr. Nag?

3 MR. NAG: I mean, if the American Board of
4 Radiology and the other boards are not capable of
5 certifying competence, I mean, how are we going to be,
6 you know, how can we even think about certifying
7 competence?

8 I would say we go back to the
9 Commissioners and say that we can talk about having
10 the knowledge, or having a body of knowledge, but not
11 certifying competence.

12 CHAIRMAN CERQUEIRA: Again, I think the
13 point that the committee had made to the Commissioners
14 was to, you know, certification of competency was
15 difficult, but that was put back into the draft rule
16 to Part 35. Dick?

17 MEMBER VETTER: In your position as
18 President of the ABR, in your opinion who should
19 determine competence of the authorized user, or any of
20 these other positions?

21 DR. HENDEE: Well, certainly in the work
22 environment that individual reports to somebody else.
23 And there is a medical board in the institution, and
24 there are supervisors over the work of the individual,
25 and those people are on-site, and over time if the

NEAL R. GROSS

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

1 person is incompetent, that information will come
2 forward.

3 But I can't see doing it in some sort of
4 way that a board could apply.

5 MEMBER VETTER: So whether a board
6 assesses knowledge, etcetera, or whether the NRC has
7 prescriptive hours, do either of those determine
8 whether a person is competent?

9 DR. HENDEE: No, not at all.

10 MEMBER VETTER: Ruth?

11 MEMBER McBURNEY: I agree. I would tend
12 to not want the word competence in there if it meant
13 something other than have the knowledge and training,
14 and so forth, to do the job.

15 Or to redefine competence in terms of just
16 what you had read earlier, as to what the board
17 certifies, or attests to.

18 CHAIRMAN CERQUEIRA: Sally?

19 MEMBER WAGNER SCHWARZ: I was just
20 thinking that it is possible that the words need to be
21 changed to essentially state that certifying -- then
22 certify that a body of knowledge has been achieved, I
23 mean, accomplished.

24 DR. HENDEE: Mastery of a body of
25 knowledge and its applications?

NEAL R. GROSS

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

1 MEMBER WAGNER SCHWARZ: Correct. Just
2 change the words to essentially say -- we are all
3 saying the same thing.

4 DR. HENDEE: We are.

5 MR. NAG: And have qualification, or has
6 the requisite qualification, rather than saying
7 competency, that is one word we could use. The other
8 thing is that I would not want to add to be evaluated
9 by the hospital or by the supervisor, because that
10 could lead to a catch-22 situation.

11 If you have a new employee to do the work
12 that must mean having an NRC authorized user, he
13 cannot get that unless he is working, and has been
14 supervised by somebody else. So I would not want to
15 have, you know, someone in the department supervising
16 people, and get the license.

17 CHAIRMAN CERQUEIRA: Jeff?

18 MEMBER WILLIAMSON: So I guess the
19 question is, maybe to Tom, can we delete the word
20 competence, and put in some more general specifier, as
21 has been discussed within the guidelines presented to
22 us by the Commissioners decision?

23 MR. ESSIG: Well, certainly the Rule is up
24 for comment, and if that is a comment that comes -- I
25 mean, --

NEAL R. GROSS

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

1 MEMBER WILLIAMSON: And I will comment,
2 just for information purposes, it may help explain
3 some of the confusion about this, is there are errors
4 in the way this draft rule, that was just distributed
5 today, are written. It really is not written, at all,
6 with the same logic as the original proposal.

7 I assume this is an error that was not
8 intentional.

9 MS. HOLOHAN: I'm Trish Holohan from IMNS.
10 The Commission SRM is specific saying we can't change
11 the preceptor statement, but we can certainly clarify
12 that the word competency means sufficient attestation
13 to demonstrate that the candidate has knowledge to
14 fulfill the duties of the position for which
15 certification is sought.

16 So we can do it in the statements of
17 consideration.

18 CHAIRMAN CERQUEIRA: Dr. Hendee, was that
19 something that the ABR would find acceptable?

20 DR. HENDEE: Yes, very much so.

21 CHAIRMAN CERQUEIRA: So clarification of
22 the word competency?

23 DR. HENDEE: Sure, define it in a way that
24 we can actually evaluate it.

25 CHAIRMAN CERQUEIRA: Yes. Ralph?

NEAL R. GROSS

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

1 MEMBER LIETO: I was going to ask Trish,
2 would that be in the definitions of Part 35, that you
3 define competency in the Part?

4 MS. HOLOHAN: No, it would be in the
5 statements of consideration for implementing the Rule.

6 MEMBER LIETO: Ruth just kind of whispered
7 to me the same comments that are going through my
8 mind, because statements of consideration, they are
9 out there that one time.

10 And I think if you had what, exactly, it
11 was right in the Rule, I don't think you would have
12 this history going on with what does it really mean?
13 And basically we are talking mastery of a body of
14 knowledge, and the ability to function independently.

15 MS. HOLOHAN: I think in addition to
16 clarifying the statements of consideration, we can
17 also clarify the forms to indicate what competence
18 means. The form 313 and we are looking to create
19 another form that boards submit.

20 CHAIRMAN CERQUEIRA: Dr. Nag?

21 MR. NAG: Yes, I think an important enough
22 point that even though what has been written, we
23 should still be able to insert, in the main Part 35,
24 rather than supplement the thing.

25 One point I think we can talk to the

NEAL R. GROSS

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

1 Commissioners, we have a meeting next week, if the
2 ACMUI feels that this is an important enough, even
3 that one word, it may be worthwhile talking directly
4 with the Commissioners.

5 CHAIRMAN CERQUEIRA: Right, so this is the
6 revision of Part -- the revision of the revision of
7 Part 35. So it is still, you know, being considered,
8 and I think could appropriate, with the
9 recommendations of the Committee, and the approval of
10 Staff, be advanced in that format.

11 So I gather, from the ACMUI, and the
12 presentation, that people agree with the ABR's
13 recommendations. Thank you. Your last point?

14 DR. HENDEE: Well, my last point is
15 composed of a comment, a statement. And my comment is
16 that the American Board of Radiology supports the
17 website listing of specialty boards that serve as
18 default pathway to service, as AMP, AMU, ANP, and
19 whatever.

20 We like the idea of web listing. However
21 --- so that is a comment. Now, the statement is that
22 in spite of that the ACMUI is on record, in a previous
23 report, of making certain recommendations that the
24 American Board of Radiology strongly objects to.

25 So I would like to make those objections,

NEAL R. GROSS

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

1 even though I realize that, in fact, there is going to
2 be no inclusion of any boards in the rulemaking
3 itself.

4 The objection goes as follows:
5 Recommendations of ACMUI dated August 1st, 2002,
6 recognized board certification by three specialty
7 boards, American Board of Health Physics and
8 Comprehensive Health Physics; American Board of
9 Medical Physics and Medical Health Physics, and the
10 American Board of Science and Nuclear Medicine and
11 Radiation Protection, as a default pathway to
12 recognition by the NRC as a radiation safety officer.

13 The ABR strongly objects to this listing
14 because it omits board certification radiological
15 physics, and in medical nuclear physics, by the
16 American Board of Radiology, as pathways to
17 recognition as a radiation safety officer.

18 Individuals presently serving as radiation
19 safety officers for many nuclear medicine programs
20 across the country are board certified in radiological
21 physics for medical nuclear physics by the American
22 Board of Radiology.

23 Further educational experiences for ABR
24 certification of these specialties meet, or exceed,
25 those for each of the three certification boards that

NEAL R. GROSS

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

1 were originally proposed as default pathways by ACMUI.

2 So we went on to say that we want those
3 two specialty certifications included, if there is
4 going to be boards mentioned in the rulemaking itself.
5 Now, we realize that no, it is not going to be the way
6 it happens, it is going to be on the website.

7 But I just wanted to be on record, here,
8 that the Board of Radiology strongly objects to being
9 excluded from the listing of boards that originally
10 ACMUI put forward. That is our statement. I don't
11 know that it needs any discussion.

12 But it does raise, now, the issue that I
13 do want to bring up. And it has to do with the fact
14 that one explanation for why the Board of Radiology
15 was excluded goes as follows:

16 Omission of ABR certification of medical
17 nuclear physics, and radiological physics as default
18 pathways to NRC recognition as a radiation safety
19 officer, has been defended by some. I got this
20 explanation from a couple of people.

21 Who point out that persons recognized as
22 an authorized medical physicist, that is, through
23 board certification by the American Board of Radiology
24 and Therapeutic Radiological Physics, roentgen ray and
25 gamma ray physics, X-ray and radium physics, or

NEAL R. GROSS

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

1 radiological physics, those are all historical
2 certifications, can serve as a radiation safety
3 officer.

4 So there was an alternate mechanism coming
5 through these therapeutic radiological certifications
6 that would allow someone to serve as radiation safety
7 officer.

8 However, this pathway to service as a
9 radiation safety officer is restricted to
10 responsibilities over "similar types of use of
11 byproduct material for which the individual has
12 experience".

13 The board certification pathway, as I
14 mentioned above, with the exception of one of them,
15 radiological physics, are designed for individuals
16 working in radiation oncology, where the uses of
17 byproduct material are for therapeutic applications.

18 It is not clear, it is not clear, whether
19 an authorized medical physicist would be considered
20 qualified, by the NRC, to provide radiation safety
21 oversight of the use of unsealed radioactive materials
22 for diagnostic procedures, or in research.

23 These diagnostic applications constitute
24 by far the most widespread use of byproduct material.
25 The ABR presumes that it is the NRC's intent to extend

NEAL R. GROSS

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

1 the radiation safety responsibilities of authorized
2 medical physicists to diagnostic applications of
3 byproduct material.

4 If that presumption is correct, then the
5 NRC should state its intent, explicitly, in the
6 proposed regulations. Can an authorized medical
7 physicist, working in radiation therapy, be designated
8 as a radiation safety officer, for unsealed
9 radionuclides used in diagnostic procedures, and in
10 research?

11 If the answer to that is yes, provided
12 they have some training in that area, which they all
13 would have, then the answer is settled. If not,
14 because the specific applications that the person is
15 responsible for are basically sealed sources in
16 therapy, then I think we've created a problem of who
17 is going to be the radiation safety officer for these
18 diagnostic nuclear medicine programs around the
19 country.

20 And I can't tell, from reading the
21 regulations, what the intent is.

22 CHAIRMAN CERQUEIRA: Richard?

23 MEMBER VETTER: I don't remember the
24 specific points of discussion. Some of this gets a
25 little convoluted. Tend to exclude anyone, but

NEAL R. GROSS

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

1 relative to the point you make about, okay, what is
2 the -- relative to a scope of that person's
3 certification, how would that relate to the scope of
4 the program if they are named RSO?

5 I can't answer that, off-hand, without
6 reviewing this in more detail. And, you know, it is
7 not ultimately our decision, anyway. But as we are --
8 I was hoping to be able to explain to you what we did,
9 and I can't remember the specifics of the discussion
10 relative to that particular point, comparing the scope
11 of AMP, for example, versus the scope of the program.

12 DR. HENDEE: Let me just respond to that
13 before Jeff. It all hangs on the definition, or the
14 interpretation of this statement, responsibilities
15 over similar types of use of byproduct material. It
16 all hangs on that, and you have to explain what that
17 means, and then I will understand what you intend,
18 what you are trying to get at.

19 MEMBER VETTER: Right.

20 CHAIRMAN CERQUEIRA: Jeff?

21 MEMBER WILLIAMSON: Well, I think similar
22 types of use means 300, 400, 600, I mean, that is the
23 way NRC categorizes them, and I'm sure that is how it
24 was intended. So I think the intent was, whether it
25 was advisable or not, that RSO of a broad scope

NEAL R. GROSS

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

1 licensee needs a broader certification credential,
2 like medical health physics, or American Board of
3 Health Physics.

4 I think that was the intent, and the
5 thought was that the smaller licensees that fall short
6 of being broad scopes, would be caught by the
7 condition at the end, which allows authorized users,
8 authorized medical physicists, and ANPs, to be
9 radiation safety officers for programs involving
10 byproduct uses similar to those of their experience.

11 But I think you've brought up a case where
12 radiation oncology in a small hospital, maybe, is the
13 main source of technical expertise for doing health
14 physics, and there really isn't a viable choice, other
15 than the ANP, to be the RSO for the whole operation.

16 And that, you know, if we don't repair
17 this, and I support your proposal that we do do
18 something to repair this, it may be that we will
19 actually be worsening radiation safety by forcing
20 these programs to have off-site RSOs, and consultants,
21 and so on, as opposed to having somebody on-site, full
22 time being the RSO.

23 So I could see that maybe the proposal
24 could do some harm.

25 DR. HENDEE: Could I just respond? I

NEAL R. GROSS

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

1 think you really want to think this through very
2 carefully. In my institution, which has a broad
3 license, and has a wide spectrum of programs, as do
4 most of your institutions, I can see where we could
5 have a person certified by the American Board of
6 Radiology and Medical Nuclear Physics, serving as
7 radiation safety officer over all the diagnostic
8 applications.

9 And we could have a radiation therapy
10 physicist serving as radiation safety officer over all
11 the therapeutic applications, and now we have two
12 radiation safety officers, instead of one.

13 So I think this is a complicated -- I
14 think it is not just small programs, it also creates
15 problems in large programs, as well. So I think you
16 really need to think this through.

17 And our recommendation, by the way, is
18 that a person certified as an authorized medical
19 physicist, should be given authority to serve in the
20 radiation safety officer over research and diagnostic
21 applications, provided that he has had some basic
22 education in the use of unsealed sources, and what
23 constitutes radiation safety and protection practices
24 for those sources. Then the problem would be solved.

25 CHAIRMAN CERQUEIRA: We are about out of

NEAL R. GROSS

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

1 time, here. Any other questions, or any other
2 comments? Yes?

3 MEMBER LIETO: I had two comments. One,
4 I think maybe you shed some light on where that areas
5 of expertise came into play. I think there was
6 concern that if you had, say, a physicist who is board
7 certified in just diagnostic radiology becoming an RSO
8 over a program with radioactive materials, that there
9 wouldn't be the expertise there, even though he was
10 the physicist of the facility.

11 And it would be that situation, and also
12 maybe a physician, whose expertise may be just in
13 diagnostic uses, and then in a program with radiation
14 oncology, Brachy therapy, might be asked to become e
15 RSO for the license.

16 That being said I definitely support your
17 points about the authorized medical physicist,
18 actually from reverse end, that someone could be board
19 certified in medical nuclear, and yet there might be
20 questions about their ability to be RSO over either a
21 brachy therapy program or a broad scope program.

22 And definitely would create, I think,
23 significant shortages of competent RSOs over those
24 types of programs.

25 DR. HENDEE: Thank you very much for

NEAL R. GROSS

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

1 hearing us out, thank you all.

2 CHAIRMAN CERQUEIRA: Thank you. All
3 right, the next presentation is a discussion of NRC
4 licensing timeliness proposal for monthly, bimonthly,
5 ACMUI teleconference.

6 MR. ESSIG: Okay. This caption for this
7 topic was only meant to serve as a point of discussion
8 to increased engagement between the Staff and the
9 Committee. And I don't believe that anybody should
10 seriously, should interpret that we were seriously
11 considering monthly and bimonthly conference calls.

12 That was not, that was just a suggestion
13 for more frequent engagement. I think on the benefit
14 side of more frequent engagement we see more timely
15 exchange of information between the Committee and the
16 Staff, more timely resolution of issues, and more
17 opportunity for the Committee to provide input.

18 Now, some of the concerns that we would
19 have with the additional engagement, what I'm talking
20 about here is more engagement than the two times
21 during the year, semi-annual meeting.

22 That, first of all, additional is more
23 time consuming on everybody's part, especially us
24 preparing for the additional engagements, in whatever
25 form they are.

NEAL R. GROSS

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

1 We have to decide, in advance, when these
2 will occur, so that we must publish these meetings in
3 the -- or these conference calls, in the Federal
4 Register.

5 And then once we do that we will kind of
6 be locked into the schedule, unless there is a very
7 serious reason to change it. Sometimes we may have
8 trouble getting a quorum together to reach resolution
9 on an issue.

10 The -- so those are just some of the
11 concerns. And, of course, then the increase in cost,
12 because we would pay the members for preparation for
13 the conference call, engaging in the call, and then
14 the follow-up activities.

15 And so as an example, if we wanted to try
16 that yet this fiscal year, it is probably going to be
17 difficult to do, because of our budget is pretty well
18 all spoken for.

19 So this might be something that we would
20 have to defer until fiscal '04. And even though that
21 is relatively fixed, there may be opportunity to do a
22 little trading within the budget. That is to reduce
23 some effort in some other area to create the resources
24 to address this area.

25 What I would suggest is that on a trial

NEAL R. GROSS

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

1 basis, starting -- let's see, our next meeting of the
2 Committee is going to be in the fall, so probably the
3 October, November time frame.

4 I would suggest that we institute a series
5 of noticed conference calls, publicly noticed
6 conference calls, to fill in the three month -- during
7 the, roughly, at the midpoint of the six month
8 interval in between meetings.

9 So that we would have, the first one would
10 probably be in the January '04 time frame, and we
11 would put out a Federal Register Notice, we would have
12 an agenda in that notice, and we would have to set up
13 a conference call bridge that interested members or
14 the public could call in to a toll free number, and
15 listen in, and we would give them an opportunity to
16 make comment if they so desire.

17 And so -- yes, I'm sorry?

18 MEMBER DIAMOND: It may be, that from the
19 discussion earlier today, we may have addressed this
20 issue. As you recall, we made a recommendation
21 earlier today, that approximately two weeks after the
22 disbursement of the Staff response, we would have an
23 open telephone conference call, ACMUI, Dr. Miller's
24 office, and the public, the purpose being primarily to
25 go and resolve issues of discord, try to move priority

NEAL R. GROSS

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

1 items forward.

2 And perhaps at that same call we could
3 also go and conduct this business. And that would
4 fall perfectly in the middle between our spring and
5 fall meetings.

6 And I think that one conference call
7 between scheduled meetings here would probably suit
8 our needs quite well.

9 CHAIRMAN CERQUEIRA: I think we had a
10 discussion this morning, and just a statement, I'm
11 against these preset monthly or bimonthly scheduled
12 meetings which, you know, if we don't have enough
13 agenda items, it is a waste of everyone's time.

14 And as we discussed this morning, in a
15 closed session, we follow-up on the minutes, and then
16 the Staff review of the previous meeting would be
17 adequate. That would be, you know, at least two
18 additional contact points a year, for a conference
19 call.

20 And we could see how that works out, and
21 then see if we need additional ones, if there are
22 burning issues.

23 MR. ESSIG: I'd like to suggest that just
24 on a trial basis, and then revisit the question. So we
25 might, possibly, go ahead and schedule two of them in

NEAL R. GROSS

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

1 2004.

2 CHAIRMAN CERQUEIRA: Yes, that would be
3 reasonable, because that would put some, you know,
4 focus time commitments from the Staff to get the
5 minutes out, and to find out whether the issues were
6 addressed.

7 MR. ESSIG: Yes, and we could cover the
8 issues that Dr. Diamond is reminding me of, and also
9 any new agenda items, any -- this would be a good time
10 to discuss any emerging issues that have come up,
11 questions and so forth.

12 Yes, Ruth?

13 MEMBER McBURNEY: Would there be a funding
14 problem to have one between this meeting and the fall
15 meeting? You said that --

16 MR. ESSIG: I would have to look into it,
17 to be sure. It is hard to say, off the top of my
18 head, but I would be willing to look into it.

19 MEMBER McBURNEY: Good.

20 CHAIRMAN CERQUEIRA: All right. Well,
21 thank you very much, and maybe we can move on to the
22 next time, which is the T&E Rulemaking Status and
23 Discussion, and Roger Broseus will be leading the
24 discussion.

25 DR. BROSEUS: I want to thank you all for

NEAL R. GROSS

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

1 having me here today.

2 CHAIRMAN CERQUEIRA: Roger, if you could
3 maybe move to the side, because you are directly in
4 front of the screen, there. Yes, just use that other
5 microphone there, get a little closer to the
6 microphone. That is good.

7 DR. BROSEUS: By the way, there are a few
8 extra slide sets here, I'm afraid we don't have enough
9 for everybody in the audience. Angie, want to put
10 these in the back?

11 This is essentially a slide set I put
12 together to cover both of our meetings today. I was
13 lucky enough to be coordinating a public meeting this
14 morning, with the Board present, and members of the
15 public, as well as briefing, so a dual purpose set.

16 Before I launch into the discussion, I
17 just want to point out that there are a couple of
18 members of our working group here in the audience
19 today. Ron Zelac is with MSIB, material inspection
20 safety inspection branch. I think that I saw John
21 Zabco. John is back here, he is with the Office of
22 State and Tribal Programs.

23 Other members of the working group, which
24 I'm the coordinator for, are David Walter, he is
25 representing agreement states on the working group.

NEAL R. GROSS

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

1 He is from Alabama.

2 Susan Chidakel is from our office of
3 General Counsel. Susan, I'm sorry, you are short, I
4 didn't see you. It is an inside joke. Sally Merchant
5 from the office of enforcement, and we also have
6 representatives from our administration and office of
7 information.

8 Some of the slides I'm going to present to
9 you today, I'm going to run through very quickly,
10 because we are short on time, and I want to be able to
11 emphasize certain areas where we are looking for some
12 input from ACMUI.

13 And this is one that I'm going to go
14 through very quickly. You guys are familiar, already,
15 I'm sorry ladies and gentlemen, with how we are to
16 where we are today, with you all briefing the
17 Commission, and so on.

18 This led to subpart J being incorporated
19 into the Rule, etcetera, Staff working with ACMUI,
20 Tony Tse is over here in the corner, he and Linda --

21 CHAIRMAN CERQUEIRA: Roger, for the sake
22 of time and discussion I -- we should acknowledge all
23 the people that have been involved, but if we list
24 everyone it is going to eat up the whole time. And I
25 don't mean to disrespect anyone.

NEAL R. GROSS

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

1 DR. BROSEUS: In the end there was a Staff
2 paper that went forward to the Commission, with three
3 recommendations, which was to use ACMUI's
4 recommendations as the basis for the Rule, it was
5 adopted by the Commission in SRM-02-0194. With the
6 proviso that we list recognized boards on our website,
7 rather than in the Rule.

8 We discussed, already, to a certain
9 extent, and others have mentioned that we have to keep
10 a preceptor statement as written in the Rule, and
11 there was some discussion of that by Dr. Hendee, with
12 the clarification that it is not clinical competency,
13 but attestation of knowledge that we are after.

14 And we have heard the comments on that,
15 and we will be working to that end. The SRM required
16 a clear radiology determination to meet criteria, and
17 they also talked about implementing procedures, which
18 I want to come back to later in my discussion.

19 Now, ACMUI members have draft rule text
20 that is pre-decisional, which the working group has
21 put together in your materials that were presented to
22 you this morning.

23 I want to mention how we got to where we
24 are at in that today. First of all, the first part of
25 your recommendation, to list the boards in the Rule is

NEAL R. GROSS

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

1 not there, because that was direction from the
2 Commission, to be on the website, and all boards must
3 be evaluated, okay?

4 We adopted most all of the changes, or
5 intended to adopt most all the changes in the word of
6 the Rule or the new Rule text that ACMUI presented,
7 but we found some need for wording changes, which are
8 reviewed in some slides that come up later.

9 There are also some changes you introduced
10 into what have been commonly termed alternate pathway,
11 which go a little bit beyond, in some cases, just
12 writing rule text for recognition of boards, and the
13 working group looked at that, too.

14 Now, one of the things that I want to
15 mention, specifically, is ACMUI recommended that
16 individuals, that T&E of an individual be evaluated to
17 make sure that they have training or experience with
18 new modalities, or new applications, or the ones they
19 are going to be working with.

20 And an example of where that came in was
21 in 35390, and your recommendation was the final little
22 D in parenthesis. Now, you won't find it written that
23 way in the draft that the Staff has prepared. We
24 changed the numbering around to try to avoid
25 redundancies.

NEAL R. GROSS

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

1 So, in general, there may be some cases
2 where our numbering is a bit different from what you
3 had in your draft. There are references in this
4 presentation to numbering, they are the numbering in
5 the revised draft proposed rule text, that is in the
6 left-hand column of that table.

7 Another example of changes that we came
8 across that feel are needed, and where the numbering
9 needs to be addressed is in 392 and 394, there are
10 back references to the experience requirements that
11 ACMUI recommended, were oral administrations, for
12 example.

13 And so the Staff has found a need that we
14 are going to have to address, making sure that cross
15 reference within the Rule is taking care of, when
16 there are cross references back to 390. And we didn't
17 see those changes in the ACMUI text.

18 The next point I want to get to, where we
19 need some advice, is ACMUI recommended including the
20 Royal College of Physicians and Surgeons of Canada in
21 the list of approved entities for recognition of
22 residency programs, and excuse my use of the term, and
23 also as one of the boards that would be in the pathway
24 for recognition of board certifications.

25 The Staff feels that we don't have a clear

NEAL R. GROSS

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

1 basis for including the Royal College of Physicians
2 and Surgeons of Canada in the Rule. And so we would
3 like to solicit some input from ACMUI on the basis for
4 that.

5 CHAIRMAN CERQUEIRA: Jeff?

6 MEMBER WILLIAMSON: Well, I'm confused,
7 because I thought we were taking all references to
8 specific boards out of the rule. That I thought your
9 revised rule text was going to have them all on a web
10 page, so why does it matter whether we answer the
11 question now?

12 DR. BROSEUS: There is a, and you will
13 have to look at the Rule text later on. I wish I had
14 time to go into these in detail, I just can't. There
15 is a paragraph, or a section in here, where the
16 Canadian Board is referenced in the Residency area,
17 but not in the Board certification pathway.

18 DR. DIAMOND: Yes. I think you're correct
19 on that point. Just from a writing standpoint, the
20 reason that language was probably included was simply
21 that of precedent. When we were making a team to
22 rewrite these for clarification and updating we did
23 not go and substantively change that type of
24 information, so I cannot go and tell you why it is
25 that way except that we did not add nor delete in our

NEAL R. GROSS

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

1 early draft versions. For example, the same thing
2 would hold with the American Board of Osteopathic
3 Radiology. When we made an attempt to delete that as
4 an authorized user enumerated board, we ran into all
5 that trouble with that.

6 DR. BROSEUS: The key issue here is it's
7 a foreign board, no intent to separate out Canada from
8 the rest of the world or whatever.

9 MS. MCBURNEY: It's an accreditation.

10 DR. BROSEUS: Pardon me?

11 MS. MCBURNEY: It's an accreditation
12 rather than --

13 DR. DIAMOND: Yes. I don't think that's
14 a board.

15 MS. MCBURNEY: It's a residency program.

16 DR. BROSEUS: A residency program. So we
17 need a basis for including that. Given the amount of
18 time I have, I'd like to move on, and then we have
19 some time for more questions and discussion at the
20 end, we'll go with that.

21 Going up to Slide Number 8, staff decided
22 to recommend inclusion of -- I'm trying to present
23 this efficiently. In the current rule, specialty
24 awards may be recognized if they meet the requirements
25 in the so-called alternate pathway. And there was

NEAL R. GROSS

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

1 some discussion in fact during your meeting last
2 summer that that option be continued as a way for a
3 board to satisfy NRC requirements. But it didn't come
4 through in the final version of the document that you
5 presented in the options paper.

6 Staff feels that keeping that option as
7 one mechanism by which a board may satisfy NRC
8 requirements is something we should have. It also
9 satisfies the potential need of there is one board
10 that has been recognized using that pathway, and we
11 want to make sure that they don't lose their
12 certification by some change to the rule.

13 I'd like to just hold the questions, if I
14 can, to go through a couple more points.

15 CHAIRMAN CERQUEIRA: But it's an issue
16 that does need to be brought up, I think. Jeff?

17 DR. WILLIAMSON: The intent of our group
18 was to come up with general criteria that would not
19 exclude the Board of Nuclear Cardiology and that would
20 replace the more prescriptive requirements. As you
21 know, we accepted that there was significant value
22 added by the examination process and therefore felt
23 somewhat more justified in making the alternate
24 pathways more prescriptive, but I think the intent was
25 all along that the alternate pathway requirements

NEAL R. GROSS

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

1 would at least be necessary conditions for fulfilling
2 the more general requirements so that any board that
3 satisfied the alternate pathway requirements would
4 satisfy the general ones. That was the intent, so I'm
5 not sure why it's necessary. Because I'm reading the
6 text of your revised rule. I was very confused, and
7 I thought that there was an error in transcribing it.
8 And as I read it more carefully there may not be, but
9 it's very convoluted.

10 DR. BROSEUS: Let me see if I understand
11 what you said. Right now the rule allows a board to
12 be recognized if they meet the alternate pathway. And
13 you see that as something that's just to continue.

14 DR. WILLIAMSON: No. We thought that we
15 were covering that case by adopting a more general set
16 of criteria, that any board which met the alternate
17 pathway requirements would also meet the general
18 requirements minus the examination.

19 CHAIRMAN CERQUEIRA: This went back to
20 long discussion about hourly requirements and
21 eligibility requirements for the board, and I think
22 several years back the feeling was that if a board
23 could demonstrate that they had certain requirements
24 in terms of content and hours, that that was one of
25 the prerequisites for them being considered for the

NEAL R. GROSS

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

1 boards, and that was one of the criteria that was
2 used. And I think it was the feeling that that should
3 be continued to a large extent because it showed that
4 at least the candidates for the board had had the
5 minimum requirements for the alternative pathway. So
6 I think the feeling of the Committee was to continue
7 that.

8 DR. WILLIAMSON: To continue there might
9 be some concern to recognizing and promoting a board
10 that didn't require a peer review examination. That's
11 also another concern, because you know what boards NRC
12 recognizes has sort of impact on educational and
13 training policy that goes beyond the specific
14 application here.

15 DR. BROSEUS: When I finish up I'm going
16 to -- I'll say it now -- I'm going to ask for feedback
17 from you on some of the points I've made. But I will
18 take right now absent additional feedback on this
19 topic that it's the consensus not to put an "or" in
20 there which would permit the boards to be recognized
21 using the current system, basically.

22 CHAIRMAN CERQUEIRA: I didn't understand.

23 DR. BROSEUS: It's not clear?

24 CHAIRMAN CERQUEIRA: No.

25 DR. BROSEUS: Let me take an example.

NEAL R. GROSS

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

1 DR. EGGLI: Why don't you take 390 and
2 just walk us through 390 and what you mean. Take Page
3 11, I mean just to grab one that I'm looking at right
4 now.

5 DR. VETTER: What about 290 since that's
6 the Board of Nuclear Cardiology. It's under 290,
7 isn't it?

8 MR. WILLIAMS: I don't know if that's a
9 good case.

10 DR. BROSEUS: Can we go with a simple case
11 for the sake of example, okay? It's at the beginning
12 on the first page.

13 PARTICIPANT: Which page are we talking
14 about?

15 DR. BROSEUS: Of the draft. At the bottom
16 we have a certified -- or Number 2 -- "Certified by
17 specialty board for the certification process includes
18 all the requirements in Paragraph B of this section in
19 the certifications we have recognized by the
20 Commission on Agreements States." So this is
21 basically retaining that, and it's my understanding
22 that ACMUI doesn't want to do that. In other words,
23 the could do what you wrote as the criteria for
24 recognition of a board, which I'll loosely term
25 academic intestine, or meet the alternate pathway,

NEAL R. GROSS

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

1 which is allowed now.

2 CHAIRMAN CERQUEIRA: It wasn't that the
3 alternate pathway alone would be sufficient, because
4 the examination and all those things needed to be
5 looked at, but I'm just a little confused.

6 DR. WILLIAMSON: Two ninety isn't a good
7 example because this is one in which we did say, I
8 think, that the qualifying features of a board for
9 imaging and localization actually would be the \$700,
10 all that business. So this actually -- we lied to Dr.
11 Hendee.

12 DR. BROSEUS: For RSO, ANP and AMP -- I
13 think AMP, I'm not sure, I'd have to look at it.

14 DR. WILLIAMSON: But the AMP is --

15 DR. BROSEUS: In some cases it wasn't
16 required.

17 DR. WILLIAMSON: Yes, that's right. So
18 the AMP and I suspect maybe the Radiation Oncology
19 authorized user for sealed source for radiotherapy may
20 have been different.

21 CHAIRMAN CERQUEIRA: Ruth?

22 MS. McBURNEY: I would think that for
23 Radiation Safety Officer we would not want it just to
24 be the alternate pathway inclusion, the 200 hours, for
25 a board to be recognized, that the board certification

NEAL R. GROSS

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

1 should be the bachelor's degree and graduate degree
2 and minimum of 20 college credits and so forth.

3 DR. VETTER: The intent of the
4 Subcommittee was, I didn't have this in front of me
5 before, but it was not to -- the intent was to not
6 exclude any boards who had already been recognized.

7 MS. McBURNEY: Right.

8 DR. VETTER: So the Nuclear Cardiology
9 Board. And therefore when we wrote this we
10 accommodated that within our proposal. The intent
11 also at that time was not to provide that pathway for
12 any other boards but rather to write general criteria
13 for which the boards would qualify.

14 DR. BROSEUS: Well, I've thrown in a red
15 herring which I'll pull out of the water unless by the
16 end of our -- unless later on you have additional
17 thoughts. So I'll pull that out, okay? Okay. Now
18 with that, I might move on. To me it was an important
19 issue to make sure we're doing the right thing with
20 this rule.

21 MR. LIETO: Are you pulling out the "or"
22 or whatever comes after --

23 DR. BROSEUS: Well, for example, on Page
24 1 at the bottom of this draft, where there are --
25 where there's a retention of a board meeting the

NEAL R. GROSS

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

1 current rule as an alternative to what ACMUI wrote,
2 I'll pull that off. I think I've confused things too
3 much, and unless ACMUI feels that we should be doing
4 something more than -- Dick just said it, I think, and
5 I think it's a settled issue here.

6 Let me move on. There are some slides
7 that I want to go over very quickly because we are
8 very short on time. And what I'm going to ask is that
9 the information I'm presenting in these slides that
10 you consider this and if we have time for me to come
11 to them, but I doubt that we're going to, but that
12 ACMUI provide some feedback to me later on. And it's
13 where I've talked about terminology, using quantities
14 for where a written directive is required rather than
15 therapeutic quantities and so on.

16 So I'm going to skip over slides up
17 through Number 12 and go on to implementation with one
18 exception. And during the discussion by Dr. Hendee in
19 our meeting this morning -- let me look at my notes
20 here -- I heard in the meeting earlier on that it
21 wasn't ACMUI's intent to prescribe numbers of hours of
22 training. However, in certain cases, the way you
23 wrote the proposed rule, by referencing what's already
24 in the rule that actually happened. And so I take it
25 that you did not mean to overwrite that, and do we

NEAL R. GROSS

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

1 need an example?

2 DR. WILLIAMSON: I think that you're
3 absolutely right. In reviewing what we originally
4 wrote for 190, 290 and 390, we kept the hours of
5 training and experience and the detailed breakdown in
6 tact I think under the belief that that requirement
7 was considered uncontroversial in terms of board
8 eligibility compliance. Now, that may not be true,
9 and if that's -- we explicitly decoupled those in the
10 case of 400, 600, the AMP and the Radiation Safety
11 Officer, but we did not decouple them for 100 to 200
12 and 300.

13 DR. BROSEUS: Okay. Mr. Malmud?

14 DR. MALMUD: I apologize for my ignorance,
15 but I am totally confused by what you are trying to
16 get me to understand.

17 DR. BROSEUS: That's my fault.

18 DR. MALMUD: May I ask what's the first
19 point that you would like me to understand under the
20 proposed rule to amend 10 CFR Part 35 requirements D
21 and E, these slides, as it applies to this text?
22 What's the first item that you would like me to
23 understand.

24 DR. BROSEUS: To understand or to get
25 feedback on?

NEAL R. GROSS

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

1 DR. MALMUD: I didn't hear you, I'm sorry.

2 DR. BROSEUS: To understand or to get
3 feedback, I'm sorry.

4 DR. MALMUD: To understand. I can't give
5 you feedback until I understand it.

6 DR. BROSEUS: Okay. The very first one is
7 that we used ACMUI's recommendations, the basis for
8 draft and proposed for the text that you have in the
9 left column of that handout.

10 DR. MALMUD: You are proposing that on
11 Page 1, Item 35.50 be accepted as it is.

12 DR. BROSEUS: No. No. It's for you to
13 look at and review. This is our draft. This is first
14 column in this handout that you have --

15 DR. MALMUD: Yes.

16 DR. BROSEUS: -- is our Working Group's
17 first draft, our best attempt to get what ACMUI wanted
18 to --

19 CHAIRMAN CERQUEIRA: Roger, could you get
20 closer to the microphone? I think some of the
21 audience in the back probably -- yes. All right. So
22 current rules means that revised Part 35 --

23 DR. BROSEUS: Yes. Yes.

24 CHAIRMAN CERQUEIRA: -- which was
25 published in May of 2002 and became the rule --

NEAL R. GROSS

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

1 DR. BROSEUS: Yes. Yes.

2 CHAIRMAN CERQUEIRA: -- in October 24,
3 2003, that there was a draft proposal that was put
4 together by Dick Vetter and his Committee addressing
5 some of the problems that we had not dealt with
6 adequately in terms of board certification and other
7 things. And so that was submitted to the Committee.
8 Now, the draft proposed, which is on the left hand
9 side of Page 1, that is your modification of what was
10 sent to you? Is that --

11 DR. BROSEUS: This is what we have come up
12 with as draft proposed rule text based on ACMUI's
13 recommendations and then qualified with the points
14 that I'm making where we saw a need for changes of
15 wording and so forth.

16 DR. DIAMOND: See, Roger, the problem is
17 this: I have my redline copy of all the work that
18 Dick's Committee went through, and this is the first
19 time I've seen your draft modifications. As I'm going
20 through, there are differences in numbering, there's
21 differences in wording, there's differences in syntax
22 and structure, and I'm getting one hell of a whopper
23 headache over here trying to figure out if the
24 response I'm giving to you and Dr. Hendee is still
25 what I tried to write or what Jeff tried to write.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Well, it was the old
2 -- the revision or the revision of the revision, and
3 I'm not sure we can adequately deal with this seeing
4 it for the first time.

5 DR. DIAMOND: It's really difficult
6 because I'm probably the only one here that has all
7 this redline, what we were trying to do, how we
8 proceeded with it, and I've been here for 20 minutes
9 --

10 CHAIRMAN CERQUEIRA: I'm doing basically
11 three and a half years worth of the Committee's work,
12 to a large extent, because the revision of the revised
13 rule was dealing with -- you know, making some
14 modifications to address specific issues that had
15 arisen. And this really kind of takes it in a whole
16 other direction that I'm not sure we want to go in.
17 Ralph?

18 MR. LIETO: Can I make a recommendation
19 that you take what the Subcommittee submitted to the
20 Working Group and do an editing with the strike-
21 throughs and redlining and so forth? That way we will
22 be able to compare. That way we can give you feedback
23 as to what you're doing that meets the intent of the
24 Committee as well as do we really have some points of
25 contention. Because --

NEAL R. GROSS

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

1 DR. BROSEUS: Yes. I hear you.

2 MR. LIETO: And I think that might be the
3 easiest place to go from here.

4 CHAIRMAN CERQUEIRA: Trisha, do you want
5 to make a comment?

6 MS. HOLOHAN: I agree with that comment.
7 If we could do what Dr. Lieto suggested and do a
8 redline strike-out of the ACMUI Subcommittee's
9 recommendations and give them the revised rule
10 language that the Working Group has come up and make
11 corrections, yes.

12 CHAIRMAN CERQUEIRA: But I'm a little
13 disappointed that this far into the process this is
14 basically being presented to the Committee without
15 having had some discussion with Dr. Vetter and his
16 group. I think there should have been discussions
17 with them, and certainly any kind of presentation to
18 get meaningful advice from the ACMUI should have been
19 given to us earlier.

20 DR. NAG: Manny, I'd like to make a
21 suggestion. Whenever we are having a Subcommittee
22 meeting reform and making a major discussion and
23 changes, we have the appropriate member of the NRC be
24 placed in there so that they are aware of the
25 discussion, because otherwise we write up a

NEAL R. GROSS

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

1 recommendation and give it to them. They may not be
2 fully aware of all the discussions that have gone on,
3 and it goes round and round and round. If they are
4 there at the beginning, they know why we make certain
5 recommendations and why that was done, and that
6 miscommunication would be less.

7 MS. HOLOHAN: But if I can make one
8 comment. Really what we need from you today is the
9 basis for the Royal College of Physicians in Canada.
10 And you indicated that there wasn't a real basis, and
11 --

12 CHAIRMAN CERQUEIRA: I'm not sure we
13 understood it, to be honest, and I don't think we can
14 just take one specific thing out of the whole package.

15 DR. WILLIAMSON: Could I make a
16 recommendation?

17 CHAIRMAN CERQUEIRA: Sure.

18 DR. WILLIAMSON: I think that these are a
19 whole panoply of very complicated issues has been
20 raised. I don't think we can do justice to any of
21 them, including the Canadian College issue, so I
22 recommend that we schedule a Subcommittee meeting with
23 Roger and others who are involved, publicly noticed if
24 necessary in the near future, to work through these
25 nitty gritty details and then report back to the

NEAL R. GROSS

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

1 parent Committee. I really think that we need to do
2 much more work, have a lot of advance time to read
3 through this document. I think we've been apprised of
4 some of the issues. We did have a large briefing book
5 put together for us on all the different specialty
6 board, which may well have included the Canadian
7 organization, so we'll have to do a little research on
8 that issue.

9 CHAIRMAN CERQUEIRA: I think definitely --
10 I mean the Subcommittee did a lot of work, the main
11 Committee and those of us who've been on this thing
12 for four years have spent a lot of time, and you're
13 sort of relatively new into the process. There's a
14 lot of stuff that's going on, and to just get this now
15 without being able to review it in detail I don't
16 think is going to be meaningful to you.

17 DR. BROSEUS: I appreciate that. Part of
18 this is an artifice of the time constraints we're
19 under to get something out and have it in place before
20 Subpart J disappears.

21 CHAIRMAN CERQUEIRA: Well, but that's why
22 this Subcommittee did its work in a very timely
23 fashion. I think Dr. Vetter should be commended --

24 DR. BROSEUS: Well, I wasn't saying --

25 CHAIRMAN CERQUEIRA: Well, but to get it

NEAL R. GROSS

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

1 out -- just to get it out without making it accurate
2 we're going to run into the same problem we had the
3 first time.

4 DR. DIAMOND: It's very important. This
5 document under Dick's leadership we met a timeline for
6 July of 2002 and we worked our tails off to make it
7 happen. And it would have been much better had we had
8 our submitted language and then perhaps your revisions
9 or a redline of the same, because there's -- this is
10 no basis for comparison today.

11 CHAIRMAN CERQUEIRA: And some discussion
12 with the group. The group would have been willing to
13 discuss this with you, and any kind of redlining
14 without understanding some of the reasoning that went
15 into it is just going to be more work, and I think
16 some discussion with Dick or with the Committee would
17 really identify some of these issues, giving people
18 the chance to go back and review why certain decisions
19 were made. That's critical.

20 DR. BROSEUS: I'm going to have to ask
21 Trish and Sandy about what we can do timewise to
22 accommodate that suggestion and how we can move
23 forward. One suggestion is to distribute a redline
24 strike-out to have reaction back. Another one is for
25 the Subcommittee to reconvene and talk and so on. And

NEAL R. GROSS

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

1 I can't say yes or no.

2 CHAIRMAN CERQUEIRA: Well, just a comment
3 on my part. Getting back to some of the discussions
4 we had this morning and where the communication
5 between the Committee and the staff has fallen apart,
6 this is a clear example of it, and I think the
7 Committee feels frustrated that we spent a lot of
8 time, a lot of work, we set timelines that we're going
9 to be able to get the revision out in a timely fashion
10 to meet the 2005 implementation deadline, and all of
11 that work was not dealt with appropriately by the
12 staff. You were not involved in the process from the
13 beginning, so I don't want to fault you, but I think
14 we need to communicate with the Committee so that
15 we've spent the time giving you the recommendations
16 and you're recreating a lot of work that with some
17 input from the Committee could have been verified and
18 you wouldn't have had all these issues.

19 DR. VETTER: Let me just say that Roger
20 did call me on one occasion a couple of weeks ago to
21 try to clarify a few things. This is the first
22 opportunity I've had to see anything in writing. But
23 I don't want us to go away thinking that Roger and his
24 Subcommittee weren't attempting to communicate with
25 the Committee.

NEAL R. GROSS

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

1 DR. BROSEUS: I do want to say that we
2 were diligent about being careful to take ACMUI's
3 recommendations to heart and where we had differences
4 to identify them. And my purpose in coming here today
5 was to identify those defenses. I think all the
6 difficulties are arising from there's so much to deal
7 with in such a short period of time.

8 PARTICIPANT: Roger, we can't hear you
9 back here.

10 DR. BROSEUS: I'm very sorry. I said I
11 just wanted to point out that we were very diligent in
12 working to make sure that we used ACMUI's
13 recommendation, as modified by the SRM and so on. And
14 my purpose in coming here today was to identify where
15 those differences came up. I think that the
16 difficulty arises we have such a short period of time
17 to review it that that's the hurdle. I've asked for
18 some advice on what I can do from our Deputy Division
19 Director, and can you help me out on this a little
20 bit, Trish?

21 MS. HOLOHAN: And I just wanted to point
22 out that there's very few changes -- there's about
23 half a dozen changes from what the ACMUI recommended,
24 except for the preceptor statement that was directed
25 by the Commission to be identical to the current rule.

NEAL R. GROSS

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

1 Otherwise, there's about half a dozen changes, and I
2 wanted to say that we can certainly work with the
3 Subcommittee or the full Committee in resolving this,
4 but our timing is such that we have to get a final
5 rule up to the Commission by the end of July. So
6 whether we do it by Subcommittee, and we're certainly
7 happy to work with them, or the full Committee --

8 CHAIRMAN CERQUEIRA: Well, I'd recommend
9 that you work with the Subcommittee at this point,
10 because they've been involved in the issues.

11 DR. BROSEUS: I'd like to remark about the
12 recommendation of preparing a redline strike-out. The
13 way the rule language is structured and so on, a
14 redline strike-out in making a direct comparison
15 between ACMUI's draft and what we have would be
16 somewhat difficult, and there may even be a need to
17 identify differences as I have today, because it's not
18 just a matter of feeding it into the computer and out
19 comes the redline strike-out, because there are so
20 many different --

21 CHAIRMAN CERQUEIRA: Roger, can you bring
22 the microphone closer?

23 DR. BROSEUS: Yes. There are so many
24 differences that we're not going to be able to just
25 feed this into the computer and get a redline strike-

NEAL R. GROSS

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

1 out. I'll leave that as it is.

2 So what I'm hearing is that we need to get
3 back together with the Subcommittee maybe chaired by
4 Dr. Vetter and look at what we've done?

5 CHAIRMAN CERQUEIRA: Richard, are you and
6 the Subcommittee willing to do it?

7 DR. VETTER: Can this be done by
8 conference call?

9 CHAIRMAN CERQUEIRA: I think that would be
10 the most efficient, and it's a subcommittee so we
11 don't need all the public notices, correct?

12 PARTICIPANT: No.

13 PARTICIPANT: Maybe two weeks notice.

14 CHAIRMAN CERQUEIRA: Two weeks? Okay.
15 All right.

16 MR. LIETO: I'm confused. Now, the
17 Subcommittee is going to work with Roger. What about
18 the rest of the Committee?

19 CHAIRMAN CERQUEIRA: Once they've had a
20 chance to go through, I think, make some of the
21 clarification points, then it needs to come back to
22 the Committee for the review of it. To get the whole
23 Committee involved I don't think is going to be an
24 efficient use of the time. It would be better don
25 with a small number of people who are intimately

NEAL R. GROSS

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

1 involved with developing it and then bring it back to
2 the main Committee.

3 MR. NAG: There's a problem with the
4 timing because they have to do this by the end of
5 July. If the Subcommittee works with Roger, when does
6 the whole Committee get together? And then by July
7 they have to send it to the Commission.

8 MS. HOLOHAN: And we have to send it out
9 to the Agreement States as well for a 30-day comment
10 period.

11 DR. BROSEUS: Is it possible to work with
12 the Subcommittee and have them bring substantive
13 issues back to ACMUI?

14 CHAIRMAN CERQUEIRA: No. I think they can
15 issue it to the whole report. We don't have to
16 physically, publicly meet on it. I think it can be
17 sent out to them as a draft, solicit comments and then
18 the comments can be sent to me and I can -- if there
19 are substantive disagreements, then I can make the
20 decision whether we need to convene a conference call
21 of some sort, but I think that's the most expedient
22 way to get it done.

23 MS. HOLOHAN: Can I make another proposal?

24 CHAIRMAN CERQUEIRA: Yes.

25 MS. HOLOHAN: If we send it out to the

NEAL R. GROSS

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

1 Agreement States as well as the full Committee at the
2 same time and get your comments and we can get the
3 Agreement State comments too.

4 CHAIRMAN CERQUEIRA: Okay. Jeff Brinker?

5 DR. BRINKER: If you can't supply us, and
6 I hear that you may not be able to in appropriate
7 fashion, a redline comparison, it might be helpful for
8 you to reproduce your new wording with highlighted or
9 annotated explanations of what you think are
10 substantive changes that you had to introduce, felt
11 you had to introduce and perhaps why there was a
12 change so that as we go over this ourselves, we could
13 rapidly identify where a change was made and get some
14 idea of why you changed it.

15 CHAIRMAN CERQUEIRA: I think that would be
16 an appropriate thing. We've gone over our break
17 period. I think we should break and try to reconvene
18 at two o'clock. Now, Roger, I don't mean to cut you
19 off but we're starting to fall behind.

20 DR. BROSEUS: I understand.

21 CHAIRMAN CERQUEIRA: And so the plan is to
22 basically have you work with the Subcommittee to get
23 the intent of some of these issues and then try to
24 come up with a version that will go to the main
25 Committee and the Agreement States at the same time to

NEAL R. GROSS

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

1 try to meet a July 1 timeline.

2 MS. SCHWARZ: I'm just thinking that in
3 terms of a redline copy at least it would be good to
4 see what we had written originally as the Subcommittee
5 on the one side and then what you're writing on the
6 other side, just so that they sort of line up and we
7 can see where you've changed things as you go, even if
8 it's not really truly redlined.

9 DR. BROSEUS: Would that be more useful
10 than having a side-by-side comparison of revised
11 proposed rule versus the existing rule?

12 DR. NAG: It would be more helpful to have
13 what the issue and what the Subcommittee proposed and
14 what you propose side by side.

15 MS. SCHWARZ: Right.

16 DR. NAG: That would be more helpful.

17 CHAIRMAN CERQUEIRA: That would be
18 helpful. Jeff, one last comment.

19 DR. WILLIAMSON: Okay. I think it's
20 unfortunate we didn't get to the one substantive point
21 that I'm really concerned about that could make quite
22 a mess of this. We are required to put the preceptor
23 back in in exchange for program director, and I think
24 if it's left in such a position as to be a
25 qualification for a board, we could be precisely back

NEAL R. GROSS

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

1 where we were, so I think some thought how to
2 incorporate the preceptor requirement the Commission
3 has imposed on us without making it impossible for the
4 boards that exist to qualify is a challenge that I
5 wish we would have had some time to talk about.

6 CHAIRMAN CERQUEIRA: Yes. Okay. Let's
7 try to reconvene at 3:05. Thank you.

8 (Whereupon, the foregoing matter went off
9 the record at 2:57 p.m. and went back on
10 the record at 3:09 p.m.)

11 CHAIRMAN CERQUEIRA: All right. "Sealed
12 Source Model Numbers as License Conditions." Donna-
13 Beth Howe, Ph.D., will now do the less controversial
14 presentation, I hope.

15 (Laughter.)

16 DR. HOWE: Well, I think based on this
17 morning, I'm not sure I'd go there. Essentially this
18 is one of the issues that the ACMUI brought up as a
19 recommendation at the last advisory committee meeting,
20 and Angela later on will be going through the other
21 recommendations and the results of those
22 recommendations.

23 So if you look in your tabs, update
24 recommendation for fall 2002 meeting, you'll see on
25 page 2 of 3 a little bit more text that goes with,

NEAL R. GROSS

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

1 that explains the resolution.

2 I only have essentially four slides. Two
3 of them are to remind you of what the current
4 regulation is, and the other one is to give you the
5 recommendation and then the results.

6 Okay. At the last advisory committee, the
7 ACMUI recommended that NRC initiate a rulemaking
8 process to modify 10 CFR Part 35 to overrule 10 CFR
9 Part 30.32(g)(1), to allow more generic listing of
10 interstitial seeds and sources on NRC licenses.

11 Well, the staff took your recommendation,
12 and they evaluated it. They put it in the context of
13 what else is happening at the NRC, and they came to a
14 determination that they were unable to support the
15 stated rulemaking initiative.

16 And I've summarized the staff's reasoning
17 on the next slide, and you'll see, I think -- as you
18 were settling in, I was trying to indicate that you'll
19 see on one of your later tabs a little more lengthy
20 discussion of this.

21 But essentially the staff decision was
22 based on protecting public health and safety. They
23 felt that the rulemaking would ultimately reduce the
24 radioactive source accountability, and in today's
25 environment after 9/11, the NRC and the Commission are

NEAL R. GROSS

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

1 very concerned about source and material
2 accountability and security.

3 They felt that the regulation in Part 30
4 as it stands insures licensee maintain a full
5 accountability, and it assist them in making an
6 accurate inventory and in preventing losses of their
7 sources and devices.

8 And by identifying the requirements for
9 all sources and devices, they thought they were
10 reasonable in assuring accountability and that was a
11 result of 9/11, it's not prudent at this time to
12 reduce accountability requirements.

13 And they looked at this issue in
14 relationship to the Commission actions with other
15 sources and devices, specifically looking at what
16 we're thinking of doing with the general license
17 devices, which would be in a similar category.

18 And then the next slide was just to remind
19 you of what 30.32(g)(1) says. You have two
20 alternatives. One is to identify the sources or
21 device by manufacturer and model number as it's
22 registered with the Commission in the sealed source
23 and device registry.

24 The other would be to provide additional
25 information which is much more lengthy in 32.210, and

NEAL R. GROSS

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

1 the last slide shows you that.

2 We will point out that you only have to
3 identify the source or device by manufacturer and
4 model number. So if you have a device with sources in
5 it, you can identify the device by manufacturer and
6 model number, and then the sources that go with it
7 will automatically be understood.

8 So you asked if I brought a
9 noncontroversial issue, and based on this morning, I
10 know it's not a resolution that the ACMUI wanted to
11 hear, but this is where the staff came out.

12 CHAIRMAN CERQUEIRA: Okay. Jeff, your
13 hand was up first.

14 DR. WILLIAMSON: Well, I guess I don't
15 understand how this jeopardizes source accountability
16 or health and safety. I think one of the applications
17 we had in mind where there would be a serious problem
18 is prostate brachytherapy, where the number of seed
19 models available on the market are from two in 1999 to
20 now nearly 20, and essentially prostate brachytherapy
21 seeds have become commoditized, and you know, this
22 would be a serious restriction in the ability of
23 hospitals to negotiate for the best price for seeds
24 that many regard as generically equivalent.

25 So I'm wondering if some other solution

NEAL R. GROSS

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

1 that wouldn't have the implications for other devices
2 couldn't be developed whereby, for example, in the
3 source accountability process within Part 35 you
4 required recording of the model number to be done with
5 the other information, but yet would free the user or
6 licensee from having to write a license amendment
7 every time they wanted to change source vendor.

8 So this was the issue. So I'm wondering
9 if with a little more thought put into the matter, if
10 a solution couldn't be developed that would eliminate
11 this essentially nitpicking requirement that doesn't
12 serve public health at least within the context of
13 interstitial brachytherapy, but yet respond to the
14 concerns, the general, I'll admit, very vaguely stated
15 concerns about public health and safety and
16 accountability that you mentioned.

17 DR. HOWE: I think right now the
18 recommendations that are being made to the licensees
19 is that they up front list as many manufacturers and
20 model numbers as are on the market in order to
21 maintain that flexibility.

22 CHAIRMAN CERQUEIRA: Jeffrey, what's wrong
23 with them doing that? Is there a negative to that?

24 DR. WILLIAMSON: Well, yes. New sources
25 seem to be appearing and disappearing, you know, still

NEAL R. GROSS

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

1 at quite a clip.

2 CHAIRMAN CERQUEIRA: Okay. So, again,
3 it's just that new things come out all the time, and
4 it sounds like the rate of new systems is very rapid.

5 DR. NAG: I think there be confusion in
6 the part that when you see they are new in the sense
7 of a model number, but essentially they're the same.
8 They have the same or very similar number of
9 millicurie or the same material, whether iodine or
10 paladium. It looks the same. The size are the same.

11 So there is no essential difference
12 between these 15 or 20 new sources. So there should
13 be no difference in terms of basic safety, in terms of
14 public safety whether they are using Model A, B, C, D,
15 E, or F.

16 So I think you can very easily write a
17 generic statement "encapsulated radioactive iodine" or
18 "encapsulated paladium," and that's it, rather than
19 saying Model XYZ from Theregenics (phonetic) or Model
20 ABC from this company.

21 CHAIRMAN CERQUEIRA: So, Dr. Howe, that's
22 not a possibility based on your interpretation of the
23 rule; is that correct? I mean, that would be an easy
24 fix.

25 DR. HOWE: I think our guidance right now

NEAL R. GROSS

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

1 from our general counsel is that the requirement in
2 30.32 stands, and to meet that requirement a licensee
3 needs to provide the manufacturer and model number of
4 sources, or if you're lucky enough to have a device
5 that has a number of sources, then you can do that for
6 the device.

7 MR. LIETO: That doesn't happen with IDBT.
8 You have to list -- you get approved for the device.
9 Okay? They come out with a new source that goes into
10 the source registry, just a different activity source.
11 You have to amend your license, and so that doesn't
12 really occur.

13 If the issue is about accountability and
14 inventorying, okay, I'll be honest with you. Thirty
15 doesn't have anything to do with it. Okay? You have
16 to keep inventories already as a part of Part 20 and
17 Part 35 and doing inventories on your sources. In
18 fact, you do it on more sources than are listed
19 actually on your license because you're doing it for
20 your dose calibrator sources, all of these other
21 things that are not listed specifically in your
22 license by model number.

23 You're doing accountabilities, leak
24 testing to meet that requirement. So Part 30 really
25 I don't believe -- if the issue is that you need to

NEAL R. GROSS

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

1 have it registered because Part 30 says that for
2 accountability, really licensees are doing it to meet
3 the other regulations for sources that aren't even
4 covered by this.

5 And so like I said, also every time you
6 get a new source or let's say you have a device that's
7 approved and a different vendor comes out with a
8 source that's compatible with that and the source has
9 been registered in the source registry. You still
10 have to go back and amend your license for that source
11 in that device.

12 DR. HOWE: And Part 20 has your security
13 and accountability requirements. The group that
14 evaluated your request believes that Part 30 also aids
15 in, and the General Counsel has made a decision that
16 when the licensee provides this information, that it
17 goes onto the license, and then NRC can also search.
18 There are licensing databases to determine who has
19 specific sources.

20 CHAIRMAN CERQUEIRA: But, Dr. Howe, you
21 said counsel made recommendations, but the staff
22 itself that reviewed it, did you have any concerns,
23 you know, relative to the safety of the public,
24 patients, and users?

25 DR. HOWE: I am the messenger.

NEAL R. GROSS

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

1 (Laughter.)

2 DR. HOWE: And I was not part of the group
3 that made the decision. So I cannot --

4 CHAIRMAN CERQUEIRA: Is General Counsel
5 Here who reviewed it?

6 MS. CHIDAKEL: I am here from the Office
7 of General Counsel.

8 CHAIRMAN CERQUEIRA: Can you use the mic?

9 MS. CHIDAKEL: What do you want to know?

10 (Laughter.)

11 PARTICIPANT: What is the basis of the
12 decision?

13 MS. CHIDAKEL: I'll tell you the truth.
14 I will have to take your concerns and questions back.

15 I'm sorry. Hi. I'm aware of this opinion
16 by the Rulemaking Division of the Office of General
17 Counsel. However, I am just really here more to
18 listen to Donna-Beth today rather than to address the
19 issues. I really came here because of my working
20 group affiliation with Part 35 on that rulemaking on
21 the T&E.

22 If you have specific questions or
23 concerns, I think the best thing to do would be to
24 just let me know them and let me take them back to the
25 office and consider them rather than giving you

NEAL R. GROSS

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

1 answers off the top of my head.

2 MS. WILLIAMSON: State your name, please,
3 for the record.

4 MS. CHIDAKEL: I beg your pardon?

5 MS. WILLIAMSON: State your name for the
6 record.

7 MS. CHIDAKEL: Oh, Susan Chidakel, C-h-i-
8 d-a-k-e-l.

9 CHAIRMAN CERQUEIRA: Great. Well, thank
10 you, Susan.

11 MS. CHIDAKEL: And I'll be happy, you
12 know, to consider your questions, but I just don't
13 feel prepared right now just to give you answers on
14 this.

15 CHAIRMAN CERQUEIRA: Jeff?

16 DR. WILLIAMSON: Could you identify the
17 safety and health hazards that you think this change
18 would -- well, two questions. What are the health and
19 safety hazards you think would result from this
20 change?

21 And, two, if the issue is that this is a
22 very general restriction where you think it has value,
23 for example, making people list the model of Cobalt 60
24 teletherapy sources in their license, you don't want
25 to get rid of that.

NEAL R. GROSS

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

1 Is it not the case that in Part 35, which
2 is more specific, you can have rules that contradict
3 for a very limited class of sources the Part 30 and
4 Part 20, and then those rules would, in fact, prevail
5 but only over that limited domain?

6 DR. HOWE: The concept that you could have
7 more restrictive language in Part 35 that would be
8 more appropriate for 35, that's true, and your
9 recommendation was taken to the Rulemaking and
10 Guidance Branch, also the branch that I'm in, and the
11 division, and they looked at your issue in the scope
12 of what the Commission is doing right now in all areas
13 and decided that this was not the time to go forward
14 with this rulemaking initiative.

15 As the messenger, I cannot give you the
16 discussion and rationale that went through as they
17 came to this discussion. I can only reiterate the --

18 DR. WILLIAMSON: Couldn't a more surgical
19 and restrictive exemption to 30.32 be made within the
20 language of Part 35 that wouldn't extend to all of
21 these other sources, sealed sources, that may be of
22 concern to that group?

23 Because it's hard for us to believe that
24 iodine and Iridium 192 interstitial sources are the
25 cause of their concern.

NEAL R. GROSS

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

1 DR. HOWE: I wasn't there, but my
2 understanding is there was a concern that at the time
3 when the Commission is going forward to identify
4 sources and may be moving in a direction from
5 generally licensed to considering whether some of the
6 generally licensed devices need to be regulated more
7 tightly and may even go into specifically licensed,
8 into specific licenses, that the staff didn't feel
9 comfortable moving in the opposite direction to these.

10 DR. WILLIAMSON: But we are not under a
11 general license. This has nothing to do with that
12 issue.

13 CHAIRMAN CERQUEIRA: Donna-Beth, as a
14 health physicist --

15 DR. HOWE: Yes.

16 CHAIRMAN CERQUEIRA: -- I mean, the
17 question was asked in terms of risks to patients,
18 physicians, you know, users, and the public. Do you
19 see any risk how not listing an individual, you know,
20 manufacturer, serial number, and everything on the
21 license would somehow impose a greater risk to those
22 groups as a physicist?

23 DR. HOWE: Let me pass that to Ron Zelac.

24 DR. ZELAC: This is Ron Zelac, for the
25 transcriber.

NEAL R. GROSS

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

1 I was not involved in the decision on
2 this.

3 (Laughter.)

4 DR. ZELAC: Nor was I involved in the
5 follow-up to it. However, I have heard peripherally
6 that one of the reasons that was stated for not moving
7 in the direction of having, if you will, a general
8 entry on the license was that if the licensee was
9 contemplating the use of a particular manufacturer's
10 sealed sources and had to supply to the agency the
11 model of that source and the manufacturer, this gave
12 the licensing agency, us in this case, the opportunity
13 to be sure that that particular source was, in fact,
14 registered through the sealed source and device
15 registry and had been deemed satisfactory for the
16 intended medical use.

17 If it was a general authorization that the
18 licensee had, a particular licensee could be
19 approached by some organization claiming that, in
20 fact, the source was registered, and if the licensee
21 didn't demand proof of that, they could be, in fact,
22 moving in the direction of starting use of a source
23 which had not been deemed yet as satisfactory for such
24 applications.

25 CHAIRMAN CERQUEIRA: Well, I guess I'm a

NEAL R. GROSS

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

1 little confused in the sense that, you know, if it's
2 a political or if it's sort of an NRC administrative
3 issue that, you know, for safety concerns and
4 everything they're not going to do it relative to
5 national security, that's one thing. And I guess
6 you've pretty much heard the opinion of the committee
7 that it really doesn't compromise safety in any way.

8 You know, Jeff, this may be an appropriate
9 time to basically make a motion to the committee that
10 it be reconsidered, that it's the feeling of the
11 committee that there is no additional risk to
12 patients, users, or public.

13 DR. NAG: Well, I think what may help,
14 just like there used to be misunderstanding or lack of
15 communication between staff and ACMUI, maybe a member
16 of ACMUI would talk with the General Counsel who may
17 or may not have the full knowledge about the
18 differences between different models and different
19 types of sources. That might clear up that issue in
20 some way so that, you know, we have more communication
21 not only with the staff, but more communication with
22 the General Counsel.

23 CHAIRMAN CERQUEIRA: Yeah, I think that
24 would be appropriate because, I mean, you know,
25 obviously as you said, you're the messenger. Counsel

NEAL R. GROSS

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

1 wasn't involved, and so the committee has made a
2 recommendation, you know, feeling that this was the
3 best thing to do, and now we're told we can't do it,
4 but are not able to really discuss with anyone who was
5 involved in the decision process.

6 DR. WILLIAMSON: Yeah, with no good
7 reasons being provided other than rumors.

8 CHAIRMAN CERQUEIRA: And that's
9 frustrating. So I guess, Jeff, did you say you had a
10 motion?

11 DR. WILLIAMSON: Yeah, I guess. Whereas,
12 the ACMUI sees no patient, no conceivable patient or
13 public health hazard from listing interstitial
14 brachytherapy sources generically on license
15 applications, the ACMUI asks that NRC reconsider and
16 develop a strategy for eliminating this burdensome
17 licensing requirement for this narrow class of
18 sources.

19 CHAIRMAN CERQUEIRA: Excellent. Do we
20 have a second on that?

21 Okay. Further discussion?

22 DR. BRINKER: Can I ask one question of
23 Mr. Zelac?

24 CHAIRMAN CERQUEIRA: Yes.

25 DR. BRINKER: Because his point did ring

NEAL R. GROSS

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

1 a little bit in my mind.

2 Do people who make these sources not have
3 to have some sort of regulatory certification to sell
4 them for medical use?

5 DR. NAG: FDA.

6 DR. BRINKER: So if they have that,
7 doesn't that preclude that some unauthorized product
8 might be introduced surreptitiously, or whatever that
9 word is?

10 DR. HOWE: I can clarify a little bit of
11 that, and then I can pass it back to Ron, and that is
12 that we have a good example with the Novoste,
13 intervascular cardiology. Novoste went to FDA for
14 approval, but they had an IDE exemption in order to
15 use the Novoste product before they got FDA approval.

16 So they were able to use the sources.
17 They elected not to get into the sealed source and
18 device registry until they had finalized the product.
19 So in that case we had research basically going on in
20 the broad scope licenses because the broad scope
21 licenses have a little bit more leeway on the sources
22 that they hold in which the source wasn't part of the
23 registration process until later in the game.

24 Most of the other sources and
25 manufacturers we had have come in for the sealed

NEAL R. GROSS

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

1 source and device registration early on, and they've
2 been in the registration as soon as they've gone out
3 for use.

4 CHAIRMAN CERQUEIRA: But this is an
5 exemption, right? I mean --

6 DR. HOWE: That's just an example.

7 DR. DIAMOND: That's not a fair
8 comparison, however, because you know, as we made our
9 recommendation and as Jeff recapitulated it, this is
10 a specific example dealing with permanent interstitial
11 seeds with isotopes and designs that have been in
12 existence for many years.

13 Your example cites a different modality.

14 DR. HOWE: But I'm citing an example in
15 which there are cases in which there are sources out
16 there being used in medical that may not have gone
17 totally through the FDA process, nor gone through our
18 sealed source and device registry process.

19 DR. WILLIAMSON: But you see, you don't
20 need to do this because already it says in Part 35
21 that the sources that are allowed for specific scope
22 licensees in 35.400 already are in the SSDR. I think
23 it's very clear in part 35.

24 So now you're saying, well, you don't
25 believe that users are capable of following the rules

NEAL R. GROSS

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

1 and that they're going to go off and use non-SSDR
2 approved sources if you don't check specifically which
3 ones you order.

4 Now, what is is the basis of performance
5 based regulation and this nitpicking and
6 prescriptiveness? You know, the basic philosophy of
7 Part 35 and the revised licensing applications is to
8 minimize this and put responsibility on the users and,
9 you know, audit their performance and see if they're
10 doing it right and punish them if they're not.

11 CHAIRMAN CERQUEIRA: Exactly. That was
12 the whole basis for the --

13 DR. WILLIAMSON: So what you should do is
14 keep the requirement in Part 35 that the maybe model
15 number be logged as part of the inventory, and then
16 you have the legal basis for checking their
17 performance on this.

18 So, you know, why do you have to have
19 duplicative requirements for the same thing? It's
20 already spelled out in Part 35?

21 CHAIRMAN CERQUEIRA: One last comment and
22 we should really vote and move on.

23 MR. LIETO: There were just two points I
24 wanted to make, if you can take back, and one is that
25 the motivation for this is to reduce the burden on

NEAL R. GROSS

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

1 licensees in regions to going through a paper shuffle
2 process because that's all this is, and what happens
3 is that you will be delayed. It can take up to three
4 months, you know, to get approvals. Okay?

5 So during that time period you can't use
6 that source even though it's in a registry and the
7 fellow across the street is using it in the same type
8 of a hospital distinctly because the paper work isn't
9 there. Okay?

10 The other thing is that when you're
11 inspected during inspection, they don't look at your
12 model numbers. I've never had an inspection where
13 they ask you, "What model number is that source?"

14 What they're concerned about is what your
15 inventory is and what that inventory -- does it
16 coincide with what your possession limits are and is
17 it, you know, in accordance with those isotopes?

18 I've never had an inspector come through
19 and look at, you know, what's the model number on
20 this. Okay. Show me that the model number in this
21 device is the one that you're approved for.

22 Because, you know, there's no way to prove
23 you wrong. You think you could go in the HDR machine
24 and look at the model? No.

25 (Laughter.)

NEAL R. GROSS

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

1 DR. WILLIAMSON: Okay? You just have to
2 take that the manufacturer sent you the right thing.
3 Now, could he send you the wrong thing? Very likely.
4 Okay. I mean, I shouldn't say very likely. Very
5 possibly.

6 But who's going to know?

7 DR. NAG: That is an example where I think
8 NRC is making a laughingstock of itself, and we would
9 like to give you advice that is very relevant, that is
10 simple, and yet not impeding on any recent safety or
11 any health hazard, and you know, because of your
12 prescriptiveness you are using and hear our
13 suggestion.

14 And this is the type of interaction where
15 I think the ACMUI feels very frustrated. You have
16 given an example, one example.

17 CHAIRMAN CERQUEIRA: Right. I think we've
18 shot the messenger enough now. So let's -- we have a
19 motion. We've had discussion. I call for a vote.

20 All those in favor of Jeff's motion to go
21 to the NRC.

22 (Show of hands.)

23 CHAIRMAN CERQUEIRA: Opposed?

24 (No response.)

25 CHAIRMAN CERQUEIRA: Dr. Howe, thank you

NEAL R. GROSS

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

1 very much.

2 MR. ESSIG: Is it clear what you're going
3 to come to the NRC and ask us to do?

4 CHAIRMAN CERQUEIRA: To reconsider --
5 Jeff, do you want to?

6 Well, you should be able to pull the --

7 MR. ESSIG: To undertake a rulemaking to
8 change this?

9 DR. WILLIAMSON: Yeah, to develop an
10 alternative rulemaking that addresses this narrow
11 class of sources and, you know, does not compromise
12 safety with the other sources that evidently this
13 group, who's unwilling to share their rationale with
14 us, is concerned about.

15 MR. LIETO: Well, he didn't say
16 rulemaking. He said alternative pathway.

17 CHAIRMAN CERQUEIRA: Pathway.

18 MR. LIETO: Rulemaking could be one, but
19 it also could be just a change in how headquarters
20 tells the regions to handle licensing.

21 CHAIRMAN CERQUEIRA: Interpretation or
22 guidance.

23 DR. HOWE: Well, I think in this
24 particular case you need rulemaking because --

25 DR. WILLIAMSON: But I said alternative

NEAL R. GROSS

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

1 approach.

2 DR. HOWE: -- because a number of years
3 ago, and Susan is right, a number of years ago OGC
4 interpreted Part 30 to mean that licensees needed to
5 provide this information in order to get a license,
6 and it needed to be updated on amendment process.

7 And so the only way to not provide this
8 information is to go to rulemaking, and that's a
9 pretty serious step for the NRC. You might be better
10 if you can articulate why. This is the rationale the
11 staff gave, if you look at your --

12 DR. WILLIAMSON: But it's too vague to
13 make any sense. I mean, the specifics --

14 CHAIRMAN CERQUEIRA: And there's no
15 discussion.

16 DR. WILLIAMSON: The only specific that's
17 been brought up is your fear that somehow users are
18 going to use non-SSDR approved sources who are
19 specific licensees.

20 MS. CHIDAKEL: I'm sorry. I want to
21 apologize. I want to make it clear that I have not
22 been involved in this effort from OGC. So you know,
23 it's certainly not any reluctance on my part to share
24 our rationale as far as the Office of Legal Counsel,
25 you know Office of General Counsel goes.

NEAL R. GROSS

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

1 Again, you know, I have not been involved
2 in this. So I need to go back to my office, and if
3 you want answers I'm sure that I can help you get
4 answers as to what the rationale was. It's not an
5 unwillingness to share a rationale. It's, frankly, on
6 my part, like I said, a lack of knowledge because I
7 have not been involved in --

8 DR. WILLIAMSON: Well, I didn't mean to
9 suggest you personally were --

10 MS. CHIDAKEL: No, I know that.

11 DR. WILLIAMSON: -- but whoever is
12 responsible has failed to share the rationale with us.

13 MS. CHIDAKEL: You know, I want to speak
14 on behalf of the staff, too. I don't think there's
15 any unwillingness to share any information.

16 CHAIRMAN CERQUEIRA: But I think we need
17 to move on. I think that the motion was basically to
18 consider alternative ways. If rulemaking is the only
19 way to do it, then I would expect during the next
20 conference call we have with the staff, they would
21 tell us that it has been brought to the Commissioners'
22 staffs and it has been discussed and, you know,
23 rulemaking is the only way to make a change.

24 And then we can basically give you some
25 feedback. Thank you very much, Dr. Howe.

NEAL R. GROSS

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

1 The next item is National Materials
2 Program Pilot Project on operating experience
3 evaluation, and Michael Markley.

4 Again, both for the presenters and the
5 people asking questions, we kind of need to keep
6 focused and moving. So I don't want to cut off
7 discussion or presentations, but if we're making the
8 same point over and over again, I will try to cut you
9 off more than I have.

10 MR. MARKLEY: One thing I'd like to do, I
11 do have some members of the pilot project here. So I
12 would like to also have the ones who are remotely
13 located on the bridge so they can have the benefit of
14 your wisdom.

15 CHAIRMAN CERQUEIRA: Sure.

16 MR. MARKLEY: If that's okay.

17 (Pause in proceedings.)

18 MR. MARKLEY: Marsha, are you there?
19 Debbie?

20 MS. GILLEY: This is Debbie.

21 MR. MARKLEY: Hi, Debbie. We're here now
22 and we're getting ready to start.

23 MS. GILLEY: Great.

24 MR. MARKLEY: We'll get it extended a
25 little bit of time also.

NEAL R. GROSS

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

1 I apologize for the delay.

2 CHAIRMAN CERQUEIRA: No problem.

3 MR. MARKLEY: Just to mention real
4 quickly, the members of the pilot team are Cynthia
5 Taylor from Region II, and she's in the audience here
6 in the back; Marshal Howard with the State of Ohio;
7 and Debbie Gilley with the State of Florida. And I
8 know that we have Debbie on line. I've been unable to
9 reach Marshal today. So I'm not sure whether she's
10 here or not.

11 CHAIRMAN CERQUEIRA: Okay, great.

12 MR. MARKLEY: Okay. Now, the reason I'm
13 here today -- let me see if I can get rid of that.

14 CHAIRMAN CERQUEIRA: Just click somewhere
15 on the screen.

16 MR. MARKLEY: Okay.

17 CHAIRMAN CERQUEIRA: It should -- click
18 the other side. Yeah, there you go.

19 MR. MARKLEY: Okay. Thank you very much.

20 The reason I'm here today is really to
21 seek your wisdom. I'm coming early in the process.
22 We've developed the charter.

23 CHAIRMAN CERQUEIRA: Right move.

24 (Laughter.)

25 MR. MARKLEY: Well, I've had a little bit

NEAL R. GROSS

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

1 of experience with advisory committees. So I know the
2 benefits that we can derive from it or hope to, and so
3 today I want to get your thoughts early as we develop
4 the work product plan.

5 We hope to come back again in the fall and
6 tell you where we are in the process, and as we
7 approach completion next year, tell you some of the
8 things we found and some of the recommendations and
9 solicit your agreement, disagreement, and support.

10 CHAIRMAN CERQUEIRA: Just click on the
11 other button. I think it will advance it.

12 MR. MARKLEY: Okay. It doesn't like it,
13 Mr. Brown. There we go.

14 Okay. The purpose of the pilot is it
15 originally started out as an event evaluation, and
16 because of things that have changed, operating
17 experiences that have occurred, we've expanded it to
18 cover really a broader issue other than just event
19 evaluation and how you would evaluate individual
20 events.

21 So what we're hoping to do is to, you
22 know, use common operating experience information from
23 licensees in trending and in an integrated way. It's
24 not an evaluation of agreement state performance, but
25 we're trying to use information and data to make

NEAL R. GROSS

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

1 better decisions in terms of how we allocate resources
2 and what we use for our decisions in the regulatory
3 process.

4 We want to develop a structured process
5 for evaluating that data such that whether the
6 agreement states or the NRC were using it, if you had
7 the same inputs, the process being similar, you should
8 come up with reasonably similar outcomes.

9 So in the process, we're going to take a
10 test case area, use some criteria that we will have
11 developed collectively between the team members and
12 evaluate it and see how we can examine the process and
13 reengineer the methods and tools of evaluation, and
14 then from that we would hope to derive other
15 applications and to use more broadly in the oversight
16 process.

17 We want to focus on cumulative data. Our
18 processes may differ right now in some ways, you know,
19 from state to state and from the NRC in how we treat
20 some of these, but the attributes and the objectives
21 of what we're trying to accomplish are pretty much the
22 same.

23 DR. WILLIAMSON: Can I ask you to define
24 cumulative data and performance so that we understand
25 what you're talking about?

NEAL R. GROSS

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

1 MR. MARKLEY: Well, that's what this slide
2 is about. So what do we mean by operating experience?

3 Domestic and foreign event reports,
4 inspections; special studies that may have been done
5 whether by the NRC or by industry; generic reviews,
6 whether it's an individual event generic review or a
7 review of a population of events. Industry-wide
8 analyses, there are lots of different organizations
9 out there looking at their little cut set of the
10 industry, and it's not just medical. It's the
11 industrial applications and the whole breadth of the
12 materials area.

13 And we want to use risk insights and
14 metrics. There has been some studies done, but we
15 really I don't think have been very successful so far
16 in integrating risk insights in how we make decisions.
17 Let's just say we have an event. How are we using
18 risk metrics?

19 We developed NUREG 6642, but in terms of
20 how we get that into the process of making decisions,
21 whether for inspection follow-up, enforcement and
22 things like that, those are the kind of things that we
23 want to look at and see how we can better use risk
24 information.

25 And to look at possibly developing

NEAL R. GROSS

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

1 performance indicators or thresholds for regulatory
2 action. There's, you know, certainly no benefit in
3 spending a lot of time looking at lower tier criteria
4 even if it is something that may not be a full
5 compliance. If we need to change a regulation, then
6 we need to change a regulation.

7 If there's a reason why there are things
8 happening out there that cause there to be a lot of
9 amendments or emergency actions on a licensing basis,
10 those are the kind of things that we would like to be
11 able to pick up along the way.

12 And so the process that we're really
13 driving toward is how do we modify our oversight
14 programs, inspection, licensing, and enforcement.

15 CHAIRMAN CERQUEIRA: Yes, Tom.

16 MR. MARKLEY: Okay. That's where we are.

17 So the scope of activities within the
18 context of the pilot is evaluating events for generic
19 implication, possible regulatory action.

20 Consider the processes that we've looked
21 at in terms of the materials, the issues, and then
22 adverse licensee performance.

23 As you probably know, one of the things
24 that has been developed and approved since the
25 original materials program was the AARM process, the

NEAL R. GROSS

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

1 agency action review meeting.

2 So we want to make sure that what we're
3 doing dovetails and comports with those types of
4 pieces of information we're interested in as well, and
5 so, you know, with our special events and you were
6 talking about what do you mean by operating experience
7 or data; special studies provide us with a lot of
8 insights across a variety of levels, like the St.
9 Joseph's event or Schlumberger or for the reactors,
10 Davis-Besse.

11 And so there are crosscutting issues that
12 affect all of our programs that we want to learn from
13 and fold into the process.

14 DR. WILLIAMSON: Just a comment. I mean,
15 you mentioned maybe some nuclear reactor events that
16 perhaps most of us aren't familiar with.

17 MR. MARKLEY: Right.

18 DR. WILLIAMSON: I personally have very
19 little grasp of how what you're talking about relates
20 to our field.

21 MR. MARKLEY: Well, some of the problems
22 with Davis-Besse, and I'll use that as an example,
23 there were operating experiences. They had
24 indications from other licensees where they had
25 defects that were not taken into consideration fully.

NEAL R. GROSS

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

1 The NRC didn't act fully, whether it was training
2 issues or inspection issues or materials issues, root
3 cause analysis.

4 There are things that cross-cut these
5 types of programs that are really generic to all of
6 the regulatory processes, not just reactors. And so
7 if there are things that are out there -- and there is
8 an entire population of work going on on the reactor's
9 area in response to Davis-Besse.

10 And along those lines, NMSS has created an
11 operating experience committee to look at how that
12 affects each of the NMSS divisions. And I'm chairing
13 that committee as well as this pilot. So we do have
14 some continuity in that process. I did the initial
15 Davis-Besse evaluation as well.

16 So it's not trying to drag reactor issues
17 here, but there are common threads. Management
18 expectations of what we would have our inspectors
19 looking at that were not fully implemented.

20 So the proposed framework, hopefully what
21 we derive out of all of this is some recommendations
22 on improving the procedures, how we review things,
23 evaluation methods, the sources of information that we
24 would consider, the methods to better communicate.

25 One of the main things that I think is the

NEAL R. GROSS

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

1 near term payback, the agreement states, as well as
2 the NRC do a lot of things, but we don't necessarily
3 do a great job at communicating the results of those
4 studies or evaluations with each other.

5 So in my thinking one of the near term
6 paybacks is better communicating, and part of that is
7 with you and key stakeholders, such as yourselves, but
8 with agreement states.

9 If we have a piece of information or a
10 study that we've done, it should be fully available,
11 and the state should be fully aware of all of those
12 things that we're doing. And, likewise, if they have
13 issues that we should maybe disseminate more fully
14 among the non-agreement states, those are the kind of
15 things we want to do.

16 We want to make the process work. I mean,
17 that is really in my view -- and, of course, I can't
18 predict how things will go, but that's the easy win-
19 win, is improving the communications.

20 The data analysis and the metrics that we
21 might use are the harder things that will take more
22 time and will be debated certainly a lot more fully.

23 So at the end point I don't see either the
24 agreement states or us having a windfall in resources,
25 and if we don't find ways to do things smarter and

NEAL R. GROSS

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

1 better and reduce burden on ourselves and
2 theoretically down the road for licensees, as well,
3 then we will have failed. We have to find ways to
4 work smarter and use our resources better.

5 Okay. Where we are today. The pilot
6 charter has been approved. We have the participants.
7 We may add more over time. It depends on how things
8 go. But we have a good core to get started, and we're
9 doing the best we can, you know, in partnering with
10 the states, trying to keep them involved.

11 Really we can't do this without the
12 states. It's absolutely essential. One of the key
13 points that was originally laid out in the materials
14 program were things that they could pick up and adopt.
15 It seems to me that it's really more of the things
16 that we can all do together better.

17 I met with CRCPD in the earlier part of
18 this month, gave them a similar presentation to what
19 I'm talking to you about here today: about feedback,
20 about the extra member, Debbie from Florida, and so it
21 was beneficial for me in many ways to get the feedback
22 in the sense of the things that are important to them.
23 It was absolutely essential with this kind of a pilot.

24 I see down the road as we get some results
25 and see, you know, the fruit of our labors, if you

NEAL R. GROSS

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

1 want to call it, we will need to have public meetings
2 and get other stakeholder input, but right now we're
3 still at that early developmental stage.

4 Okay. As I mentioned before, there's an
5 operating experience group. Between NRR and Research,
6 they have a steering committee, a task force, a
7 working group. They have about 20 people working on
8 this.

9 At this point in time it's really just
10 myself and our friends in Region II and in the two
11 states that we have. So we can't spend the resources
12 that they're throwing at it, but what we are doing is
13 because of this working group, we're going to tie in
14 the state representatives on the meetings that we have
15 every two weeks. We're going to have, you know, the
16 reviews of the things that NRR and Research are doing
17 so that the pilot will be fully up to date with
18 everything that's going on there, and we want this
19 thing to be a national materials program, not just an
20 NRC materials program or an agreement state program.

21 But we do need to be consistent and to
22 make things comport with what the agency is doing on
23 a broader basis, and so this particular committee is
24 not -- we don't have a charter. We do have a mission
25 statement, but the intent of it is to be decision

NEAL R. GROSS

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

1 driven, not to develop a lot of paper other than the
2 things we need to support the decisions and
3 recommendations that would affect the NMSS and
4 materials type programs.

5 We will still maintain the continuity.
6 We'll still have single points of contact, which at
7 this point in time is me, but you know, that's the
8 intent.

9 We don't need to create a lot of paper
10 with boundary conditions. We can pull more things in
11 as we realize things along the way and make changes.

12 The research is evaluating options for how
13 they can support a more robust materials program,
14 which is good. Right now they're focusing a little
15 bit more on the generic safety issue aspects, but for
16 the most part they're looking for opportunities. So
17 we're going to see how it will fit. Right now I can't
18 predict what that will be.

19 And one of the things that we passed out
20 at the CRCPD meeting -- and these are the same kind of
21 questions we would hope to get feedback from you on --
22 are how can we use this information; how can we better
23 community it between us and the agreement states; how
24 can the information and tending optimize our programs
25 and better help us utilize our resources?

NEAL R. GROSS

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

1 We don't have a lot of resources to apply
2 to these kind of things, and so we really do need to
3 work smarter.

4 And how can we use risk insights? And
5 from my view that's really one of the major tools and
6 opportunities we have to reduce burden, look at the
7 risks, and see how those lead us to making sounder
8 decisions, things that are more risk significant and
9 should have more attention.

10 If something is not very risk significant,
11 we shouldn't be spending a lot of time on it. There's
12 no advantage to the NRC or the licensees wasting
13 resources on things that are not risk significant.

14 CHAIRMAN CERQUEIRA: Excellent. Well,
15 thank you very much.

16 Have we got some questions? Dick.

17 DR. VETTER: Thanks for coming to us real
18 early in the process. That's very nice to see what
19 you're thinking.

20 MR. MARKLEY: Thank you.

21 DR. VETTER: I think this process supports
22 a learning organization, and I would view the entire
23 regulatory community working together as an
24 organization in this endeavor.

25 It also has the opportunity or provides

NEAL R. GROSS

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

1 the opportunity to promote consistency among
2 regulators, agreement statements, NRC, et cetera, and
3 I hope there's a possibility of extending that to non-
4 agreement states.

5 MR. MARKLEY: Certainly.

6 DR. VETTER: I think it also supports a
7 performance based system. You could use it to help
8 make the checklist longer, but I think with the NRC's
9 philosophy in recent years becoming more performance
10 oriented, I think this actually does that.

11 One thought for you to consider is whether
12 or not the data that you're collecting to help the
13 regulators couldn't also be useful for the regulatees.

14 MR. MARKLEY: Absolutely.

15 DR. VETTER: And there might be some
16 mechanism to share that. So if you see a trend in
17 something occurring around the country --

18 MR. MARKLEY: Right.

19 DR. VETTER: -- in addition to sending out
20 -- I mean, you'll do that now occasionally on I forgot
21 what you call it; a letter that goes to regulators
22 saying -- regulatees, licensees.

23 MR. MARKLEY: Information notice?

24 DR. VETTER: Information notice.

25 MR. MARKLEY: Right.

NEAL R. GROSS

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

1 DR. VETTER: It might be something that's
2 more regular.

3 CHAIRMAN CERQUEIRA: Ruth.

4 MS. McBURNEY: I don't know if it was
5 brought up at the CRCPD meeting, but I know that some
6 states -- well, one of the universities in Texas has
7 taken a lot of our inspection data and done some
8 trending analyses on how many violations of different
9 types and the severity levels, and so forth in the
10 different types of licensees, has taken data from some
11 other states, too, along those lines.

12 And I think that would probably be
13 beneficial if you could have them analyze, you know,
14 NRC's data along those lines and --

15 MR. MARKLEY: Right. We would love to see
16 what they're doing.

17 MS. McBURNEY: Yeah.

18 CHAIRMAN CERQUEIRA: I think one other
19 area, you know, trying to get cooperation between NRC
20 and the agreement states is with the Part 35 revision.
21 The training and experience guidelines, I think,
22 potentially can create a lot of paper work for the
23 users, as well as for the NRC in the agreement states,
24 and a compliance was supposed to be, you know,
25 complete agreement between the two.

NEAL R. GROSS

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

1 But we've been hearing rumblings that some
2 of the agreement states are a little unhappy with
3 this, and I think trying to look at the process, the
4 simplification, that would be very, very useful.

5 For the sake of time, unless anybody has
6 any burning questions, I think maybe people could talk
7 to Michael afterwards, but thank you very much for --

8 MR. MARKLEY: Thank you.

9 CHAIRMAN CERQUEIRA: -- including us in
10 the process, and we'd really like to take part in
11 whatever way possible that we can.

12 Thank you.

13 The next presentation is the "Content and
14 Status of the Direct Final Rule to Clarify
15 Definitions, Notification Requirements, and Record
16 Keeping Requirements and to Eliminate a Certain
17 Restrictions." Dr. Tse, welcome.

18 DR. TSE: Thank you, Mr. Chairman and
19 members of ACMUI and ladies and gentlemen.

20 Mine will be relatively simple compared to
21 the others you heard prior to me. So I'll be going
22 relatively quick, and if anybody have any comments,
23 please just stop me.

24 I'm going to discuss very briefly about
25 Part 35 direct final rule, which is a clarifying and

NEAL R. GROSS

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

1 one minor amendment.

2 Why do we -- first of all, the status.
3 Next slide, please. The status. The rule was
4 published in April 2003, and one month public comment
5 period, which the direct final, as you know, is we
6 publish a proposal and a final rule.

7 So the proposed rule public comments would
8 be -- ends tomorrow. As of today, I have not received
9 any comments. I checked with the Web site on the
10 rulemaking Web site. I did not see any comments
11 either. So I think probably by tomorrow we will not
12 receive any adverse, significant -- significant,
13 adverse comments.

14 Therefore, if that's true, the rule would
15 be effective on July 7th, 2003.

16 Next please.

17 Why do we need a direct final rule?
18 Because after the publication of Part 35 rule, the
19 staff has identified certain areas might need
20 clarification or change, and there are some necessary,
21 apparently necessary inconsistencies and also
22 unnecessarily restrictions.

23 Next.

24 What are the changes? The first one is
25 the apparent inconsistencies. I say "apparent"

NEAL R. GROSS

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

1 because if you read the rule as a whole, it's not
2 inconsistent because Subpart J was put in, and to
3 include the Subpart J, you need to look at
4 implementation section to understand that.

5 But if somebody just looked at the rule by
6 itself, then they may say in, for example, 290, 390,
7 only the new items, new T&E are listed without listing
8 920, 930, et cetera.

9 So to avoid these apparently
10 inconsistencies, it's better to insert these sections
11 into various training, T&E, and also 100, 200, 300
12 because that's the preparation of unsealed sources.

13 So we add those Sections 920, 900, et
14 cetera, into the appropriate regulations and then said
15 prior to October 24, 2004, these sections also
16 applicable.

17 Next one.

18 In some sections, an emergency situation.
19 The one requirement you say that the licensee should
20 notify the RSO, and also the AU. The AU may not be
21 there if a patient may be in an emergency situation or
22 dies. So we change that to an AU. Therefore, any AU
23 would do.

24 Next, please.

25 This is truly for clarification. In this

NEAL R. GROSS

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

1 section, Section A says that licensee may perform the
2 calibration by himself, and then Section B says the
3 licensee may use somebody else's number like a
4 manufacturer and so on, but doesn't have a connection
5 between A and B.

6 So somebody raised the question. So to
7 make sure, we just add those phrases in there to make
8 the connection.

9 Next.

10 This one is to eliminate unnecessary
11 burden or restriction. In the regulation, current
12 regulation, the training of ophthalmic use of
13 Strontium 90 can be only done at the medical
14 institution, and staff believes there is no reason why
15 the training cannot be done by an authorized user in
16 a medical private clinic or eye ophthalmic office, and
17 that's what this change is.

18 The next one is a correction.

19 Anyone have questions? Oh, sorry. Next.

20 The next one is the correction which for
21 some reason the National Institute of Standards and
22 Technology become National Institute of Science and
23 Technology, which in the United States we do not have
24 such an institution.

25 (Laughter.)

NEAL R. GROSS

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

1 DR. TSE: And I checked with this. Korea
2 has one.

3 (Laughter.)

4 DR. TSE: But I checked the other place.
5 Everything is right, except in this section is
6 incorrect. So we just make a correction.

7 The last one, next, please; the last one
8 is also for consistency. In the section requiring
9 calibration, it says that calibration can be done by
10 the licensee or by manufacturer or by calibration
11 laboratories.

12 But in the corresponding record keeping
13 section, it doesn't say that. It just says requires
14 signature of AMP, and we believe should be consistent
15 if the action section requires the last individual or
16 also accepting the manufacturer or other calibration
17 laboratory's calibration.

18 Then the record keeping shall say those
19 people, and that's what to make it consistent.

20 Okay. I think I finished. Any questions,
21 please?

22 CHAIRMAN CERQUEIRA: Rick.

23 DR. VETTER: That was so good. Could you
24 add a little sentence somewhere that says any source
25 could be used for interstitial purposes?

NEAL R. GROSS

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

1 (Laughter.)

2 DR. TSE: I think some other staff member
3 will take care of that.

4 DR. DIAMOND: I myself developed a
5 designate competency will make you the arbiter of
6 competency for all AUs.

7 DR. TSE: I'm not sure I qualify for that.

8 CHAIRMAN CERQUEIRA: Well, thank you very
9 much.

10 DR. TSE: Oh, by the way, I take this
11 opportunity to also thank the members of the
12 subcommittee and committee when I was working on this
13 paper. I really appreciate your help.

14 Thank you.

15 CHAIRMAN CERQUEIRA: Excellent. Thank you
16 very much.

17 The next presentation is "HHS Database of
18 Regulatory Actions: Status and Discussion." Linda
19 Psyk.

20 MS. PSYK: Okay. Are we on? It's hard
21 for me to hear up here. Can you hear me back there?

22 Thank you. I like the nods of the head.
23 Thanks.

24 Okay. Good afternoon. Are we all still
25 awake?

NEAL R. GROSS

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

1 Okay. My name is Linda Psyk. I'm from
2 the Division of Industrial and Medical Nuclear Safety.

3 We're going to switch topics a little bit.
4 I'm going to briefly cover the health care integrity
5 and protection database.

6 What I'm going to discuss shortly today is
7 the purpose of the health care integrity and
8 protection database. From here on in I'm going to
9 refer to it as "database" so that we all know what I'm
10 talking about.

11 I'm going to describe a little bit about
12 what the NRC will report and how we will report this
13 information.

14 I'm going to give the status of our
15 management directive. The management directive is
16 actually our procedure that NRC will use in order to
17 identify what needs to be reported and how we will
18 report it.

19 I'm also going to provide some examples of
20 some past actions that we will be reporting to the
21 database.

22 And finally, I'm going to discuss the
23 responsibility of the agreement states in reporting.

24 I didn't realize it was set up to do this
25 individually. Excuse me.

NEAL R. GROSS

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

1 Okay. What is the HIPDB or database? The
2 Health Insurance Portability and Accountability Act of
3 1996, this is referred to as HIPAA. I'm sure we all
4 know what HIPAA is at this point.

5 Basically HIPAA was promulgated due to the
6 burden of health care fraud in the United States.
7 HIPAA required the Department of Health and Human
8 Services to create a national fraud and abuse control
9 program.

10 In response to this, the HIPDB, or
11 database, was established to compile certain final
12 adverse actions, which were taken against health care
13 practitioners, providers, and suppliers.

14 It's important to know that the contents
15 of the database are going to be confidential. Access
16 will not be allowed to the general public.

17 Entities reported to the database will be
18 notified. So if an individual or an entity is
19 reported, they will be notified by the HHS that they
20 were reported to the database, and they will be able
21 to access that information.

22 Information will also be available to the
23 state and federal agencies, health plans, health care
24 practitioners, providers, and suppliers, as I said,
25 requesting information concerning themselves.

NEAL R. GROSS

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

1 The database requirement is codified in 45
2 CFR Part 61. It requires reporting from state and
3 federal government agencies who license or certify
4 health care practitioners, providers, or suppliers.

5 Also, it requires that health plans, such
6 as insurance or programs that provide health benefits,
7 that these organizations also report to the database.

8 What is the NRC going to report?
9 Basically there are three criteria that determine
10 whether or not that action will be reported.

11 The first one is it must be a final
12 negative action or finding.

13 The second criteria is that the actions
14 are made publicly available.

15 The third one and the most important one
16 is that the adverse action must directly affect health
17 care. That's very important, either medical practice
18 or health care. That's the big criteria that we have
19 to -- I'm sorry. I'll just read the next.

20 An example, let me give you two examples,
21 brief examples of what NRC would report. The first
22 one would be the revocation or suspension of a
23 license. That type of adverse action will be reported
24 to the database.

25 The second example, and I'm going to give

NEAL R. GROSS

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

1 some very specific examples at the end of my talk.
2 Second example would be actions that limit the scope
3 of practice. This would include individuals that are
4 banned from NRC licensed activities.

5 The type of licensees and employees who
6 may be reported to the database include the following
7 who work under NRC license. And they can include lots
8 of different people: the physicians, the AMPs, the
9 health physicists, or as you can see the list,
10 clinics, hospitals, radiopharmacies. Any one of these
11 individuals or entities that we feel meet the criteria
12 for adverse action would actually be reported.

13 How are we going to report this
14 information? Management Directive 8.6 has been
15 drafted. Basically, the management directive gives
16 the policy and direction to our staff on how we will
17 identify who's reported, how it will be reported, and
18 so on. And this will be done by different individuals
19 in the agency.

20 For example, the regional staff will
21 identify whether or not something needs to be
22 reported. They will follow up with the licensee to
23 receive the information that they need to report to
24 the database.

25 That information is forwarded to the

NEAL R. GROSS

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

1 Office of Enforcement. The Office of Enforcement
2 actually inputs the data into the database.

3 What's the status of this management
4 directive? At the last ACMUI meeting, this topic was
5 brought up for the first time. And members of this
6 committee were concerned that we were doing something
7 that we hadn't actually informed you about.

8 So a memo went out in January of this year
9 describing the actions that we were going to take, why
10 we were going to take it. We gave you the rule
11 involved, and a draft of the management directive.
12 And also some examples of past adverse actions that we
13 will be reporting to the database.

14 Currently, the NRC offices and regions are
15 reviewing for final comment. Those final comments are
16 due back to me by the end of this month. Hopefully I
17 am going to be finished with this by August of this
18 year. So the management directive should be complete,
19 and the regional staff will start identifying actions
20 that need to be reported.

21 Okay, I'm going to briefly review some
22 examples of past actions that require reporting. The
23 first one is -- actually these two are individuals.
24 The first one is Perry Beale.

25 Perry Beale was a health physics

NEAL R. GROSS

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

1 consultant who was consulting to hospitals in Virginia
2 and West Virginia. He falsified documents for the
3 licensees that he was working for. We prohibit him
4 from working under any NRC license, or being involved
5 with any NRC licensed activities because of his
6 actions.

7 The second individual is Dr. Jose
8 Fernandez. He was a physician who had over 100
9 medical events due to an incorrectly calibrated
10 Strontium-90 device. He also failed to have a QMP and
11 an authorized user on site. His license was modified
12 to exclude the use of that Strontium-90 for ophthalmic
13 treatments.

14 Okay, I have two more examples. These are
15 examples of different facilities that will be
16 reported. The first one is the Advanced Medical
17 Imaging and Nuclear Services.

18 Their license -- they were operating their
19 license without an authorized user or radiation safety
20 officer. Their license was suspended for a certain
21 period of time. This type of action would be reported
22 to the database.

23 Second example is the Fairbanks Memorial
24 Hospital. They were issued a notice of violation with
25 an accompanied civil penalty. The licensee failed to

NEAL R. GROSS

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

1 obtain the signature of the authorized user on a
2 written directive prior to administration of a dosage
3 of I-131 greater than 30 microcuries.

4 You may question why is this reportable.
5 The reason this is reportable is because this could
6 directly affect health care. If this was not signed
7 by an authorized user, how do we know that the
8 individual administering that iodine is doing it
9 according to the written directive over that
10 authorized user. This could potentially directly
11 affect health care.

12 And I'll answer your question after I'm
13 finished. Thank you.

14 DR. DIAMOND: I'd actually like to ask for
15 it now.

16 (Laughter.)

17 DR. DIAMOND: I just want to be very clear
18 -- So I'm getting ready to go and give 100 millicurie
19 to my thyroid cancer patient up on the floor.

20 MS. PSYK: No, no, wait a minute. First
21 of all, we have to go through the first criteria. The
22 first criteria, one of the criteria, they received an
23 NOV with a civil penalty. They actually received a
24 notice of violation accompanied by a civil penalty.

25 Start from there. Now we look on. Why

NEAL R. GROSS

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

1 did they receive that notice of violation? They
2 received it because they didn't have an AU sign that
3 written directive.

4 In your instance, if something happened
5 like that in your case, you may not receive a notice
6 of violation accompanied with a civil penalty. That
7 criteria comes first.

8 Do you see what I mean?

9 DR. DIAMOND: I'm just asking a very
10 simple question.

11 MS. PSYK: Okay.

12 DR. DIAMOND: The typical patient I'll do
13 a couple times a week. I admit to the hospital. We
14 have them up there with the physicist. We went
15 through everything with the patient. Room's done.

16 What would happen if that patient of mine,
17 let's say a young lady, took that oral capsule of 100
18 millicurie of sodium I-131 three seconds before I went
19 and signed the written directive?

20 MS. PSYK: Well, first of all, you
21 wouldn't get a notice of violation for that.
22 Remember, that's what I said, the first criteria. The
23 first criteria -- this facility got a notice of
24 violation with a civil penalty.

25 In fact, if they received a notice of

NEAL R. GROSS

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

1 violation without a civil penalty, they wouldn't even
2 be included in our database. They wouldn't even be
3 something we looked at.

4 DR. DIAMOND: So this is something where
5 there was a systematic issue?

6 MS. PSYK: That's right. I'm sure there
7 was more of an issue than what I'm just describing
8 here. And that's why --

9 DR. DIAMOND: The reason I'm getting your
10 attention is because --

11 MS. PSYK: -- they got a civil penalty on
12 top of their notice of violation.

13 DR. DIAMOND: The reason I bring it to
14 your attention is because if you learn about HPOMER
15 **, generally you'll recognize that physicians
16 nationwide are furious with some of its provisions.

17 And I think we're becoming justifiably
18 paranoid in some circumstances as to some of the
19 penalties that we may be facing for inconsequential
20 activities.

21 MS. PSYK: Well, in reality, this is not
22 a penalty. What I'm talking about here is we're
23 talking about what we'd be reporting to the database.
24 That's not an actual penalty.

25 DR. DIAMOND: Aha. But you see, the way

NEAL R. GROSS

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

1 the world works --

2 MS. PSYK: No one sees that information,
3 except for --

4 DR. DIAMOND: -- this world. You live in
5 a different world, because the fact remains that this
6 information can get out. This information can be used
7 against you in a court of law. I'm just trying to --
8 we're getting a little off tangent, but I'm just
9 saying this can be very, very deleterious to a
10 person's career.

11 MS. PSYK: Okay. Well, that's duly noted,
12 although we will be going forth with this, because it
13 is the law.

14 DR. WILLIAMSON: To follow up with this,
15 if for example the AU's intent was to deliver this,
16 and that one prescription maybe out of 100 the
17 individual forgot to sign it, or perhaps it was done
18 on an emergent basis and the person failed to sign it
19 24 hours later.

20 I mean, I would expect that this is not
21 unusual, that there may be a one percent rate of
22 essentially paperwork failures that do not represent
23 a -- do not indicate a substantial problem with the
24 program. May be even self-correcting.

25 So you're going to put somebody in this

NEAL R. GROSS

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

1 database for that? That's what it sounds like you're
2 saying. This does not seem reasonable.

3 MS. PSYK: No, actually -- and actually
4 Sally Merchant's here from the Office of Enforcement.
5 She may have a few more words she wants to say about
6 that.

7 MS. MERCHANT: Well, I would like to make
8 one comment, and that's that this was not something we
9 wanted to do. This was something that was brought to
10 our attention from outside the agency, asking us how
11 are you complying with this requirement.

12 We've had to put a lot of resources in it.
13 We were -- It was not something we wanted to do. It's
14 something that we're being required to do. We kind of
15 have many of the same feelings as you do, but we don't
16 have an option.

17 DR. NAG: I think you do have an option.
18 One of the things you said was if it impaired or
19 affected any patient's safety. Now, there's two
20 things that can happen, giving an example.

21 One thing is that a level or what you
22 sign, but the level that was given was 100 millicurie
23 or whatever, 100 millicurie of I-131, and it was
24 given. And the pressure of time and so on, it wasn't
25 signed.

NEAL R. GROSS

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

1 Now, that does not affect the safety of
2 the patient, although legally because it wasn't signed
3 on the paper. And when you do an audit of 1,000
4 injections, you are going to have one or two of those.
5 And that does not affect patient safety.

6 Now, you said that you are only going to
7 report important things that have penalty and that
8 affected patient safety. So something like that
9 doesn't affect patient safety.

10 On the other hand, if that injection was
11 given, no one gave the orders, and obviously no one
12 signed those orders, then it affected patient safety,
13 and that should be reported.

14 So I think you have to make that
15 distinction between those two, although both on paper
16 looks the same.

17 MS. PSYK: But you have to realize that in
18 the first example you gave, they would not receive a
19 notice of violation. They wouldn't even be on our
20 radar. That type of situation we wouldn't have even
21 considered to look at.

22 MS. MERCHANT: Additionally, look at the
23 data on that. The EA-96, which means that's 1996.
24 That was in a period of time before we went with the
25 new rule-making; before we went with the more

NEAL R. GROSS

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

1 performance-based philosophy.

2 Hopefully if a case came to the Office of
3 Enforcement where there was no deliberate attempt to
4 do anything wrong we would certainly consider that.
5 As I said, look at it in the context.

6 The one above I'd like to comment on. And
7 in this particular case, this particular service set
8 up business, negotiated with an authorized user.
9 Never quote, "hired him or contracted him," and
10 proceeded to do more than 500 patients, with no
11 authorized user at all. They had lied about the one
12 they were putting on the license.

13 Same thing with the authorized user. And
14 I think any of you would find a problem with that.

15 DR. NAG: I don't think any of us have a
16 problem with that. The problem we have is where
17 there's some paperwork missing, and that was a
18 penalty.

19 MS. PSYK: That will not even come up on
20 our radar. That won't even --

21 CHAIRMAN CERQUEIRA: To rephrase --
22 Gentlemen, we need to go on.

23 MS. PSYK: Yes, thank you. Okay.

24 CHAIRMAN CERQUEIRA: I'm not sure what
25 additional discussion on this will do, okay?

NEAL R. GROSS

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

1 MS. PSYK: Okay. Agreement state
2 reporting. Agreement states were also required to
3 report adverse actions to the database. I was going
4 to actually ask Ruth, do you know if the State of
5 Texas has begun reporting?

6 MS. MCBURNEY: I was going to ask you is
7 that through State and Tribal Programs, or through --
8 directly through Enforcement?

9 MS. PSYK: Actually, it's the -- You mean
10 who's going to be initiating it?

11 MS. MCBURNEY: Who will report to?

12 MS. PSYK: It actually has to be every
13 government agency. So in other words, the NRC is a
14 government agency. Texas is a separate entity. They
15 will have to do their own reporting to the database.

16 MS. MCBURNEY: Directly to --

17 MS. PSYK: Directly to the database. And
18 what the NRC will do is once the management directive
19 is finalized, we will send an all agreement state
20 letter just to remind agreement states that they are
21 required to do this.

22 This came up as something several years
23 ago that we didn't even realize was out there. I
24 mean, this was published in 1996, and we didn't even
25 realize that this was a requirement.

NEAL R. GROSS

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

1 MR. LIETO: Maybe I'm missing some dates
2 here or something like that, but by what I've
3 understood here, you're going to report any actions
4 that you have taken since 1996?

5 MS. PSYK: Yes, that is correct. And I'm
6 sorry I didn't cover that. The rule became effective
7 in 1996, and I forget the exact date, which means that
8 we must go back and look at all of our enforcement
9 actions, and all of our adverse actions that occurred,
10 back to that date, and report back from that date.

11 So in other words, if something happened,
12 like I gave an example that happened in 1997, we will
13 have to report that.

14 MR. LIETO: Because I thought it didn't
15 become effective initially until like 1999 or
16 thereafter.

17 MS. PSYK: No, 1996.

18 DR. DIAMOND: It's a different provision.
19 It's come into place at different points. So for
20 example, some of the provisions relative to physicians
21 and hospitals have come into effect only within the
22 last several months.

23 There are other provisions I would gather
24 that were antecedent to that.

25 MS. PSYK: Right. Okay. In summary, I

NEAL R. GROSS

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

1 talked a little bit about the adverse actions that we
2 will report. I talked a little bit about the status
3 of our management directive and how we're going to use
4 that. And also that agreement states are required to
5 report on their own, because they are considered a
6 government agency that issues their own licenses.

7 Are there any other comments?

8 DR. NAG: Now, most of these violations,
9 if not all, would have been reported on your NRC
10 newsletter or whatever anyway, right?

11 MS. PSYK: That's right. In fact, that's
12 a very good point.

13 DR. NAG: It is something that you
14 wouldn't get otherwise?

15 MS. PSYK: That's a very good point,
16 because in fact, all the examples that I provided, all
17 of those are available because they were enforcement
18 actions and are available on our NRC website.

19 So it's not like other individuals in the
20 public couldn't see that information.

21 CHAIRMAN CERQUEIRA: Thank you very much.

22 MS. PSYK: Thank you.

23 CHAIRMAN CERQUEIRA: Excellent job. The
24 next discussion is going to be, "Written Directives
25 for Brachytherapy not Associated with Permanent

NEAL R. GROSS

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

1 Implants." And Dr. Zelac.

2 DR. ZELAC: Mr. Chairman, committee
3 members.

4 DR. NAG: Dr. Zelac, can you move to the
5 side?

6 CHAIRMAN CERQUEIRA: Use the next place.
7 Push Tom out of the way there.

8 (Laughter.)

9 DR. ZELAC: You'll see me several times
10 today and tomorrow. Initially I was asked to make a
11 presentation on that aspect of involvement with the
12 medical rule implementation that i've really been
13 working on.

14 However, I was then asked to give a couple
15 of presentations, and this is one of them, on other
16 aspects relating to, I believe, issues or questions
17 that have been raised by the advisory committee in the
18 past.

19 In this particular case, apparently there
20 was concern ont the part of someone that the
21 particular written directive requirements that appear
22 in the rule relating to brachytherapy, other than high
23 dose rate brachytherapy, were not appropriate, and
24 that they only applied, and were really applicable
25 only for permanent implants, and not for temporary

NEAL R. GROSS

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

1 implants or other types of brachytherapy.

2 So the question is are these written
3 directive requirements appropriate. The specific rule
4 section involved, and this again is the revised rule
5 that we're working with, the current rule, 10 CFR
6 35.40(b)(6), which covers the written directive
7 requirements for all brachytherapy except HTR which
8 has its own section, (b)(5).

9 The specific requirements that appear in
10 that section of the rule are that the authorized user
11 has to stay in the written directive before
12 implantation, what the treatment site is, what
13 radionuclide's going to be used as part of the
14 treatment, and what the intended dose is as part of
15 that treatment.

16 After implantation, but before completion
17 of the procedure, the authorized user on the written
18 directive needs to verify the treatment site, verify
19 the radionuclide, and now provide in the written
20 directive the number of sources that were utilized,
21 the total source strength and exposure time, or
22 alternatively the total dose.

23 Now what are the changes in this
24 particular revised rule section that make it different
25 from what appeared previously? Now the number of

NEAL R. GROSS

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

1 sources is entered after implantation rather than
2 before implantation.

3 Secondly, individual source strengths are
4 no longer required. And finally, the treatment site
5 and the dose need to be entered into the written
6 directive prior to implantation besides being verified
7 afterwards.

8 The basis for these changes: discussion
9 with the advisory committee on comments received on
10 the proposed rule. This specifically had to do with
11 the entry of the number of sources post-implantation,
12 and no need for individual source strengths.

13 And secondly, the consistency with
14 requirements for other sealed source therapies, where
15 the treatment site and the intended dose are
16 identified prior to the procedure.

17 Now, I think it's important to note that
18 so far, the requirements have not introduced anything
19 which I personally, nor in consultation with others,
20 have found to be inappropriate.

21 For example, for temporary implants,
22 afterloaders, manual afterloaders, iridium seeds, in
23 ribbons removed, temporary implants, you still need to
24 identify the number of sources, you still need to
25 identify what nuclide it was, and you still need to

NEAL R. GROSS

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

1 identify the total dose that was intended for
2 delivery.

3 DR. NAG: I have a question about that.

4 DR. ZELAC: Yes.

5 DR. NAG: I think that on your slide on --
6 before implantation, the treatment site, radionuclide
7 and dose. Why when that was there before was
8 treatment site, radionuclide and I think it was
9 activity. And that was more appropriate for a
10 removable implant, but inappropriate for the permanent
11 implant.

12 So to rectify that, they put in dose which
13 is now more appropriate for the permanent implant, but
14 may not always be appropriate for the removable
15 implant.

16 And the reason for that is once in a
17 removable implant, in a temporary removable implant,
18 you may want to put in the sources, and then do your
19 calculation and see how much of the isodose you start
20 with.

21 And you may want to change your dose
22 depending on the volume. In the removable implant,
23 many times what you can do is put the number of
24 sources you want and then calculate, find out what
25 volume you're getting.

NEAL R. GROSS

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

1 And the volume and dose are inter-related.
2 So depending on the volume you have, you may want to
3 either take down or increase the dose. So in a way,
4 if you are having only the word "dose" there, it may
5 tie the hands down for the removable implant.

6 DR. ZELAC: Well, the comment that I would
7 make is that the written directive is the intended
8 treatment plan, if you will.

9 DR. NAG: Right, but --

10 DR. ZELAC: That certainly doesn't
11 preclude modification later of the written directive
12 based on the findings associated with the treatment
13 itself.

14 DR. NAG: But say you tried to correct one
15 with dose that the previous directive was not really
16 suitable for the permanent implant, and you made it
17 now not totally suitable for the removable implant.

18 You can very easily correct that by saying
19 dose or activity. Or, you can have a separate way of
20 writing the directive for a removable implant, and a
21 separate directive for a permanent implant. Because
22 the two, although they are both brachytherapy, have a
23 different method of how you do it, and how you plan
24 it.

25 DR. ZELAC: You've indicated that there

NEAL R. GROSS

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

1 would be a better way of stating the requirement. Do
2 you find that the way that is existing in the rule now
3 would, in fact, represent a problem?

4 DR. NAG: Are you saying the old 35 or the
5 35 now?

6 DR. ZELAC: No, I'm talking about the rule
7 that we're living with right now.

8 DR. NAG: The new one.

9 DR. ZELAC: Right. That's really what
10 we're commenting on.

11 DR. NAG: Yes, it would. If in the
12 removable implant, if you are having total dose, and
13 you are saying that, well, I want to give 3500, but
14 the way the sources are placed, if you give 3500
15 you're going to overdose that area. Then if it's a
16 different volume, you say no, my intended dose is now
17 going to be 2500.

18 DR. DIAMOND: But Subir, you could modify
19 your written directive based on plan.

20 DR. WILLIAMSON: Yes, you can modify your
21 written directive. I mean, I think I agree with both
22 of you. I do believe that the way the current revised
23 Part 35 that we're now living with is written, I don't
24 think it precludes the radiation oncologist from
25 changing the prescription.

NEAL R. GROSS

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

1 It's necessary to have a two-part
2 prescription, because treatment planning is not always
3 completed by the time the sources are loaded. So
4 that's important that that be there.

5 On the other hand, I tend to agree with
6 Subir that in the old Part 35, the way the two-part
7 prescription was written it was actually more useful
8 for temporary implantation because it essentially was
9 more consistent with a set of instructions or
10 guidelines. How the patient was to be loaded, what
11 sources, what activity.

12 That's what you know at the time. You
13 don't know what the total dose is going to be or the
14 total time. So from a safety perspective, there
15 probably was a little more added value to the old
16 regulation compared to this.

17 But I don't think this is a major problem.
18 It doesn't hinder us from doing anything.

19 DR. ZELAC: Well, obviously the problem it
20 was intended to correct was having to specify in
21 advance of implantation the number of seeds that were
22 going to be utilized. And you know, that makes --

23 DR. WILLIAMSON: Right. You're trying to
24 make it work for both permanent seed implantation and
25 temporary implantation.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: So it sounds like
2 it's accomplished the purpose.

3 DR. ZELAC: Mr. Chairman, we have someone
4 from the audience.

5 MR. FORREST: Rob Forrest. I'm the
6 radiation safety officer at the University of
7 Pennsylvania.

8 Two comments on that. If some of the new
9 modalities in 35-1000 fall into this category, it does
10 present some problems, because SIRSpheres, for
11 example, is considered brachytherapy. And it would be
12 very difficult with up to 80 million spheres to
13 determine the number that was administered. So that
14 presents a problem with this regulation as written.

15 In addition to that, I heard several times
16 that an authorized user can revise the written
17 directive. But part C of that says a written revision
18 to an existing written directive may be made if the
19 revision is dated and signed by an authorized user
20 before administration.

21 So the way the rule is written right now,
22 you can't change it right in the middle.

23 DR. NAG: After completion, not before
24 completion.

25 DR. ZELAC: The other thing is, the

NEAL R. GROSS

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

1 comment is that the sections in the part of the rule
2 that I'm discussing now apply to specific modalities
3 which are covered in the base portions of the
4 regulations, and do not apply to any requirements
5 relating to 35-1000 utilizations, which will be
6 covered by microspheres.

7 And it has its own specific requirements
8 for just about everything. When they can fit and
9 match with existing requirements in other sections,
10 that's done. When they don't, then they certainly
11 don't apply, and that would be the case here in terms
12 of specifying the number of sources.

13 CHAIRMAN CERQUEIRA: So that clarifies it.
14 One last comment from Jeff.

15 DR. WILLIAMSON: Yes, I think I just read
16 the part C here that the member of the general public.
17 I think, depending upon how you interpret this, it's
18 okay.

19 It says before the administration of the
20 dosage of unsealed by-product material, the
21 brachytherapy dose. So that phrase to me implies you
22 can revise it up to and including the point where the
23 original dose is delivered. But if it goes beyond,
24 then you can't.

25 DR. NAG: Therefore, if it's in a

NEAL R. GROSS

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

1 permanent implant, the implant is never finished, so
2 you can do it up to 100 years.

3 DR. WILLIAMSON: That has never been
4 clear, and I think that's where --

5 DR. ZELAC: Well, that is currently under
6 consideration by our Office of General Counsel: when
7 does the procedure end. I will not specify, because
8 it's still pre-decisional, what their determination of
9 that was. They haven't completed it yet, but there
10 will be a stated endpoint for such procedures.

11 DR. NAG: The other question that brings
12 up is, you know, if you're taking a removable implant,
13 I am prescribing just 3,000, okay? But, because of
14 the way the sources are kept, it can go up to 4,000 or
15 5,000.

16 So now I am doing my calibration after the
17 original prescription of 3,000 is done, but before my
18 new intended, which is 5,000. So what does that mean?

19 DR. ZELAC: Well, there are two -- First
20 of all, keep in mind that the information that's asked
21 for prior to the implantation is quite general. What
22 organ are you treating? I'm treating the prostate.
23 You don't have to say the extent of it, whatever. I'm
24 treating the prostate.

25 What is your approximate intended dose to

NEAL R. GROSS

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

1 be delivered? If you give a number, there's nothing
2 to preclude you from giving a range as opposed to a
3 specific number. And as long as you are within that
4 range, you should be satisfactory.

5 Yes. The answer to the question is
6 excellent. Yes, Part 35 written directive
7 requirements appear to be appropriate for
8 brachytherapy that involves temporary implants, and
9 are not specifically written to only apply to
10 permanent implants.

11 CHAIRMAN CERQUEIRA: Thank you very much
12 Ron, excellent. All right, the next presentation is
13 on "Downloading Part 35 from the NRC Webpage."

14 MR. ESSIG: This will be very, very quick.

15 CHAIRMAN CERQUEIRA: Excellent.

16 MR. ESSIG: Shorter than the others by a
17 long shot. You have a hand-out, and I think members
18 of the public have it as well. It's titled "Saving
19 Part 35 to Disk from NRC's Website."

20 You can read that at your leisure. Any
21 credit can go to Roger Broseus for articulating this.
22 He's one of our resident computer gurus. And we tried
23 it, and it works. It's referenced to Netscape,
24 because that's the browser we use. But it should work
25 on other browsers as well.

NEAL R. GROSS

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

1 So this answers the question, hopefully.
2 There were concerns a member brought up the last time
3 about the way the website instructions, you can only
4 download a piece at a time. This allows you to
5 download the entire. Not only Part 35, but any part
6 of the regulations you want to.

7 CHAIRMAN CERQUEIRA: Fabulous. So our
8 last presentation is going to be "Society of Nuclear
9 Medicine's Suggested Guidance for Therapy
10 Applications." And Dr. Jeffrey Siegel, Society of
11 Nuclear Medicine, will be making his way to the
12 podium.

13 DR. SIEGEL: I'd like to thank the
14 chairman, members of the ACMUI, the NRC staff, for
15 allowing me to take up your very valuable time today.
16 I know it's been a full schedule. We're all a little
17 bit tired, so I'm going to be really brief.

18 As Tom Essig said, when we developed the
19 diagnostic, as you know, Part 35, divides by-product
20 material, or BM, as I like to say, into seven types of
21 medical use.

22 So therefore, out of necessity, Part 35
23 contains requirements for a diagnostic as well as
24 therapeutic medicine. So in meeting with Chairman
25 MEserve on December 19, 2001, it was agreed upon that

NEAL R. GROSS

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

1 there was a need to publish a separate, stand-alone
2 guidance document for diagnostic nuclear medicine
3 applications to simplify all the paperwork involved.

4 SNM/ACNP subsequently proposed to publish
5 a stand-alone guide for therapeutic nuclear medicine.
6 The term, of course, "diagnostic nuclear medicine"
7 does not appear anywhere in the regulations, but it's
8 understood to pertain to 35-100 and -200 material.

9 And therapeutic nuclear medicine is
10 understood to pertain to 35-300 material. And as you
11 know, the NRC does classify material as to written
12 directive or non, and physical form sealed or unsealed
13 source.

14 We know that the applicable parts of the
15 regulations you've been debating over T&E can't be
16 viewed in isolation because there are license
17 conditions and, of course, regulatory guides. NUREG-
18 1556, Volume 9, is the licensing guidance for the
19 revised 35.

20 We know that licensees must have written
21 procedures. And that's stipulated in Part 20. But
22 these policies in implementing procedures are not
23 published in the regulations. They exist only in
24 guidance base, which means from a regulatory point of
25 view, they don't exist, unless the licensee commits

NEAL R. GROSS

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

1 them to use, and therefore it becomes a license
2 condition. Otherwise, they are non-existent.
3 Guidance is guidance. It's not mandatory.

4 Generally, nuclear medicine licensees have
5 used NRC guidance. And this is the reason that we
6 decided to publish a guide as an alternative. We
7 worked collaboratively, as Tom said, with the NRC, and
8 we're very happy that the statement was made. I'm not
9 going to read it again.

10 It includes all the applicable NRC
11 regulations. Not just Part 35, but Parts 19, Parts
12 20, 30, all other applicable parts to diagnostic
13 nuclear medicine.

14 As we'll see tomorrow, the number of
15 misadministrations and medical events that have
16 occurred over the last four years as a result of
17 diagnostic nuclear medicine was two in 2000, zero in
18 2001, zero in 2002, and one in 2003. So not many
19 medical events or misadministrations.

20 It was designed to make it much easier for
21 all involved in diagnostic nuclear medicine to be
22 familiar with the regs. It's only 73 pages. It
23 contains step-by-step instructions. And again, this
24 includes everything distilled from Part 35, Part 19,
25 Part 20, Part 30.

NEAL R. GROSS

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

1 Additional guidance is necessary of
2 therapeutic nuclear medicine, and that's why we sent
3 to each member of ACMUI a copy of the companion guide
4 for therapeutic nuclear medicine. And you each should
5 have a copy of that. It's divided into six parts
6 which I'm not going to go into. Let's all turn to
7 page 36. I'm only kidding.

8 We thoroughly appreciate the review of the
9 ACMUI, and any comments you may have. And ultimately
10 we would look for ACMUI endorsement of this document
11 to the commission. And I thank you very much for your
12 attention.

13 CHAIRMAN CERQUEIRA: Thanks, Jeff. One
14 question that I have, which I sort of asked related to
15 the diagnostic, is people use this to make decisions
16 about how they set up their practices.

17 And I'm worried about liability in the
18 sense there's -- you know, when the NRC puts out a
19 guidance document, the government is behind it. Now
20 when the SNM puts out a document, who's liable.

21 And what if a physician acts in accordance
22 with these guidelines that you've put out, and then is
23 found to have significant violations, loses his
24 license or something.

25 Do they have any -- you know. Is the SNM

NEAL R. GROSS

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

1 liable in any way?

2 DR. SIEGEL: Well, we have the SNM's
3 attorney here, sitting in the background. But again,
4 these guides were written as minimal guides. They
5 were not meant to be the things you could do to the
6 nth degree.

7 CHAIRMAN CERQUEIRA: I mean, the regs
8 ultimately are what determines what's appropriate.

9 DR. SIEGEL: That's absolutely right. And
10 there's more than one way to skin a cat, as you know.

11 CHAIRMAN CERQUEIRA: Right.

12 DR. SIEGEL: And one could take the
13 guidance in 1556, Volume 9. Or one of the guides that
14 we've proposed, the diagnostic or the therapeutic
15 guide. And the question that you ask is an important
16 one, and I'm glad we do have the SNM attorney here.

17 But I think that the important thing here
18 is that in a risk-informed performance-based situation
19 that we're in. And when inspectors come in, I don't
20 know what they're going to be comfortable with.

21 So if they're not comfortable with the SNM
22 guide, but they're familiar with NUREG-1556, and they
23 see violations that don't amount to safety problems,
24 that's one issue.

25 But let's say they see violations that

NEAL R. GROSS

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

1 amount to medical events or misadministrations, which
2 is the question, and the only important question, in
3 my opinion, that you're asking. Is it because of
4 their policies and implementing procedures?

5 And I can't see that as a problem, except
6 that they're not following any policy or procedure
7 whatsoever. Like they were talking about before, a
8 facility operating without an authorized user and a
9 radiation safety officer.

10 I would suggest that knowledge is almost
11 irrelevant and unimportant, because who would consider
12 doing that? Obviously, there are people out there
13 that are doing that. But if you have no policies and
14 implementing procedures at all, you're likely to
15 experience misadministrations and medical events.

16 But if you have minimal standards in place
17 which you're following, and not even to the letter.
18 Given from the NRC's presentation tomorrow, there are
19 essentially no medical events or misadministrations to
20 speak of in this century.

21 CHAIRMAN CERQUEIRA: Okay, well that will
22 be an interesting presentation.

23 DR. SIEGEL: But I'd like for you to speak
24 on this, Bill.

25 MR. UFFELMAN: As I recall in the

NEAL R. GROSS

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

1 beginning of the guidance there's a paragraph that
2 specifically --

3 MR. ESSIG: Name please?

4 MR. UFFELMAN: Bill Uffelman, Society of
5 Nuclear Medicine. I'm general counsel and director of
6 public affairs. U-F-F-E-L-M-A-N and I'll give you my
7 card when I'm done.

8 But basically recall, your whole -- the
9 way you behave is directed by the regulations, Part
10 35, Part 20, et al. The guidance, both the NRC's
11 guidance and the SNM guidance, are just that.
12 Guidance.

13 Ultimately, the regulation is what
14 controls your activities. And your license, which you
15 said, I'm going to do these things. And so in effect,
16 the guidance that SNM prepared, that the NRC reviewed
17 and said yep, this meets it too. Both of those, the
18 NUREG and that, both of them are just that. Guidance
19 on how to comply.

20 If your attorney, or your RSO, or somebody
21 else said, hey, here's something we can do that
22 conforms, you can do that too. It becomes, though,
23 when you're inspected, is there some something that
24 you can point to and say I did that because it made
25 sense.

NEAL R. GROSS

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

1 And again, it goes back to it's a
2 performance-based standard, and if you're performing,
3 then you have met the criteria, the fundamental
4 criteria of the regulation.

5 Are you, in fact, having misadventures out
6 there, or is everything hunky-dory in accordance with
7 --

8 CHAIRMAN CERQUEIRA: Right, but some of
9 those are subject to interpretation. As you've heard
10 today, what we've put down and the way it's being
11 interpreted is not always the same.

12 And I think once you've created guidance
13 documents, then our constituents could basically be
14 following recommended policies, but may end up giving
15 them a violation.

16 I see that the NRC guidance documents are
17 basically from them, and probably are, you know,
18 they're probably a little bit more protective in terms
19 of what people do.

20 Does the NRC give the same weight to the
21 SNM guidance for diagnostic and therapeutics?

22 MR. UFFELMAN: On the diagnostic, the NRC
23 put its name on the cover of the publication. As an
24 alternative to NUREG Volume 9.

25 CHAIRMAN CERQUEIRA: But does that mean

NEAL R. GROSS

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

1 they fully endorse it, the way they do their own
2 guidance documents?

3 MR. ESSIG: For the diagnostic, I think we
4 -- that's --

5 MR. UFFELMAN: That's --

6 CHAIRMAN CERQUEIRA: Is that what counsel?
7 I guess she's gone. Okay.

8 MR. UFFELMAN: That's why they licensed
9 it. They licensed it from us to publish it as an
10 alternative to NUREG Volume 9.

11 MR. ESSIG: An acceptable way of
12 implementing --

13 CHAIRMAN CERQUEIRA: I guess having this
14 in the minutes of the meeting, or at least in the
15 transcript, I think makes me feel a little more
16 confident.

17 DR. SIEGEL: That's a very important
18 point, because when we were speaking with staff and
19 the commissioners --

20 CHAIRMAN CERQUEIRA: Right.

21 DR. SIEGEL: Guidance being guidance.
22 They didn't give it the same weight as the regulation.
23 And I'm glad Bill brought up that point, because given
24 that this is guidance, and that there are alternative
25 methods, and this is sort of "use at your own risk".

NEAL R. GROSS

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

1 One certainly can't escape, I guess,
2 liability in the sense that somebody's going to say,
3 well, I saw this here, and because I did this, look
4 what happened.

5 MR. UFFELMAN: That's a challenge I would
6 willingly face in court.

7 DR. SIEGEL: But that's also something
8 that could happen as a result of somebody following to
9 the letter NRC guidance.

10 DR. BROSEUS: Mr. Chairman, I have a
11 comment.

12 CHAIRMAN CERQUEIRA: Yes.

13 DR. BROSEUS: I'm not going to speak to
14 the liability issues, but it might be useful, and I
15 will make sure that a copy arrives for ACMUI tomorrow.
16 There was a regulatory -- a RIS. What does RIS stand
17 for? Regulatory Issues Summary.

18 And that stated clearly what the NRC's
19 intent was with regard to making the Society's guide
20 for diagnostic uses available to the public. And
21 we'll make that available tomorrow.

22 MR. ESSIG: I had mentioned that earlier.

23 CHAIRMAN CERQUEIRA: Okay, that will be
24 good. Now, the other question is, I mean this is
25 coming from the SNM on therapeutics. And are there

NEAL R. GROSS

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

1 any other stakeholders who should have input into
2 this?

3 DR. NAG: I do not have input into this
4 document. But what I'm wondering is is such a similar
5 guidance required, or would it be helpful for the NRC
6 if, for example, the ASTRO would develop something
7 similar for therapeutic radiology?

8 DR. SIEGEL: See, I hoped that when we had
9 these workshops that Tom was talking about several
10 months back, that more of the professional societies
11 would have come forward.

12 And I'm quite surprised that in the 50 or
13 60 or so years, nobody has come forward. And that we
14 were as a professional organization the first to come
15 forward to have some professional standards.

16 I mean, purportedly professional health
17 physicists have the training and experience that they
18 shouldn't be following guidance blindly. Not that
19 guidance necessarily is bad, but they ought to have
20 their own organization, or professional standards with
21 which to operate.

22 DR. WILLIAMSON: We do, I just want to
23 interject. The AAPM, the ACR, ACMP, have many
24 standards of practice in radiation oncology dealing
25 with --

NEAL R. GROSS

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

1 DR. SIEGEL: No, no, I know that you do.

2 DR. WILLIAMSON: Okay.

3 MR. UFFELMAN: The other -- The reason we
4 wanted to bring this to you today was if you recall
5 when we did the diagnostic, we had distributed for
6 peer review to a couple hundred people.

7 And you all said, well gee, we didn't see
8 it. The notion was it's here. And as Jeff said,
9 there's a comment sheet there that we invite your
10 comments.

11 We hadn't intended that it would get into
12 the publicly released pieces that went out, but that's
13 okay if they want to comment too. But obviously, the
14 copyright remains in the SNM, and what we were looking
15 for was input from you all on the document because we
16 will be publishing it as an SNM document.

17 And if, you know, somehow, some way, the
18 NRC also recognized it, that's a nice thing too.

19 CHAIRMAN CERQUEIRA: Any other questions
20 for Dr. Siegel? Thank you very much, Jeff.

21 DR. SIEGEL: Thank you very much.

22 CHAIRMAN CERQUEIRA: So that ends today's
23 session. Jeff?

24 MR. LIETO: Just quick. I notice that the
25 timeline for review is May 10.

NEAL R. GROSS

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

1 DR. SIEGEL: Oh, that's fine. Obviously
2 that can't happen.

3 (Laughter.)

4 MR. LIETO: Thank you for recognizing
5 that. But what -- I mean, are you looking at
6 something, since most of us have just gotten this
7 within the past week, what are you looking at?
8 Something like within 30 to 60 days, or what?

9 DR. SIEGEL: I think if you could do that,
10 that would be great.

11 MR. LIETO: Okay.

12 DR. VETTER: And where do we send the
13 comments?

14 MR. UFFELMAN: I think the address is
15 inside.

16 DR. SIEGEL: Should be a comment sheet.

17 MR. UFFELMAN: Does it say somewhere 1850
18 Samuel Morris Drive?

19 DR. VETTER: No. There's a comment sheet,
20 but no address on it.

21 MR. UFFELMAN: The letterhead on the
22 front. Send it to the Publications Department,
23 Society of Nuclear Medicine, 1850 --

24 DR. SIEGEL: Or give them your home number
25 so they can call at night.

NEAL R. GROSS

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

1 MR. UFFELMAN: No, I don't want to talk to
2 them. And Jeff gave you way too much time. If, in
3 fact, you could comment in the next two to three
4 weeks, that would be appreciated, because we're going
5 to the annual meeting.

6 My anniversary is the 21st. So somewhere
7 around the 21st of June we'll be at the annual
8 meeting. And the notion was we would be able to say
9 the review had been completed by the time we got
10 there.

11 CHAIRMAN CERQUEIRA: Excellent. Tom?

12 MR. ESSIG: Just one point. I realize
13 we're about to adjourn the meeting for the day.

14 CHAIRMAN CERQUEIRA: The open session.

15 MR. ESSIG: Just wanted to mention that we
16 will reassemble. And I think those of you that need
17 security badges need to pick them up over at the other
18 building. I believe that's the arrangement.

19 CHAIRMAN CERQUEIRA: Should we do that and
20 then come back?

21 MR. ESSIG: And you can do that, and then
22 come back. And why don't we take about 10 minutes,
23 then resume our closed session from this morning.

24 MS. WILLIAMSON: Before everybody leaves,
25 can I make some quick announcements concerning your

NEAL R. GROSS

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

1 badges. Just real quick, just a minute. To get your
2 new badges, all you have to do is walk over to the
3 other building and surrender your current badges.
4 That's it.

5 Ms. McBurney, I need to talk to you.

6 (Laughter.)

7 (Whereupon, the above-entitled matter
8 went off the record at 4:55 p.m. and went
9 back on the record at 5:08 p.m.)

10 DR. WILLIAMSON: I think on the remaining
11 concerns of Part 35, we clearly have the issue of
12 licensing conditions for sealed, interstitial
13 brachytherapy sources, that remains an issue that
14 we're quite concerned about and should probably be
15 mentioned to them.

16 Another one that is a concern for me was
17 alluded to in the last session, which, you know,
18 basically the Office of General Counsel is going to
19 decide almost, you know, what fraction of properly
20 done prostate implants today are going to be medical
21 events tomorrow.

22 You know, and this is the issue of how to
23 interpret the language of what's permitted in
24 permanent brachytherapy in terms of prescription
25 revision. And just so you know what the issue is, is

NEAL R. GROSS

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

1 that implants are preplanned based on minimum dose to
2 the prostate capsule, usually.

3 But when implants are executed, you know,
4 because of the inability to place the seeds precisely
5 where you want to and seed migration and prostate
6 edema and so forth, the minimum dose on average that
7 you get at the end of the procedure when you do a
8 post-implant CT and look at it, comes out to be
9 sometimes only 60 percent of what that was prescribed.

10 So practically speaking, what is used is
11 the dose to 90 percent of the target volume as a
12 parameter for determining how good the prostate
13 implant is. And somehow, you know, we have to have
14 some influence on this process to make sure that a
15 realistic, a clinically realistic interpretation of
16 how to write written directive for prostate implant is
17 developed, or the NRC could be swamped with thousands
18 of meaningless medical events.

19 DR. NAG: Now let me add a couple of
20 things. It also depends, when you're saying the dose
21 is often implied, you are saying that the dose is
22 13,000 or 15,000, is purely obviously because it
23 depends on how you do the volume of the prostate.

24 And we have done this at the study between
25 our members. We had asked them excellent work known

NEAL R. GROSS

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

1 like a Therapist to circle the prostate, and all the
2 ten circles were different. And I can give you that
3 study.

4 So if you take the dosimetry from those
5 ten people, from the same implant, same prostate, that
6 those were different in the prostate by ten different
7 people.

8 And in all, all the human control, the
9 dose in the, I wouldn't say meaningless, but it
10 depends on how you are interpreting the dose. So just
11 because we like 13,000 or 15,000, that doesn't
12 necessarily mean, you know, that you're under those in
13 the prostate, all were those in the prostate.

14 And the important thing is that the
15 therapy of the basin not undermine the, because they
16 are basically cured.

17 DR. WILLIAMSON: So I have great concern
18 when I hear about an attorney who has like no
19 conception or understanding of the clinical process
20 and what constitutes, you know, essentially an
21 avoidable technical error, and what constitutes a
22 properly done prostate implant.

23 CHAIRMAN CERQUEIRA: So this is a concern
24 that we need to bring up with them.

25 DR. WILLIAMSON: Absolutely.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: And maybe the two of
2 you, since, you know, this is not an area where I have
3 a lot, maybe you could just draft a few slides for me,
4 and we can get those in.

5 So issues related to therapy with, you
6 know, issues for brachytherapy for, that's one area of
7 concern.

8 DR. NAG: Especially permanent implants.

9 CHAIRMAN CERQUEIRA: Permanent, okay.

10 DR. WILLIAMSON: Yeah.

11 CHAIRMAN CERQUEIRA: And then we have the
12 issue of the training and experience which, again, I
13 just got a list from Lloyd. So far three states have
14 bought into the NRC proposal, the agreement states.

15 But the others we haven't heard from. We
16 have no idea how they are going to deal with this.

17 DR. WILLIAMSON: Lloyd just entered the
18 room.

19 CHAIRMAN CERQUEIRA: Did he? Okay, yeah,
20 Lloyd and I were talking. And so, you know, and I'm
21 not sure there's anyway of knowing at this point what
22 they remaining agreements states will do with this.
23 And certainly for the physician authorized users it's
24 going to be a major problem.

25 MS. MCBURNEY: 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 MS. MCBURNEY: Just speaking for one
3 agreement state, we have adopted everything except
4 the, just about, except the training experience. And
5 we were waiting until we get all this, the other
6 issues worked out on that.

7 CHAIRMAN CERQUEIRA: Right. And Wisconsin
8 is doing the same thing.

9 MS. MCBURNEY: So that we wouldn't have to
10 do two rule makings dealing with training experience,
11 that we would just do one. And I think a lot of the
12 states are waiting for this additional rule making
13 before they --

14 DR. WILLIAMSON: Are you going to
15 represent the state of this in your general summary
16 about the ACMUI?

17 CHAIRMAN CERQUEIRA: No. One of the items
18 is just sort of a --

19 MS. MCBURNEY: Implement.

20 CHAIRMAN CERQUEIRA: Yeah. ACMUI feedback
21 on the status of implementation of the revised 10 CFR
22 Part 35. And, you know, we don't have all that much
23 feedback at this point. I haven't, you know --

24 DR. WILLIAMSON: Well, is the training and
25 experience a separate agenda item or covered under the

NEAL R. GROSS

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

1 --

2 CHAIRMAN CERQUEIRA: No, it's not a
3 separate agenda item. It's going to be covered under
4 here.

5 DR. WILLIAMSON: I think that it might be
6 good to maybe, I don't know if Dick will be attending
7 this or not.

8 CHAIRMAN CERQUEIRA: The commission
9 briefing?

10 DR. WILLIAMSON: Yeah, to make some
11 comments about residual issues and some responses to
12 --

13 MS. MCBURNEY: Yes, he is going to be --

14 CHAIRMAN CERQUEIRA: He is going to be
15 there, right.

16 DR. WILLIAMSON: So you don't need to
17 cover that, then.

18 CHAIRMAN CERQUEIRA: Right.

19 MS. MCBURNEY: Right.

20 CHAIRMAN CERQUEIRA: Okay. Well, what
21 other, you know, again I don't have to go on very
22 long. I think that some of these issues about the
23 prostate -- yes, what else?

24 DR. WILLIAMSON: Well, I think that since
25 you're covering, generally, the status of the ACMUI,

NEAL R. GROSS

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

1 as our Chairman, I think you should allude the issues
2 of communication and our concern, you know, about, you
3 know, what we talked about this morning.

4 So I think you should summarize that and
5 summarize our proposal.

6 CHAIRMAN CERQUEIRA: Right. For the
7 follow up conference.

8 DR. WILLIAMSON: Yeah, that we've sort of
9 settled on the third way, which is, you know, we want
10 to have some kind of a codification of how, I don't
11 know, not disputes exactly, but you know --

12 CHAIRMAN CERQUEIRA: Sort of follow up on
13 important issues.

14 DR. WILLIAMSON: -- how are advice needs
15 to be handled when we get a negative reception over
16 some issue we feel strongly.

17 DR. MILLER: I think what you're looking
18 for is in instances where you have a passion about a
19 certain recommendation that you've made and the staff
20 doesn't take you up on your recommendation, you'd like
21 to make sure that the Commission is aware of, of your
22 concerns and your position.

23 DR. WILLIAMSON: So I think a little bit
24 about some of the past history and our recent concern.
25 I'm sure this has probably reached them if any of the

NEAL R. GROSS

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

1 Commissioners have ever looked at the transcript or
2 the summary of our minutes.

3 It would be worth summarizing this when --

4 MR. ESSIG: And I think it would be worth
5 contrasting the difference between this Advisory
6 Committee and the other two. Namely, that they report
7 directly to the Commission and they issue a letter
8 from the Chairman of the Committee to the Chairman of
9 the Commission with recommendations.

10 Whereas, this Committee reports within
11 NMNS and because of its narrower focus, in large
12 measure, and so that the recommendations come up and
13 in a way that could be a lead in to what you're going
14 to share with them then.

15 CHAIRMAN CERQUEIRA: Okay, all right. So,
16 okay, now that's a good point. The structure, the
17 reporting structure for this Committee is different
18 from the other two that -- okay.

19 DR. NAG: Manny, I have one thing.
20 Whether it would be worthwhile to bring up the example
21 we had this afternoon where you had 15 or 20 different
22 types of sources with them all essentially similar,
23 but because of the way they were interpreted you have
24 to get a license every time you change from one to the
25 other with no base and consequences.

NEAL R. GROSS

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

1 DR. WILLIAMSON: I think that's on your
2 list, right?

3 CHAIRMAN CERQUEIRA: Yeah, the first two
4 items.

5 DR. WILLIAMSON: Yeah, the licensing --

6 CHAIRMAN CERQUEIRA: Licensing conditions
7 for interstitial and implanted brachytherapy devices,
8 yeah. And you guys are going to give me some, well
9 some, just some of the talking points, because, you
10 know, it's really important.

11 MR. ESSIG: Could I suggest that since
12 Paul Lohaus and his staff are here --

13 CHAIRMAN CERQUEIRA: Yes.

14 MR. ESSIG: -- they came this morning. We
15 had to turn them away and they've come back now. And
16 we can talk about Ralph's slides.

17 CHAIRMAN CERQUEIRA: Excellent, yes.

18 MR. ESSIG: And, Paul, if you want to come
19 up to the table here and this is, Ralph Lieto has the
20 lead for this, on the 28th, this presentation is on
21 the, on the agenda.

22 He is going to be summarizing on behalf of
23 the Committee and we stumbled on a couple of things
24 this morning. So, that we're, so, Ralph, do you want
25 to kind of pick up and maybe Paul can help answer the

NEAL R. GROSS

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

1 issues.

2 MR. LOHAUS: Hello.

3 MR. LIETO: Where do I start? Here. I
4 think in basically some of the comments I got back
5 from the Committee members this morning, I think the
6 stumbling block had to do with the issues regarding
7 areas of concern.

8 And that there was support for the
9 alliance concept or methodology of program, National
10 Material Program, which was the working group
11 recommendation.

12 And that there were four main components
13 of that alliance program. And the one, or one of the
14 four that was of concern, potential concern, had to do
15 with NARM, regulation of NARM.

16 And its potential increased regulatory
17 burden, impact and so forth. Where we really got into
18 stumbling I think was on understanding, I think, from
19 the working group report that was reviewed and
20 presented at the last meeting.

21 It had to do with state program issues and
22 funding. Okay. And the alliance program, that is
23 really in essence not much, I'm sort of asking a
24 question, is not much of a change than what is going
25 to be existing now, except you're going to have NARM.

NEAL R. GROSS

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

1 Is that accurate?

2 MR. LOHAUS: Let me, in response, let me
3 provide a little background information because on one
4 hand the alliance structure that the working group
5 recommended, is really a further evolution and
6 advancement of where the National Materials Program is
7 today.

8 And I always like to start out and
9 indicate that there is a National Materials Program
10 today. It's basically, what the program is, in terms
11 of the states and the NRC.

12 And over the past several years, and it's
13 really more than several years now, we've been very
14 effective in terms of using a combination of state and
15 NRC resources through a working group process to
16 address areas of new guidance, rule making activities,
17 common regulatory issues.

18 And working groups will develop a product
19 that can then be utilized, whether it be by NRC or the
20 state. And that is really at the heart of the
21 alliance concept. What the alliance concept or
22 structure does though, as envisioned by the working
23 group, is it expands that out and has additional
24 factors that you don't necessarily see in today's
25 program.

NEAL R. GROSS

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

1 The concept of using centers of expertise.
2 For example, you can see that in places today. For
3 example, Texas took a lead earlier and developed a
4 well walking rule that was sort of a center expertise
5 and they took the lead to develop that.

6 But you don't see that in a, in a heart
7 sense as a structure or practice that's carried out.
8 The alliance also includes a concept of what's called
9 the administrative core. And I have a hard time
10 getting my hands around exactly what the
11 administrative core is.

12 Because if you look at this and you look
13 at the alliance process, there needs to be an
14 organization, and right now I think NRC is probably
15 that organization, that helps take on accountability,
16 make sure products, when they are needed, are
17 completed.

18 Completed on schedule. That they meet
19 their intended purpose. That they are the right
20 standards of quality, etcetera. And the alliance
21 concept, as you see that in the working group report,
22 it talks about this administrative core, but it's not
23 really clear exactly who that administrative core is
24 or how it functions.

25 And it could be a consortium of CRCPD,

NEAL R. GROSS

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

1 OAS, and NRC. It could be CRCPD. It could be NRC.
2 And that's something that I think will have to be
3 sorted out in the future. And I think today, if I
4 were to answer the question, it's really NRC sort of
5 has the lead and carries out that responsibility.

6 But it's done through some of the kinds of
7 mechanisms and processes that you would see in an
8 alliance program. And that's one of the reasons that
9 when we went back to the commission on the pilot
10 projects, the staff recommendation, and this was
11 really not only a staff recommendation, but a
12 recommendation that CRCPD and OAS agreed with, was to
13 use what we called a blending of the current program.

14 The current program as it exists today,
15 and the alliance option, which is to try and push
16 further the state of the art in the evolution in terms
17 of how the alliance process could work in the future.
18 But there are some unanswered questions.

19 MR. LIETO: So it continues to be a hybrid
20 of agreement and non-agreement states?

21 MR. LOHAUS: In this case, it's
22 principally NRC, agreement states and CRCPD and, on
23 occasion, a non-agreement state if there is an issue
24 that, where we want non-agreement state input. But
25 the primary, central focus of this, is really

NEAL R. GROSS

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

1 agreement states.

2 Not non-agreement states. Although, when
3 you bring CRCPD into this, you bring in both agreement
4 and non-agreement states. And I realize that's hard to
5 make that differentiation, but I think in terms of
6 looking at the National Materials Program, it would be
7 best characterized as NRC and the agreement states.

8 I would not bring the non-agreement states
9 in. But, what you're seeing on certain issues, such
10 as regulation of NARM and questions like that, which
11 have an impact on agreement state programs, what we're
12 doing is we're involving CRCPD and bringing in,
13 through that organization, a non-agreement state
14 perspective to have the benefit of those views on
15 questions that have an effect on the non-agreement
16 state programs. Ruth?

17 MS. MCBURNEY: Yeah, I would add that
18 normally if, on matters of byproduct material and so
19 forth, even the CRCPD puts someone in from an
20 agreement state on working groups and steering
21 committees, to the mix.

22 MR. LOHAUS: And that's, that's a very
23 good point. Because if you look at the process of
24 developing the suggested state regulations, one of the
25 things that we've tried to do more recently is to try

NEAL R. GROSS

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

1 and work NRC's rulemaking process and work the
2 suggested state regulation process in parallel.

3 Which means that the, the individual
4 within that conference committee that has
5 responsibility for that particular suggested state
6 regulation part, would work, if we had a working group
7 set up to deal with that, would work on that working
8 group.

9 So you'd have both the benefit of the
10 conference committee and the working group and the
11 cross over that would occur, so the two could proceed
12 in parallel. And we tried to do that on Part 35, as
13 well as I think you're aware, and that was one of the,
14 it wasn't really a pilot, but it was, the process, the
15 idea was to try and work that process in parallel.

16 And some of it worked well, and some of it
17 didn't work quite so well. There's, we're going to,
18 as we continue to do this, gain experience and reflect
19 that back. But I think that to say that the
20 non-agreement states are part of the National
21 Materials --

22 MR. LIETO: I guess that's still a
23 fundamental issue that I think was not clear in the
24 report or maybe misunderstood from the report is that
25 when you say NRC, okay, does that include individual

NEAL R. GROSS

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

1 states?

2 For example, Michigan is an NRC-regulated
3 state. So when you're talking NRC, do you mean
4 Michigan? Do you mean Minnesota?

5 MR. LOHAUS: No. NRC, solely NRC.

6 MR. LIETO: Okay. That's, that's, I
7 think, part of the issue here. Okay. You're saying
8 it doesn't involve non-agreement states. Okay. So
9 where do they fall in the alliance? They're not part
10 of a National Materials Program?

11 How do you call it a National Materials
12 Program, if the states that are regulated by the NRC
13 are not part of the process. See, my, well, I
14 understand the alliance about, with the agreement
15 states, okay.

16 And that's what I think is part of the
17 misunderstanding. Maybe it's a misunderstanding or
18 confusion. Is that, it seemed like an alliance, the
19 alliance is that the states, all states sort of
20 achieve an agreement state status.

21 And you have the NRC as this, or whatever
22 Agency, CRCPD, OAS, whatever, or a hybrid of the
23 three, as this, in alliance with the states.

24 MR. LOHAUS: If the atomic energy --

25 MR. LIETO: Because you keep talking

NEAL R. GROSS

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

1 states and NRC, and that's where I'm trying to
2 understand. I understand where non-agreement states
3 fit in, or agreement states fit in. Where do the
4 non-agreement states fit ?

5 MS. MCBURNEY: They are regulated by NRC.

6 MR. LIETO: But he just said they are not
7 part of NRC.

8 MR. LOHAUS: No, they are regulated by
9 NRC, but I guess I was looking at this through the
10 standpoint of if you were to look at the National
11 Material Program and in terms of where that program is
12 today, it addresses Atomic Energy Act materials, and
13 it consists of the agreement state programs and NRC's
14 regulatory program, which covers the suite of
15 agreement material licensees, Atomic Energy Act
16 materials licensees nationally.

17 It does not include a non-agreement state,
18 such as Michigan.

19 DR. WILLIAMSON: But if you expand the
20 legislative mandate, if you amend the Atomic Energy
21 Act to include NARM, then you are going to force the
22 non-agreement states either to become agreement states
23 or shut down their non-regulatory programs and make
24 way for you.

25 MR. LOHAUS: I mean that's certainly an

NEAL R. GROSS

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

1 issue that would need to be addressed as a part of
2 consideration of any legislation to amend the Atomic
3 Energy Act to consider NARM. It's how you would
4 handle states, non-agreement states, that have NARM
5 Programs.

6 And some register, some license, there's
7 differing degrees. But I think in general most of the
8 non-agreement states do have programs of regulatory
9 oversight over NARM. And that's a question, as a part
10 of the legislation, if that were to be considered,
11 that would have to be addressed.

12 DR. WILLIAMSON: I think we should stick,
13 I'm just making a suggestion to you, Ralph. Because
14 I think to get caught up in all of this bureaucratic
15 -- I don't understand hardly a word you've said, to be
16 honest with you.

17 This whole program sounds so vague and
18 ephemeral and I think this is an administrative issue
19 that impacts the regulatory agencies and the state,
20 and you know our mandate is to speak for medical
21 licensees, in both agreement and non-agreement states.

22 So I think we should maybe put the
23 emphasis of your presentation on the potential
24 negative impacts of regulating NARM by NRC or some
25 combination of NRC and the agreement, plus or minus

NEAL R. GROSS

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

1 non-agreement states.

2 Which, you know, that's a big mess. I
3 think, you know, we're concerned about increasing the
4 cost or availability of PET imaging for our patients.
5 We are concerned that, you know, we're taking a
6 problem where we don't see, basically taking a set of
7 radiation medicine procedures where there's no
8 perceived problem or public health hazard, and all of
9 a sudden imposing a regulatory burden on it.

10 You know, and we don't see the rationale
11 very clearly. We are concerned that by NRC taking on
12 the mandate to have to develop the expertise to handle
13 a whole new set of medical applications that they
14 don't have familiarity with, with an ever shrinking
15 population of licensees, that this is going to
16 increase the cost burden to all licensees that
17 continue to be regulated by NRC.

18 So I think these are some issues we're
19 concerned with and are reflected in our transcript of
20 the October meeting.

21 MR. LIETO: And I think, my feeling is
22 just pulling that whole slide out. I think this slide
23 about state programs is a, it's quicksand. And so,
24 there is other ways I'd rather drown.

25 DR. WILLIAMSON: I just think it's too far

NEAL R. GROSS

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

1 from our community to worry about.

2 MR. LIETO: Maybe just not try to profess
3 or maybe create more confusion than already exists,
4 and some misrepresentations to the Commission.
5 Definitely we don't want to do that. So I think it
6 might be because this is so much in the early phases.

7 And I think, as Mike pointed out earlier,
8 there's, which was before this, that there are pilot
9 programs going on in some aspects that, you know,
10 maybe the thing to do is just make sure that we just
11 address the PET issue and the issues about cost.

12 MR. LOHAUS: What I was going to offer is
13 in the pilot programs specifically, is that recognize
14 that the report that we provided to you, is a working
15 group report. That report was provided to the
16 Commission. The Commission has not endorsed or
17 accepted or approved any particular option.

18 They have not endorsed the alliance option
19 in particular or approved the alliance option in
20 particular. But what they have done is provided
21 direction to the staff, and in a sense, to the states,
22 to work together on five pilot projects using a
23 blended approach.

24 Which is really using the existing
25 program, but sort of pushing that a little bit further

NEAL R. GROSS

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

1 in the direction of the alliance. And based on the
2 results of that and the report is due to the
3 Commission in November of '04. Then there will be
4 further consideration of whether there should be any
5 additional direction or guidance provided to the
6 staff.

7 And I think, in this case, the states
8 relative to how that, how the program should be
9 managed and going forward. So I think you're very
10 correct in terms of the, it's maybe premature at this
11 time given the fact that the pilots are underway.

12 We're trying to develop a better base of
13 information so all of us can better understand and the
14 Commission can get a better base of information to
15 make some of these decisions. And it maybe premature
16 to try and force some --

17 CHAIRMAN CERQUEIRA: Premature to have
18 answers, but at the same time, these are issues that
19 need to be addressed. And I would be rather in favor
20 of bringing it up now, while it's in a draft form,
21 rather than waiting until it becomes more solidified.
22 Charlie?

23 DR. MILLER: Let me see if I can help you.
24 Maybe I'll make it worse, but I'll try not to. On
25 Jeff's concern, I mean if the committee has got

NEAL R. GROSS

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

1 concerns about, specific to NARM regulation, and the
2 NRC regulating NARM, on the one hand you can say,
3 well, since it's just the legislative proposal at this
4 point in time, the Commission has no authority yet, so
5 what can you gain by addressing the Commission.

6 But on the other hand, if you feel strong
7 enough about that, as a Committee, about concerns
8 about the NRC doing that, you have two choices, as I
9 see it, to go forward.

10 You can let the Commission know what your
11 concerns are, so as the Commission addresses with
12 Congress comments on proposed legislation, they can
13 factor that in. Or, each of you, by other means, can
14 lobby the Congress with regard to your concerns.

15 But as a committee, I would think the best
16 you could do now is to say to the Commission, here are
17 our concerns about the NRC doing this. And as the
18 legislative proposal goes forward, the NRC does
19 periodically get the opportunity to comment on those.

20 And the Commission, in its wisdom, could
21 decide if they wanted to do that or not.

22 CHAIRMAN CERQUEIRA: I think it would be
23 important to bring it up. Is that, is that the --

24 MS. MCBURNEY: Yes, I do.

25 CHAIRMAN CERQUEIRA: -- anybody opposed to

NEAL R. GROSS

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

1 keeping it on the agenda?

2 MR. ESSIG: Let me just add one point,
3 though.

4 CHAIRMAN CERQUEIRA: Sure.

5 MR. ESSIG: That we'll do a little role
6 reversal. I'm going to give you some advice.

7 CHAIRMAN CERQUEIRA: Okay.

8 MR. ESSIG: Okay. The advice that I would
9 give you is that recognize that the Commission has
10 already endorsed the need to regulate NARM, specific
11 sources now, not, probably not even those that are
12 used in most routine, run-of-the-mill diagnostic
13 programs.

14 And I'm sure PET isn't even on the radar
15 screen of concern. What the concern was that, as I
16 think I hopefully mentioned earlier today, when I was
17 describing it as the whole source security issue that
18 we're dealing with now for Atomic Energy Act material.

19 The impetus for the NRC proposing to the
20 White House that we jump on this bandwagon was the
21 idea that there may be some sources, either discreet
22 naturally occurring materials, like Radium 226, that
23 were used a number of years ago in medical
24 applications.

25 Or some discreet sources of

NEAL R. GROSS

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

1 accelerator-produced materials, although maybe not
2 used in medical applications, might be used in other
3 applications like industrial radiography and so on.

4 My advice would be that you just simply
5 recognize that the Commission has some concerns over
6 the security of all sources, including
7 accelerator-produced, and that was the basis for
8 mentioning, for endorsing that proposal to Congress.

9 And then you can say, however, the baggage
10 that goes with that, as far as we're concerned, is
11 that NRC would be regulating, as Jeff was saying, in
12 the states that opt not to become agreement states,
13 that we would then be the regulatory authority.

14 And the baggage that goes with it, is that
15 we, the NRC then, would be regulating things like PET.
16 But we didn't start off to do that. We started off to
17 level the playing field in terms of security sources.

18 DR. WILLIAMSON: So I think to --

19 MR. ESSIG: So that's an important point
20 to recognize so you don't --

21 CHAIRMAN CERQUEIRA: Right. I think Ralph
22 --

23 MR. ESSIG: -- because you're weighing in
24 on something the Commission has already decided more
25 or less to do for a different reason and just

NEAL R. GROSS

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

1 recognize that.

2 DR. WILLIAMSON: To maybe argue that for
3 these medical sources, there isn't really this
4 security risk. And bring that point that we're going
5 to have to suffer and maybe our patients will suffer
6 and, you know, it's going to cause, certainly a lot of
7 confusion and chaos with no really incremental
8 improvement in safety, public safety in this sphere of
9 unauthorized usage of sources. Okay.

10 CHAIRMAN CERQUEIRA: Excellent. Ralph,
11 you've got all this down. We're behind you, don't
12 worry.

13 MR. LIETO: Verbatim.

14 (Laughter.)

15 CHAIRMAN CERQUEIRA: Yeah, I think they
16 are good points, yeah.

17 DR. VETTER: Have the agreement states all
18 been notified of the existence of the program?

19 MS. MCBURNEY: Oh, yes.

20 MR. LOHAUS: Yes.

21 DR. VETTER: Have the non-agreement states
22 who are applying to become agreement states, been
23 notified of the program?

24 MR. LOHAUS: Yes. And when you refer to
25 the program, you're talking about --

NEAL R. GROSS

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

1 DR. VETTER: The National Materials
2 Program.

3 MR. LOHAUS: Yes. As a matter of fact,
4 one of the things that we've tried to do is to have a
5 very open process. And at the CRCPD meeting we had a
6 special topic session, where each of the Chairs for
7 each of the five pilots presented information on what
8 we're doing.

9 And we answered questions and talked about
10 some of the issues that we're going to have to be
11 dealing with. We were trying to get everybody
12 thinking about this and feeding back into the process.

13 And I agree, Dr. Cerqueira, that earlier
14 is better than later. And we do seek and desire, and
15 the Commission does desire and seek feedback. And
16 that was identified in their SRM. So, and I know and
17 appreciate the earlier comments that you all provided
18 to us.

19 And those, we have those and they are
20 being factored into our process as well. So, that's
21 --

22 CHAIRMAN CERQUEIRA: So, I think there's
23 agreement. Now, Ralph, what other issues do you have
24 for Paul? Is that it?

25 MR. LIETO: Well, I think the issues about

NEAL R. GROSS

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

1 the costs, that was going to be one of the other
2 points, was that, again, it came from the state
3 versus, the state issues in that the current structure
4 is that the cost of the program from NRC is a
5 fee-based program that, you know, basically you have
6 to assign fees to cover your annual operating budget,
7 okay.

8 And that, with this shift in the program,
9 okay, there is a concern that how is that program
10 going to be able to be maintained without
11 significantly increasing the cost to NRC-regulated
12 licensees, okay, with that type of structure.

13 In that there really needs to be a part of
14 the, or the funding mechanism needs to be a part of
15 the Congressional. A suggestion would be that if
16 you're going to go this way, you need to look at,
17 relook, re-evaluate in the way that you could do the
18 funding.

19 MR. LOHAUS: That's a, yes, a very good
20 point. And the key for the consideration by
21 Commission in looking at the National Materials
22 Program, because the thought is if you look at this,
23 about 75 percent of the licensees are in agreement
24 states, yet the bulk of the infrastructure work is
25 basically done by NRC.

NEAL R. GROSS

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

1 And part of the concept in the National
2 Materials Program. And it's reflected in the alliance
3 process is that there be a shifting, if you will, a
4 more equitable shifting and shearing of the
5 infrastructure work load by the states in state
6 licensees. And that part of the concept.

7 But, again, there is a long way to go
8 before that comes out and the question of funding and
9 how you handle that in fees and things like that is a
10 very key issue here because of the --

11 DR. WILLIAMSON: You still face the issue
12 that you're going to take over a whole bunch of
13 non-agreement states' programs, probably, in this
14 area. And, you know, you have to develop in-house
15 expertise to handle TARs and accelerator expertise and
16 so on, and this is a concern of ours.

17 MS. MCBURNEY: You're just trying to make
18 a NARM issue.

19 CHAIRMAN CERQUEIRA: The NARM issue. We
20 need to keep going, otherwise -- any other questions
21 for Paul?

22 DR. WILLIAMSON: I mean I think the idea
23 of apple pie and motherhood and so on applying to the
24 existing domain, you know, is one thing, and maybe it
25 will help save some costs. Maybe there is a chance.

NEAL R. GROSS

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

1 But I think, you know, the concern of the
2 committee, as expressed in our last meeting, is you
3 are now introducing a new source of disequilibrium and
4 funds are going to flow in and out.

5 The states are all strapped for budgets,
6 maybe even more than the federal government, since
7 they can't deficit spend and to sort of expect the
8 states to take on part of this infrastructure load may
9 not be very realistic.

10 CHAIRMAN CERQUEIRA: Excellent point.
11 Okay, Ralph, anything else for Paul?

12 MR. LIETO: Thank you, Paul.

13 MR. LOHAUS: Okay, thank you very much.

14 CHAIRMAN CERQUEIRA: Thank you. We
15 appreciate you spending your time. All right, so,
16 Ralph, do you have any other points?

17 MR. LIETO: No.

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

20 MS. MCBURNEY: Mine is on the emerging
21 technologies and issues subcommittee. And basically
22 I'm going to be just talking about the process. And
23 then if we can reach consensus tomorrow on some, and
24 identify some of the issues involved with the three
25 initial licensing guidance input that we have asked to

NEAL R. GROSS

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

1 do, then I will bring that up at the briefing.

2 But, in order to do slides, I could only
3 do what we have done so far, and that's identify the
4 --

5 DR. WILLIAMSON: We haven't done anything
6 so far. I mean, I'm supposed to be on the
7 subcommittee, I've never gotten a call about a
8 meeting.

9 MS. MCBURNEY: I sent out an e-mail asking
10 for input early on. I didn't get any, and so we are
11 meeting at this meeting and that's part of tomorrow's
12 agenda.

13 DR. WILLIAMSON: Okay.

14 CHAIRMAN CERQUEIRA: Right, right. And
15 there's going to be quite a few items on the agenda
16 from the various interest groups tomorrow, that I
17 think will -- but unfortunately I think it's just
18 going to be, you know, another turf issue that's going
19 to come up, and I'm not sure how much --

20 MS. MCBURNEY: On the training experience
21 issue.

22 CHAIRMAN CERQUEIRA: Right. Right.

23 DR. NAG: One question on that. Is there,
24 I mean I've heard rumors, a move to get interstitial
25 brachytherapy out of 1,000 and into the regular

NEAL R. GROSS

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

1 brachytherapy? And if so, what mechanism? That's
2 one. Number two, what is the mechanism when it's
3 something new coming up, it comes under 1,000, but
4 once it becomes an accepted practice, after two or
5 three or four years, it will have to go under one of
6 the other therapies, what mechanism for that?

7 CHAIRMAN CERQUEIRA: That's sort of an NRC
8 staff question. I don't, do we have a precedent that
9 something was approved under the 1,000 --

10 DR. NAG: Well, the 1,000 just came out.
11 So there will be no precedent. But, I mean, you can
12 never, if something is emerging, I mean, you know,
13 something emerges then it becomes a routine.

14 MR. ESSIG: Well, I suppose you would
15 contemplate a rule making initiative at some point.
16 Either from outside --

17 DR. HOWE: I think you could look at the
18 gamma knife and the HDR and you'd see. I think you
19 could look at the gamma knife and the HDR and see that
20 those were new technologies back in the '90s.

21 They developed to the point where there
22 was enough use and enough licensees needing it, that
23 it became a part of the new Part 35. You're wrong in
24 that there maybe some emerging technologies that never
25 are large enough to require rule making.

NEAL R. GROSS

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

1 There may be some very small things that
2 are emerging technology that may stay in 1,000
3 forever. Now there may be other technologies that
4 really take off, and it becomes a point where they
5 justify their own particular rules.

6 And then you would want to go through the
7 rule making process like you did with the gamma knife
8 and the HDR, to bring that guidance into a legitimate
9 --

10 DR. NAG: I mean in that, I mean, for
11 example, interstitial brachytherapy in 1,000, but if
12 you're using iridium afterloading, that's the same as
13 brachytherapy.

14 And if you are using a high dose rate for
15 intravascular HDR brachytherapy. So at some point
16 things will have to be moved. Then this is something
17 that I heard over the grapevine that once the
18 intravascular brachytherapy has been moved into
19 brachytherapy, this just a little more, there is
20 something about that. Does anyone know?

21 DR. HOWE: At this point, for NRC it's a
22 rumor. We, it was indicated in the Statements of
23 Consideration as a 35.1000 use. And so that's where
24 it is right now with its guidance up on the web site.

25 CHAIRMAN CERQUEIRA: So, do we want to

NEAL R. GROSS

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

1 bring that up before the Commissioners? I'm not sure
2 we have anything --

3 DR. NAG: If we don't have anything, I
4 wouldn't --

5 CHAIRMAN CERQUEIRA: Okay, so we agree not
6 to do that. What else, so basically, and what
7 potential could emerge tomorrow from the discussions?

8 MS. MCBURNEY: If we get some consensus on
9 training experience, for example, for each of those
10 three items. I've got an outline of what I'd like to
11 go over.

12 DR. WILLIAMSON: Could I ask a question of
13 clarification?

14 CHAIRMAN CERQUEIRA: Yes.

15 DR. WILLIAMSON: I think it would be, many
16 of the proposed recommendations make reference to the
17 vendors' product insert and instructions for dosimetry
18 and so on. Could that be made available to us
19 tomorrow so we can have that to refer to you?

20 Could we get copies of them? Because I
21 think it is going to be very difficult to conduct a
22 technical conversation about these things without that
23 material. We once had it, I think about two years
24 ago, two or three years ago.

25 I remember seeing the TheraSphere product

NEAL R. GROSS

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

1 insert duplicated. But since the, you know, your
2 proposal makes reference to that, we're going to have
3 a tough time if we don't have a copy.

4 DR. NAG: We've never seen a Sirtex
5 insert. We had seen, there was a small presentation
6 from TheraSphere from, from MDS Norton, but we've
7 never had a presentation from Sirtex.

8 Which is similar in some ways, but
9 dissimilar in many other ways.

10 DR. WILLIAMSON: So, we need those
11 materials.

12 MR. ESSIG: I'd have to ask my staff here.
13 Do we know if we have those?

14 DR. HOWE: We have some of those
15 materials. Are you talking about everything in 1000
16 or --

17 DR. WILLIAMSON: No, no, just the products
18 that are going to be discussed tomorrow.

19 DR. NAG: The iodine for leocite. The
20 Sirtex.

21 DR. HOWE: Because tomorrow, at one point
22 or another, we're talking about all the things in
23 1000.

24 DR. WILLIAMSON: Well, I think the use, I
25 guess, if you're involved in orchestrating the

NEAL R. GROSS

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

1 discussion and you know the proposals make reference
2 to, you know, those vendor supplied materials, I'd say
3 use some judgment in, you know, duplicating what you
4 think would be necessary for us to be able to have an
5 -- because otherwise we're going to be asking, well,
6 you say you recommend what the vendor says to do, and
7 then you'll have to be telling us all about what the
8 vendor said.

9 MR. ESSIG: I mean, if we have some vendor
10 supplied material, we'd be happy to share it with you.
11 It's just --

12 DR. WILLIAMSON: Well, you must, because
13 you based your proposed -- I read through the slides
14 and they make references to it that you would endorse
15 certain --

16 DR. HOWE: In most cases we talk about
17 vendor training because we believe the vendor is the
18 best person to train people on the new device. They
19 know the ins and outs, they want the product to roll
20 out while they have the knowledge base.

21 But I don't think we talk about following
22 other package inserts, because we're not tied to
23 package inserts. Although we do for, the question
24 came up on how do you determine if you've got the
25 material into the, you know, you have source material

NEAL R. GROSS

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

1 left over, you have material left over at the end and
2 the vendors have come up with some radiation detection
3 devices that they measure certain distance around the
4 four sides of the delivery system, and we allow that
5 to be used.

6 DR. WILLIAMSON: Here's where your
7 proposed guidance, on Page 2 of 7, for Y-90
8 microspheres prescribed dose means the total dose
9 documented in the written directive.

10 And somewhere in here you made reference
11 to how it was specified by the --

12 DR. NAG: I think the first thing that we
13 are asking is that some of us may have some idea what
14 Sirtex is, what TheraSphere is. And others may have
15 absolutely no idea.

16 Now we cannot give you any knowledgeable
17 guidance if we have no idea what it is. So if you
18 have any information on what that product is, and I
19 mean, I know all of these, something, they do have a
20 brochure that they have sent out. I have it at home.
21 Just, I mean, give us those handouts.

22 MS. SCHWARZ: These are the ones that I
23 mentioned here in your slides.

24 DR. HOWE: A lot of the information we
25 have is from direct communications with the

NEAL R. GROSS

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

1 manufacturers on how their product works, etcetera.
2 And so we don't --

3 DR. NAG: They didn't give you those
4 handouts? Normally, I think, I get, we are consumers
5 so they send it to us. We have it.

6 DR. HOWE: We don't necessarily have all
7 the labeling that goes with it. In some cases we have
8 the labeling that was submitted with the premarket
9 approval applications, that have since been updated.

10 I mean we try to stay current with what
11 they're doing by talking to the manufacturers, but I
12 don't believe we've tied anybody to the package
13 insert. We tie it to the written directive, but
14 that's, that's not the same as a package insert.
15 That's the NRC written directive.

16 DR. WILLIAMSON: Oh, I understand the
17 difference.

18 DR. HOWE: Yeah.

19 DR. NAG: They didn't give you a three or
20 four page thing about what, you know, and what the,
21 and how it is --

22 DR. HOWE: We have some documentation on
23 that, but we don't necessarily have the most recent
24 stuff that the manufacturer has.

25 DR. NAG: It doesn't have to be most

NEAL R. GROSS

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

1 recent. It has to be something that says what it is
2 and how, what are the safety problems and how the
3 manufacturer addressed the safety problem. I know
4 they do have that in their handout.

5 CHAIRMAN CERQUEIRA: So you would like
6 that material tomorrow?

7 DR. NAG: If you have it.

8 CHAIRMAN CERQUEIRA: If you can find it.

9 DR. HOWE: We'll try.

10 CHAIRMAN CERQUEIRA: If you can get
11 copies, that would be fine. If you can't, I think we
12 can go on. If the manufacturers were here, they
13 probably would have it.

14 MS. MCBURNEY: For our initial charge for
15 the subcommittee is just limited to the IBB, they Y-90
16 microspheres and the GliaSite. And part of what I
17 would like to get input from the subcommittee on is
18 the training experience.

19 What sort of physician training? How much
20 vendor training? If there's to be a team approach,
21 what's the team to be comprised of? Presence and
22 duties of the team members, and the written directive
23 content.

24 DR. NAG: And what time, what time do we
25 have for the subcommittee to meet? Are we going to

NEAL R. GROSS

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

1 meet separately or --

2 MS. MCBURNEY: It's at the end of
3 tomorrow. It's like from 3:00 --

4 DR. WILLIAMSON: I think another issue
5 we'll have to take on with all these specialized
6 devices is to what extent is NRC going to step in and,
7 you know, basically, impose upon users the requirement
8 to follow exactly the product insert or the, you know,
9 and so forth.

10 For example, in intervascular
11 brachytherapy they limited the indications that are
12 allowed under NRC licensing guidance to in-stent
13 restenosis.

14 DR. HOWE: That was originally. We're now
15 a much broader authorization. It's for intravascular
16 brachytherapy use.

17 DR. DIAMOND: But we had a guidance
18 document issued, oh, it's been over a year now, that
19 clarified the issue that no longer would it be
20 construed that an off-label use of one of these
21 devices would be considered a misadministration.

22 So, for example, at our institution, we
23 routinely will go and use vascular brachytherapy for
24 in-stent restenosis in the peripheral arterial system.
25 We've done saphenous vein grafts.

NEAL R. GROSS

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

1 We've done brachycephalic arteries,
2 arterial venous fistulas, the whole works, following
3 that guidance released over a year ago.

4 CHAIRMAN CERQUEIRA: Yeah, that's good.
5 But this is going to be on tomorrow's agenda. And you
6 know, it's ten to six, we really kind of need to wrap
7 up the Commissioner's Briefing and not go over all of
8 these points tomorrow.

9 So that would take, right. And then, you
10 know, we can see what, some of your things, and then
11 it sounds like the SNM is going to be here and so
12 there's going to be quite a bit of a --

13 MS. MCBURNEY: And ASTRO and some of the
14 others.

15 DR. WILLIAMSON: Perhaps, it will not be
16 possible for you to make a good outline of slides
17 until after tomorrow. You know, it's very speculative
18 what the major issues would be.

19 CHAIRMAN CERQUEIRA: And I think you have
20 to be aware that, you know, we want to get them to the
21 Commissioners, but at the same time some of these
22 issues are only going to be discussed today and
23 tomorrow and, okay.

24 And, Dick, do you want to go over the T
25 and E recommendation.

NEAL R. GROSS

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

1 DR. VETTER: Sure. T and E. The purpose
2 of this was simply to bring the Commission up-to-date
3 on the ACMUI T and E recommendations. The first thing
4 I want to do is express to them our appreciation for
5 the opportunity to address T and E issues through an
6 ACMUI subcommittee mechanism.

7 The, Slide 2, Page 2, shows that we still
8 do, we have the old method for becoming an authorized
9 RSO, AMP, nuclear pharmacist or authorized user. It's
10 through the old Subpart J, but this is very temporary.

11 You know, this was not very prescriptive.
12 Certification by Boards on a list or meeting some
13 specific training requirements. The revised 10 CFR
14 35.50, was very prescriptive requiring Boards to
15 incorporate into their qualifications very
16 prescriptive training requirements.

17 ACMUI had a problem with this because it
18 created some unintended consequences. There was only
19 one Board, out of the many Boards in the country, that
20 met these requirements.

21 None of the others met the requirements
22 which resulted in an increased burden on NRC staff to
23 look at the alternate pathway qualifications for
24 everyone who wanted to become any one of these
25 authorized individuals.

NEAL R. GROSS

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

1 We felt it marginalized Board
2 certification and it undermined and affected industry
3 standard. Consequently, the ACMUI called this to the
4 Commission's attention in February of '02, appointed
5 a subcommittee that same month who's charge was to
6 develop a proposal establishing Board certification as
7 the default pathway.

8 DR. WILLIAMSON: But they know all this.
9 So, do we want to spend all this time going over the
10 history? Because they're the ones who have thrown the
11 ball back in our courts now.

12 DR. VETTER: Well, that's what the, you,
13 let me finish and you can tell me. So far, how much
14 time have I used? Okay, ACMUI subcommittee then held
15 a public meeting, they held two public meetings.

16 Made recommendations to NRC in August of
17 last year. Options made for October 30th. The
18 Commission made their decision on February 12th. The
19 Commission decided to accept the recommendation of the
20 ACMUI to allow Boards to certify these authorized
21 individuals rather broadly, rather than requiring
22 Boards to incorporate various prescriptive
23 requirements for recognized individuals.

24 However, the Commission did re-institute,
25 against the ACMUI's recommendation, the preceptor

NEAL R. GROSS

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

1 certification. The impact of that decision is that
2 default pathway through professional Boards has been
3 re-established as was currently present in the
4 temporary Subpart J.

5 And this will now allow many Boards to
6 certify individuals who will meet the requirements for
7 the various responsibilities in Part 35. However, it
8 does not, it does create the problem relative to
9 preceptor requirements.

10 What I'd like to say about that is, ACMUI
11 is very happy to work with the NRC staff to resolve
12 satisfactory implementation of it. And that's the end
13 of the story. What did I leave out, that you think I
14 should be --

15 DR. WILLIAMSON: Well, I think, you know,
16 the residual issues that are of importance is if the
17 preceptor requirement is left in as a Board
18 qualification criteria --

19 DR. VETTER: I'm not going to say that.

20 DR. WILLIAMSON: Yeah, but that's a
21 problem. None of the Boards will probably comply with
22 that because they don't require the people who sign
23 off on the diplomates to be authorized users or
24 authorized medical physicists on licenses and so on.

25 That's a little different kind of world.

NEAL R. GROSS

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

1 And so I think to comment that that's one problem we
2 have to resolve. You know, a second problem that was
3 raised is the C-3, the 190, no, the 100, 200 and 300
4 categories still mention hours of combined didactic
5 and practical experience with, you know, sort of an
6 outline of what that's supposed to consist of.

7 And then we have to determine, you know,
8 whether the ABR diagnostic radiology and the various
9 nuclear medicine Boards satisfy that requirement.

10 So it might be necessary to fine tune
11 these. Maybe we don't want to say that to them. I
12 don't know what's wise and prudent to say to them.
13 But that's the issue. That's what really has to be
14 done. Is we have to really --

15 CHAIRMAN CERQUEIRA: Let's go back and try
16 to deal with each one of those. Because, you know,
17 the thing with the preceptor statement, we had put in
18 pretty strong recommendations to take that out, but it
19 came back as in there.

20 And the reason we had put this in, in the
21 beginning, Jeff, was, you know, this whole, we wanted
22 to put some bite into that preceptor statement so that
23 the NRC didn't have to assume the responsibility.

24 And that's why we put it in originally.
25 And I think the NRC, at this point, is quite willing

NEAL R. GROSS

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

1 to let the Board, you know, it's not a competency,
2 it's mastery of the body of knowledge for clinical,
3 which is what we tried to make.

4 You know, the ABR tried to make and I
5 think Roger's committee, to some extent, was going in
6 that direction. But it seems like what Roger
7 presented today was, you know, a shifting of what this
8 consists of.

9 DR. WILLIAMSON: He's now in the room.

10 CHAIRMAN CERQUEIRA: Well, I'm not going
11 to say anything nasty.

12 DR. WILLIAMSON: The CRM says preceptor
13 requirement has to be there, okay. And the only way
14 to eliminate that as a requirement is to make a pitch
15 to the Commission to change their SRM.

16 Now, I don't know if that's wise or
17 prudent to go after that because it was a three to two
18 vote. I think maybe to point out that it's a problem
19 and that, you know, we'll accommodate it, you know,
20 probably by rewriting the logic of the rule.

21 One, you know, there are some other
22 solutions that I think would keep Board certification
23 as an important component.

24 CHAIRMAN CERQUEIRA: And it wasn't clear
25 to me by how we were going to do that as a result of

NEAL R. GROSS

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

1 today's discussion. There was this mention made that
2 we could define it as, you know, this competency was
3 mastery of a body of knowledge that can be --

4 DR. WILLIAMSON: That's a different issue,
5 actually. That's a different issue, yes.

6 DR. NAG: That's a different issue. The
7 word competency versus having mastery --

8 CHAIRMAN CERQUEIRA: But isn't that in the
9 preceptor statement?

10 DR. WILLIAMSON: No. That's not in,
11 that's in the purpose of the exam. We specified that
12 one of the required components of a recognized Board
13 certification process is that it has an exam that
14 tests the competency of the x, y, z to, you know, do
15 a, b, c.

16 So, you know, it was recommended that we
17 have to change that, and it sounds like that can be
18 done without running afoul of the Commission's SRM.
19 But this issue of the preceptor is sort of a hard
20 constraint as far as the staff is concerned.

21 You know, they can't change that and make
22 that go away. The only people that can make that go
23 away are the Commissioners. So, you know, I think
24 that a --

25 CHAIRMAN CERQUEIRA: So what do we tell

NEAL R. GROSS

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

1 them? We already told them the first time.

2 DR. WILLIAMSON: Well, I think we tell
3 them that, you know, this could potentially pose a
4 problem, but that we'll look at taking it out of the
5 requirements for Board certification process and
6 sticking it in as an additional requirement at the
7 end, along with the modality-specific training.

8 That would be a logic solution. So then
9 --

10 DR. DIAMOND: So, Jeff, when they ask why,
11 how do you respond?

12 DR. VETTER: I would recommend we not
13 propose any specific mechanism for taking care of that
14 at the Commissioner level. That we simply say we are
15 happy to work with the staff to accommodate that. And
16 leave it wide open.

17 CHAIRMAN CERQUEIRA: Given their short
18 time line of July 1st, of getting it back to the
19 Commissioners and, you know, that puts a certain
20 amount of motivation to get it done.

21 DR. WILLIAMSON: Well, you see, I think
22 it's an issue of strategy. If we felt that this would
23 destroy the proposal. Okay, to have the preceptor
24 requirement would mean that no Boards could qualify as
25 being recognized by NRC.

NEAL R. GROSS

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

1 We'd be back where we started, wouldn't
2 we? But, I think maybe there are some possibilities.

3 MS. MCBURNEY: Are most, are most Program
4 Directors not authorized users?

5 DR. EGGLI: Most Program Directors are not
6 authorized users.

7 CHAIRMAN CERQUEIRA: Right. Certainly
8 that's true in cardiology.

9 DR. EGGLI: For diagnostic radiology
10 residence use, most Program Directors are not
11 authorized users. For diagnostic radiology residency
12 it would be rare for the Program Director to be an
13 authorized user.

14 For a nuclear medicine residency, it would
15 be very likely that the Program Director was an
16 authorized user.

17 DR. NAG: In therapy they could be or --

18 DR. EGGLI: Or could not be, yeah.

19 CHAIRMAN CERQUEIRA: Right. So what do we
20 want Richard to say to them?

21 DR. WILLIAMSON: Well, that's why I'm
22 bringing the issue because what we say to them really
23 depends on our perception of how we can accommodate
24 this requirement without destroying the integrity of
25 Board certification.'

NEAL R. GROSS

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

1 That's why I'm bringing it to your
2 attention.

3 CHAIRMAN CERQUEIRA: So how do we do that,
4 Tom?

5 DR. NAG: I think we can --

6 CHAIRMAN CERQUEIRA: No, let's get from
7 Tom. Tom, how do we do that? Based on your, you
8 know, intimate contact with the --

9 DR. WILLIAMSON: Okay, I think that Rich,
10 that Dick should have a phone conference, a telephone
11 conversation with Roger or whoever and determine
12 whether it's feasible to, you know --

13 CHAIRMAN CERQUEIRA: Roger is right here.

14 DR. WILLIAMSON: -- yeah, to stick this
15 outside of the Board qualification section.

16 CHAIRMAN CERQUEIRA: Roger, why don't you
17 come forward while we have you here.

18 DR. BROSEUS: Well, be nice to me.

19 DR. WILLIAMSON: You know, anything that's
20 really, really, yeah.

21 DR. BROSEUS: -- a couple of weeks ago,
22 she said be prepared to duck. And I didn't understand
23 what he meant.

24 DR. VETTER: At least he didn't say "die".

25 CHAIRMAN CERQUEIRA: So what strategy do

NEAL R. GROSS

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

1 we take? I mean, with the issue of, you know, the
2 preceptor?

3 DR. BROSEUS: Let me tell you where the
4 working group is right now. First of all, to interpret
5 in the supplementary information, the meaning of
6 competency as being training and not being clinical
7 competency.

8 Okay, that's number one. Now number two,
9 the way we read things, in the SRM and so on, is the
10 Commission said don't change the preceptor statement
11 and certification by an authorized user is basically
12 a requirement as we read this.

13 So, what are the alternatives? That's
14 what I hear being discussed. One alternative might
15 be, you know, once this rule goes out, it isn't
16 decided. It's at the proposed rule stage, and so
17 there are other alternatives during the proposed rule
18 stage, for comments to come in, you know.

19 And if the staff sees good arguments. I'm
20 speaking now for myself as the working team member,
21 not having had this good before management, but I
22 think that this is a fairly valid statement.

23 If we see good reasoning coming in, maybe
24 even as a result of our discussions with Dick and so
25 on and you, you know, we may put that into the

NEAL R. GROSS

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

1 supplementary information or the discussions of where
2 we are with getting to the proposed rule. So I think
3 there are several ways to skin the cat.

4 DR. DIAMOND: Like what?

5 DR. BROSEUS: Like what I just said, and
6 I guess I wasn't clear. And that being that --

7 DR. WILLIAMSON: What's supplementary
8 information?

9 DR. BROSEUS: Well, we'll have, there will
10 be, there will be, I'll call preamble, front matter
11 before the proposed rule language, which is the
12 discussion of how, the rationale for the what the
13 proposed is.

14 And if we get additional information at
15 this point, I think it might be possible to say at the
16 proposed rule stage that ACMUI or others have said,
17 you know, a Program Director might be the more
18 appropriate person to do this certification.

19 And so offer that as an alternative.
20 Offer it for public comment, and possibly go to the
21 Commission with that. That's my understanding of the
22 rule making process.

23 DR. NAG: Why can't we do that now? Why
24 can't we go to the Commission now and say, you know,
25 the discussion here has led to the suggestion that the

NEAL R. GROSS

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

1 Program Director is the most appropriate person? I
2 mean we have already made those comments.

3 DR. BROSEUS: I would expect that there is
4 certainly an alternative, but things move slowly. You
5 also have new Commissioners, so the makeup of the
6 Commission isn't the same.

7 MR. LIETO: Can I make just a couple of
8 points. And this also refers to one of Dick's slides
9 also. Preceptors don't certify, okay. And I thought
10 we kind of had that, made that point. So, I mean,
11 again, I don't know if it's an old terminology that
12 kind of has come back or whatever, because this was
13 like in the proposed comments where, that this issue,
14 this specific issue came up.

15 Preceptors don't certify, okay. I mean
16 they never can and they never will. So, again, it may
17 be semantics, but it gets to this whole issue also
18 about the competency issue too, okay.

19 That, I think that, and I would like to
20 again make the recommendation, that competency go into
21 like a definition to Part 35, okay. I know that
22 they're talking about putting it in the preceptor
23 statement, okay.

24 The preceptor statements can change from
25 one administration to the next. And I think that it

NEAL R. GROSS

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

1 really needs to go in the definition of the rule, as
2 to what they are testing the competency of.

3 Okay, which is the issue that you've
4 already covered.

5 CHAIRMAN CERQUEIRA: I'm totally confused
6 on this now. I thought I understood it, you know.

7 DR. BROSEUS: I've heard two different
8 issues. One is what does competency mean, and the
9 other one is, does it have to be signed by an
10 authorized user or can it be a Program Director?

11 DR. WILLIAMSON: Those are the two issues,
12 but is there enough wiggle room in what the Commission
13 said in their SRM that competency can be redefined as
14 mastery of knowledge and body of skill?

15 DR. BROSEUS: Not anymore.

16 CHAIRMAN CERQUEIRA: See, it was my
17 understanding that the competency thing was strictly
18 in the preceptor statement. Now Jeff is telling me
19 that that's been put back into the Board. And I, you
20 know, and again, this thing is hard to read.

21 You know, first off, the pages are flipped
22 and everything else, but, you know, if I'm confused,
23 and I'm the Chairman, and I, you know.

24 DR. BROSEUS: I don't blame you for being
25 confused, there's a lot --

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Well, no, no, no, no,
2 no. But thing is, I thought we were on track. I mean
3 those of us who have been involved in the process,
4 there was a certain logic and flow to things. And I
5 thought that was included in Dick's proposal. But now
6 it's just kind of come out all --

7 DR. BROSEUS: We have identified really a
8 third issue. And that is that -- sorry, I'm not close
9 enough to the mic, thank you. As I understand it,
10 that ACMUI's intent was not to have a preceptor
11 statement as part of the qualifications, the criteria
12 for recognizing a Board certification process.

13 CHAIRMAN CERQUEIRA: I thought that was in
14 the revision of Part 35, and did we take it out
15 completely from your, the original?

16 DR. WILLIAMSON: No, no. We put it back
17 in as a Program Director's testament.

18 CHAIRMAN CERQUEIRA: Right, and then it
19 was sent back to us as, you know, as you need it to
20 certify competency.

21 DR. WILLIAMSON: That's correct.

22 CHAIRMAN CERQUEIRA: But that was in the
23 preceptor statement.

24 DR. WILLIAMSON: Yeah, well, I think that
25 there were, you know, multiple issues here. If you

NEAL R. GROSS

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

1 look at, for example, the physicist one here. I'm
2 trying to find it, on what page it is.

3 DR. EGGLI: Well, should I read
4 Commissioner Meserve's comment in that regard?

5 DR. WILLIAMSON: Well, let me just find
6 the section here under authorized medical physicist.
7 Okay, it says --

8 CHAIRMAN CERQUEIRA: See, but this applies
9 to the health, you know, to the medical physicist, to
10 the authorized user.

11 DR. WILLIAMSON: Here. Passes an
12 examination administered by diplomates of the
13 specialty Board which assess knowledge and competency
14 in clinical radiation oncology.

15 And so this was the concern that this is
16 not what the ABR and other organizations bill their
17 exams as about. So, you know, I think a third issue,
18 if you want to call it that, is to strike the
19 competency word out of the section describing the
20 Board examination, because otherwise it's making the
21 Board squeamish about --

22 DR. BROSEUS: Is that in the, I don't have
23 the stuff --

24 DR. WILLIAMSON: This is in your draft
25 rule text, and it was in our draft rule text as well.

NEAL R. GROSS

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

1 So this is a correction. I would have thought maybe
2 this is relatively minor since, you know, perhaps the
3 Commission didn't pick on this particular point.

4 DR. BROSEUS: Well, in my reading, if it's
5 in what the exam does, that's certainly within the
6 purview of ACMUI to change its mind.

7 DR. WILLIAMSON: Okay, so we can fix that.

8 CHAIRMAN CERQUEIRA: So we can recommend
9 that instead of competency, as documented by being a
10 diplomate or passing the Board, that that be changed
11 to represent mastery of a body of knowledge sufficient
12 to, you know, in a clinical setting, which is what I
13 think Dr. Hendee had said.

14 So is everybody in agreement with that?

15 DR. WILLIAMSON: I think so.

16 CHAIRMAN CERQUEIRA: And that's, again,
17 that's passing the Board. Now, just in terms of the
18 Boards alone, what are we doing about hours? Did the
19 Commissioners, were they willing to take that out?

20 Because I thought, I thought your proposal
21 that went through, certainly for the user, had hours.
22 It does.

23 DR. VETTER: That is not our proposal.
24 That's --

25 DR. EGGLI: No, but is the final revision.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: You know, I mean, so
2 --

3 MS. SCHWARZ: In the book there is a
4 section where the actual original that you compiled.
5 In the book that we received there is the listing as
6 Dick wrote it. But this is different.

7 DR. BROSEUS: Well, first of all, my
8 reading of that recommendation were for a certain
9 pathways to reference what was in the oral --

10 DR. WILLIAMSON: And we did that, that's
11 correct.

12 DR. BROSEUS: And that included hours.

13 DR. WILLIAMSON: That's right. It did.

14 CHAIRMAN CERQUEIRA: But the hours were
15 included as part of the alternative pathway.

16 DR. WILLIAMSON: No, that's not correct,
17 Manny. No, no, no, no. For 100, 200 and 300 we left
18 in, I think, 700 hours or whatever. Some number of
19 hours. And we said, we didn't specify the breakdown
20 between didactic and practical, but we said it had to
21 be didactic plus practical and enumerated the various
22 things it must include and this was just lifted out of
23 Subpart J.

24 DR. BROSEUS: Now let me add something to
25 that. My understanding of what training programs

NEAL R. GROSS

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

1 somebody has to go through, being at 700 hours is duck
2 soup.

3 DR. WILLIAMSON: Yeah.

4 DR. BROSEUS: And so to me, since it
5 doesn't specify it has to 40 hours, 60 hours there,
6 and so on, it's not a big deal.

7 DR. WILLIAMSON: So, anyway, I think that
8 this requires some discussion with the ABR to find
9 out, you know, if this is reasonable. But I would
10 have thought --

11 CHAIRMAN CERQUEIRA: Well, but the ABR is
12 not the only Board. We have, you know, for the
13 physicists we have Boards, for the physicians and for
14 the health physicists.

15 DR. WILLIAMSON: Well, this only applies
16 to 100, 200, 300, for the physics Boards, for the
17 Radiation Safety Officer and for the authorized user
18 of sealed sources, we eliminated the hours all
19 together. That is true.

20 MEMBER BROSEUS: I would recommend that
21 this particular issue be kind of tabled a little bit
22 and be discussed again when we're looking at
23 fine-tuning the words when we have our discussion
24 later on.

25 CHAIRMAN CERQUEIRA: But if this is due

NEAL R. GROSS

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

1 July 1st, we don't have that much time. And if we
2 have to meet with the commissioners next week, we have
3 to make some decision on what we feel the important
4 points are going to be so that Dick can make his
5 slides.

6 Mike has been waiting.

7 MR. MARKLEY: I think I have an approach
8 that you might want to consider. There at the draft
9 rule stage, if you have continuing concerns, it would
10 be very easy to itemize what those are.

11 And I think a good point that you could
12 deliver to the Commission would be, "We would like the
13 staff to explicitly solicit public comments on these
14 issues during the comment period." You could provide
15 them in the Federal Register notice and ask for that
16 kind of feedback.

17 CHAIRMAN CERQUEIRA: But, see, part of the
18 reason to move this forward was that we implemented a
19 rule which becomes in all the agreement states in
20 October 2005. We then put in this ability for people
21 to meet the criteria by both the new rule as well as
22 the old part 35.

23 And so in order to avoid in October of
24 2005 potential problems, we wanted to get this
25 revision of training and experience rulemaking done in

NEAL R. GROSS

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

1 time to be implemented.

2 In order to do that, we had to keep it on
3 track. And if we wait for public comments and
4 everything else, we're not going to be able to do
5 that. That may be the only option we have, but if
6 that's the case, we have to agree on that.

7 What I would like to try to do is salvage
8 it in some way possible if we can work with Roger and
9 his group to wordsmith the language so that everybody
10 is in agreement, but then we also need to make a
11 presentation to the commissioners to try to get their
12 buy in as much as possible. And that's on the 28th.

13 So those are the issues as I see it. Now,
14 if we can address those, then I think we can be done.

15 MEMBER BROSEUS: Just let me add that
16 during the board presentations this morning, our
17 discussions, I don't think this issue coming up was a
18 concern.

19 MEMBER WILLIAMSON: It was point number
20 one of Dr. Hendee's.

21 CHAIRMAN CERQUEIRA: To take out the
22 hours. He was confused about it.

23 MEMBER WILLIAMSON: No. We were confused
24 in our answer. There are hours in some of our --

25 CHAIRMAN CERQUEIRA: There are.

NEAL R. GROSS

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

1 MEMBER WILLIAMSON: Yes. And we said
2 there weren't.

3 CHAIRMAN CERQUEIRA: Yes, there are.

4 MEMBER VETTER: As the alternative pathway
5 and for --

6 MEMBER WILLIAMSON: No, no. That's not
7 true.

8 CHAIRMAN CERQUEIRA: But doesn't it say
9 that the board has as its requirements the hourly
10 requirements --

11 MEMBER WILLIAMSON: It does. So read what
12 we --

13 CHAIRMAN CERQUEIRA: So it's still tied
14 into it.

15 MEMBER BROSEUS: I think that Dr. Hendee,
16 though, expressed agreement with the approach that we
17 were taking in the end.

18 CHAIRMAN CERQUEIRA: But he was the only
19 one who made a presentation. He's one board. All
20 right? And I represent the physicians. We have the
21 physicists. Well, we don't have the physicists. We
22 have the radiation safety officer.

23 MEMBER BROSEUS: Well, we had all of them
24 --

25 CHAIRMAN CERQUEIRA: Right.

NEAL R. GROSS

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

1 MEMBER NAG: Dr. Hendee made that on the
2 basis that no hours --

3 MEMBER WILLIAMSON: We were mistaken.

4 MEMBER BROSEUS: We clarified in our
5 meeting this morning, the meeting of the boards, that
6 there were some sections in part 35 --

7 CHAIRMAN CERQUEIRA: You've told him
8 correctly. We mislead him. Okay? But that's not an
9 issue. The issue was, what does this Committee want
10 to do. You know, I think we had kept the hours in.
11 Do we want to just take them out and say that the --

12 MEMBER WILLIAMSON: Manny, could I just
13 rephrase your question a little bit?

14 CHAIRMAN CERQUEIRA: Okay.

15 MEMBER WILLIAMSON: We don't need to
16 decide what to take out or keep in at this point. I
17 think the key decision we have to make is what
18 questions require commissioner input.

19 So if this is a small change that we could
20 make in fine-tuning the rule language that doesn't run
21 afoul of the main points of their SRM, we can just do
22 it and we don't have to make a big deal next week.
23 But I think the --

24 CHAIRMAN CERQUEIRA: But the problem is we
25 are not sure if that is the case.

NEAL R. GROSS

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

1 MEMBER WILLIAMSON: No, we're not.

2 MEMBER BROSEUS: And I'm not either.

3 MEMBER WILLIAMSON: Yes. So I think we'd
4 better just mention it as an issue and not make a big
5 deal about it.

6 MEMBER BROSEUS: At the same time, this
7 gives us an opportunity to put the right spin on it
8 before the commissioners that eventually have to buy
9 it off. So it is an opportunity for us. And that's
10 why --

11 MR. ESSIG: I wanted to come back to what
12 you got from the Office of the Secretary emphasized in
13 two places where it says ACMUI should provide some
14 positive recommendations how the Committee feels it
15 can assist the NRC staff.

16 In another place, it says, "How can the
17 ACMUI help the NRC?" I think if you raised this
18 particular issue, saying, you know, you respect the
19 Commission's decision, and so it's caused us to have
20 to do some things. And here's how we're going to help
21 the staff make those things happen.

22 And so just present it in a way so the
23 Commission clearly sees that you intend to make a
24 contribution to help the staff; in other words, to
25 provide the advice that the Committee is supposed to

NEAL R. GROSS

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

1 provide.

2 CHAIRMAN CERQUEIRA: But we should give
3 them some indication of the direction we want it to
4 go. I mean, that's putting a spin on it.

5 MEMBER WILLIAMSON: I think one issue is
6 fairly clear that we can put a spin on it, and that's
7 I think that we have to say, I think, that it's still
8 our view that the issue of whether the person in the
9 board certification process attesting to the
10 candidate's readiness to sit for the exam has to be
11 decoupled from this concept of preceptor as an
12 authorized user or authorized medical physicist
13 because that is not practical given the way these
14 programs are structured.

15 It will be back at square one if we can't
16 fix this. So we will work with -- the subcommittee
17 will continue working with the staff to figure out how
18 to preserve the integrity of the board certification
19 structure in this process and try to take this into
20 account. That's the best we can say.

21 MEMBER BROSEUS: Is that coupling
22 necessary for anything other than authorized users,
23 like AMPs or ANPs?

24 CHAIRMAN CERQUEIRA: That's how we got
25 into this problem in the first place, was because most

NEAL R. GROSS

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

1 of the medical physicist programs, people didn't have
2 to take all the requirements. I mean, they could
3 dabble in one area or another. And we wanted to try
4 to make it more specific.

5 MEMBER WILLIAMSON: The problem is that
6 the boards do not require that the individuals
7 attesting to the candidates' knowledge base or
8 whatever, completion of the training program, whatever
9 word is appropriate, need not comply with this
10 additional requirement.

11 CHAIRMAN CERQUEIRA: So this side of the
12 table has been fairly quiet. I mean, Ralph, how do we
13 get out of this? What are we going to --

14 MEMBER WILLIAMSON: I don't think we know
15 yet. I think we just --

16 MEMBER LIETO: I have already done my
17 swimming with a lead preserver here. Really, I think
18 that the way that Dick was going with stating that we
19 need to work with staff to address the preceptor stage
20 and now maybe we also need to simply add that we need
21 to work with staff to address about the competency
22 issue and just --

23 CHAIRMAN CERQUEIRA: So that's easy.
24 Working with staff is just one of these general
25 things. But we've got to give them so spin. Okay?

NEAL R. GROSS

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

1 Go ahead.

2 MEMBER LIETO: But I was going to say I am
3 not too sure that you can totally get rid of the hours
4 issue because for authorized users in the diagnostic
5 modalities, especially, I believe, in cardiology,
6 that's how a lot of them become authorized users. So
7 we've got to be a little careful there.

8 With just that sort of in the back of our
9 minds, I am still kind of sitting on the fence as to
10 whether we really need to give them a spin. I don't
11 know. There's still an issue. We need to come back
12 to it. It may be coming back to you again. And we
13 are all in agreement that we need to work on it, both
14 staff --

15 CHAIRMAN CERQUEIRA: Authorized users.

16 MR. ESSIG: Well, Bob Ayres --

17 CHAIRMAN CERQUEIRA: Leon?

18 MEMBER MALMUD: I must say you lost me a
19 long time ago. Now, what issue are we talking about?
20 Are we talking about the certification for medical
21 physicist or are we talking about physicist plus
22 radiologist plus physician?

23 MEMBER NAG: Authorized users.

24 MEMBER MALMUD: Now, why are we grouping
25 them all together? Why is a physicist the same as a

NEAL R. GROSS

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

1 physician the same as a radiotherapist the same as a
2 nuclear physician? They are different. So why are we
3 making one set of rules for everybody?

4 MEMBER NAG: There are different sets of
5 rules.

6 MEMBER MALMUD: I beg your pardon?

7 MEMBER NAG: Each of them has different --

8 MEMBER MALMUD: I agree. I agree. All
9 right. I'm just asking a question.

10 Now, Dr. Hendee said he had four issues,
11 and he presented to us four issues. Those were his
12 issues, meaning the American Board of Radiology's
13 issues.

14 Is there anyone here at this table who
15 thinks that the Nuclear Regulatory Commission is going
16 to decommission the American boards of medical
17 specialties? Does anyone think they're going to be
18 that crazy and have every congressman in the United
19 States going down the throat of the NRC? Do you think
20 that your board is going to be decertified or my board
21 or your board? Of course not. That's not the intent
22 of the NRC to do that. They're not suicidal.

23 MEMBER WILLIAMSON: I wouldn't be so sure
24 about that.

25 MEMBER MALMUD: Oh, I think, listen, we

NEAL R. GROSS

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

1 are all rational beings. And these gentlemen who are
2 a part of the NRC are as smart as we are, if not
3 smarter. They're not going to do something like that.
4 No one wants to do anything like that.

5 So Dr. Hendee's question really touched on
6 something that we should be addressing. He said, is
7 the board certification adequate or must there be an
8 alternatively specified number of hours of training?

9 Now, as far as I know, no one has
10 challenged the board certification. Is the NRC
11 challenging existing board certifications --

12 MEMBER WILLIAMSON: Yes.

13 MEMBER MALMUD: -- or the ability of the
14 boards to certify?

15 MEMBER WILLIAMSON: Yes.

16 MEMBER MALMUD: You say yes. I'm asking
17 the NRC subcommittee.

18 MEMBER BROSEUS: The NRC has set criteria
19 by which the adequacy of certifications can be judged.

20 CHAIRMAN CERQUEIRA: On radiation safety
21 --

22 MEMBER BROSEUS: Yes, radiation safety.

23 CHAIRMAN CERQUEIRA: -- alone, not
24 clinical competency or all the other things, --

25 MEMBER BROSEUS: Yes, radiation safety.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: -- that's the NRC's
2 only concern, to make certain that if you're a
3 radiologist, nuclear medicine physician, cardiologist,
4 or medical physicist, you have picked up enough
5 knowledge to be able to practice in a safe manner.
6 Whether it's competent or not is not the issue.

7 MEMBER MALMUD: But the number of hours
8 that they have required was 200 to 700. What was the
9 number of hours? Does anybody remember the number?

10 CHAIRMAN CERQUEIRA: Training and
11 experience was either 700 or 1,200 hours depending on
12 whether you took it as a concurrent or whether it was
13 simultaneous for the 500 hours lots.

14 MEMBER MALMUD: But that's training and
15 experience. It doesn't say training and experience in
16 medical physics, does it?

17 CHAIRMAN CERQUEIRA: That was really up to
18 the authorized user, alternative pathway. I don't
19 know for the physicists.

20 MEMBER MALMUD: We haven't gotten --

21 MEMBER VETTER: Seven hundred hours.
22 Seven hundred hours total in categories of radiation
23 physics and instrumentation, radiation protection,
24 mathematics for training, use, and measurement of
25 radioactivity, chemistry, radiation biology.

NEAL R. GROSS

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

1 MEMBER MALMUD: The minimum length of any
2 board is 3 years, which is 6,000 hours. Two thousand
3 hours a year times three is 6,000. So 700 hours in
4 the 6,000 revolved --

5 MEMBER NAG: No, no, no. They are saying
6 in medical physics and this. The board has a problem
7 in certifying that we have given you 500 or 700 hours
8 of this basic thing. It includes a lot of other
9 things.

10 MEMBER MALMUD: I think you said math in
11 there as well, did you not?

12 MEMBER WILLIAMSON: Leon, the case is that
13 the currently published training and experience
14 requirements, basically all the boards were judged.
15 The only one that passed muster was the American Board
16 of Nuclear Cardiology. All the other boards, every
17 single one fell short and was rejected.

18 MEMBER MALMUD: That's because the
19 American Board of Nuclear Cardiology was designed
20 specifically to meet the criteria that they
21 anticipated might be imposed.

22 MEMBER WILLIAMSON: Correct.

23 MEMBER MALMUD: That did not decertify all
24 of the other boards. If it did, then tomorrow there
25 will be no one practicing any kind of radiology or

NEAL R. GROSS

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

1 radiation physics.

2 MEMBER WILLIAMSON: What do you mean by
3 "decertify"?

4 MEMBER NAG: No, no. There are two
5 different issues. One is your ability to practice
6 medicine in the subspecialty of radiation oncology.
7 The other is your ability to be an authorized user by
8 the board certification pathway.

9 MEMBER WILLIAMSON: Okay.

10 MEMBER NAG: Those are two different
11 things.

12 MEMBER MALMUD: No one is challenging
13 one's ability to practice, only to be the authorized
14 user?

15 MEMBER WILLIAMSON: That's correct.

16 MEMBER NAG: Authorized user using the
17 board certification pathway.

18 MEMBER MALMUD: As a means or an
19 alternative --

20 CHAIRMAN CERQUEIRA: Or a radiation safety
21 officer or medical physicist.

22 MEMBER WILLIAMSON: That's correct.

23 MEMBER MALMUD: Or an alternate number of
24 hours in lieu of board certification.

25 MEMBER NAG: No. It might require all

NEAL R. GROSS

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

1 that number of hours. That is why the board gave
2 certified --

3 MEMBER BROSEUS: While we're talking about
4 hours, ACMUI didn't write their draft for some areas
5 as requiring hours. It's only certain ones.

6 MEMBER WILLIAMSON: Yes, that's right.

7 MEMBER BROSEUS: So it's irrelevant when
8 we're talking about RSOs. And I can't remember
9 everything.

10 MEMBER MALMUD: What's irrelevant? I'm
11 sorry. I didn't hear you.

12 MEMBER BROSEUS: The hours issue is
13 irrelevant for RSOs and other categories. It's only
14 relevant, really, as I recall, for authorized users,
15 user categories. Okay? So it's not an issue except
16 in that area.

17 MEMBER MALMUD: So it only relates to the
18 ability to be an authorized user?

19 MEMBER BROSEUS: As I recall.

20 MEMBER MALMUD: It does not relate to
21 training --

22 MEMBER BROSEUS: Well, I came in here to
23 sit --

24 CHAIRMAN CERQUEIRA: But it does because
25 I know the radiochemists are a group that we haven't

NEAL R. GROSS

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

1 talked about. And they had like a 700-hour
2 requirement.

3 MEMBER McBURNEY: Sally knows.

4 MEMBER MALMUD: You mean they have a
5 training requirement in their own program?

6 CHAIRMAN CERQUEIRA: Right.

7 MEMBER MALMUD: Well, that's okay. No one
8 has imposed it upon them. They have decided to do it
9 themselves. So do I understand, therefore, that the
10 question is just the number of hours required to be an
11 authorized user? It has nothing to do with board
12 certification except that board certification is the
13 means to become an authorized user if you have the
14 requisite number of hours?

15 CHAIRMAN CERQUEIRA: Again, the
16 certification group of cardiology applied, met the
17 criteria, and they had hours that were put in there.

18 MEMBER MALMUD: How many hours are put
19 into nuclear cardiology requirements?

20 CHAIRMAN CERQUEIRA: Seven hundred.

21 MEMBER MALMUD: Seven hundred? Over how
22 many years?

23 CHAIRMAN CERQUEIRA: A three-year training
24 program.

25 MEMBER MALMUD: Three.

NEAL R. GROSS

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

1 MEMBER VETTER: I think we are diverging.
2 I would like to suggest -- and you can all send me
3 hate mail if you don't like this. I would like to
4 suggest that what I will tell the Commission, I will
5 try to keep this in broad terms, but what I will
6 report to the Commission is that we are happy with
7 their response reestablishing professional boards as
8 the default pathway. We will accept the fact that
9 boards will be listed on the Web site.

10 The preceptor attestation -- I'll change
11 that word -- attestation is something that we
12 originally that we did not recommend be included in
13 the process for board certification, but we will on
14 that issue work with NRC staff to resolve that issue.

15 And relative to -- let's see. Relative to
16 the issue of preceptor, well, that's all I'll say
17 about it because that involves a couple of issues.
18 One is the board side, and the other is whether it's
19 authorized user or program director. I think we can
20 work with the staff on that as well.

21 MEMBER NAG: The other question, do you
22 want to say anything about having a body of knowledge?

23 MEMBER VETTER: No.

24 CHAIRMAN CERQUEIRA: What was the word you
25 used?

NEAL R. GROSS

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

1 MEMBER VETTER: Attestation, preceptor
2 attestation.

3 CHAIRMAN CERQUEIRA: Yes. I think, look,
4 we're not going to come to any conclusions. To go
5 forward with the right recommendations and the right
6 spin, we will have to work with the staff. And I
7 think that is a very good political compromise.

8 I'm sure the commissioners may have some
9 questions that they want to bring up.

10 MEMBER McBURNEY: I think that we'll have
11 questions.

12 MR. ESSIG: One of the purposes of
13 submitting the slides in advance is because they
14 review them, they have their staffs review them, and
15 it helps prepare the commissioner for when they sit
16 down at the table, then they have some questions in
17 advance on their presentation. So that's why we have
18 talked about getting --

19 MEMBER WILLIAMSON: So I think a really,
20 really --

21 CHAIRMAN CERQUEIRA: No, no, no. Dick, go
22 ahead.

23 MEMBER VETTER: One more question. A
24 comment was made about all of this history. Should I
25 pare that down?

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Yes, yes. You know,
2 again, you've got like ten minutes. So if you do like
3 a three or four-minute presentation at most, which
4 that will give enough time for questions for issues
5 that they feel are important.

6 And, again, I think as a result of
7 tomorrow's discussions, we will know a little bit
8 better what to do with some of these things, I guess,
9 although that is only going to deal with the one --

10 MEMBER MALMUD: I'd give history as a
11 document but not actually present it because I thought
12 it was very lucid.

13 MEMBER VETTER: We could do that as backup
14 slides.

15 MEMBER MALMUD: Yes.

16 MEMBER VETTER: Right. Okay.

17 CHAIRMAN CERQUEIRA: Excellent.

18 MEMBER WILLIAMSON: Although they poked
19 fun of my extensive backup slides once when I did
20 that.

21 CHAIRMAN CERQUEIRA: We've come around to
22 your way of thinking on this.

23 MEMBER WILLIAMSON: I think in general, a
24 very careful review of that SRM and the residual
25 issues, just identifying them, that we think are

NEAL R. GROSS

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

1 important and pointing out the issues and, as Dick
2 said, we'll work with the staff to try to resolve
3 them. And I think mainly that is what they would like
4 to hear, probably our response to their SRM. They
5 have thrown the ball in our court now.

6 MEMBER VETTER: I think so.

7 CHAIRMAN CERQUEIRA: And we talked about
8 it during the open meeting, but what I would like to
9 do is maybe Dick -- were you involved in the therapy
10 writing or was that David Diamond?

11 MEMBER WILLIAMSON: I wrote most of the
12 therapy ones.

13 CHAIRMAN CERQUEIRA: All right. So maybe
14 the two of you and I could talk to Roger and sort of
15 try to -- because we're still all a little confused.
16 We need to go back, look at the material, talk to
17 Roger and his group to sort of give them some advice.

18 And then we're going to have this meeting
19 or conference call of the subcommittee. Hopefully by
20 that time, a lot of these things will be worked out
21 because that has to be an announced public meeting,
22 which means it is going to be in two weeks, the
23 soonest.

24 And then hopefully from that, we will be
25 able to get a recommendation or an agreement with

NEAL R. GROSS

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

1 staff and the subcommittee which we can then send out
2 to the full ACMUI Committee with the hope and
3 intention of trying to meet the July 1st deadline.
4 Right?

5 MEMBER BROSEUS: The idea was to reconcile
6 what we could and distribute to the agreement states
7 and to the ACMUI Committee.

8 CHAIRMAN CERQUEIRA: And to the Committee.
9 That's fine. That's great. Excellent. I would like
10 to thank everybody --

11 MR. ESSIG: Could I mention one quick item
12 while we are still in the closed session, which is the
13 comment earlier or, actually, the presentation from
14 SNM on the therapy guide.

15 We have no plans. The NRC staff has no
16 plans to review that. We have been asked to review
17 it. We do not plan to review it. Meaning no
18 disrespect to anyone in the room, but the SNM part of
19 the therapy scene is a pretty kind of minority player.

20 CHAIRMAN CERQUEIRA: Yes. That's why I
21 brought it up.

22 MR. ESSIG: So we have just finished
23 NUREG-1556, Volume 9. The ink is sort of dry on it.
24 Why would we undertake a review of some other guidance
25 that is more or less contained in -- people may not

NEAL R. GROSS

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

1 like the way it is worded and all, but I just wanted
2 to make that point clear.

3 Neither are we going to ask you as a group
4 to undertake a review. If you are doing a review,
5 it's --

6 MEMBER LIETO: I would definitely support
7 that, that stance, Tom. I just kind of opened a
8 couple of pages. There were some things that said,
9 "Well, you should do this." I think for actual
10 regulations, it said, "You must."

11 So if that is the kind of guidance that we
12 may be running into, it may be more extensive than
13 what we have time to do, especially if they're only
14 giving us three weeks to give them a response, which
15 I think is a little --

16 MR. ESSIG: And we also made reference
17 today to the regulatory issues summary, where we
18 stated that the SNM diagnostic was -- I don't want to
19 say we endorsed, but we said it was an acceptable way.
20 So you can read what we said about it.

21 CHAIRMAN CERQUEIRA: But you have to be
22 careful whether your name is going to be linked to it.
23 That's why I kept bringing up all these issues of, you
24 know, your support. And you're going to assume some
25 liability.

NEAL R. GROSS

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

1 It is something that's out there, but
2 unless it's really been reviewed extensively by the
3 NRC --

4 MR. ESSIG: All we say is one key
5 sentence, "The SNM's guide for diagnostic nuclear
6 medicine provides information that may be useful to
7 nuclear medicine professionals in understanding the
8 applicability of NRC requirements for medical use of
9 -- in diagnostic settings." That's part --

10 CHAIRMAN CERQUEIRA: And is the NRC still
11 going to be on all of this?

12 MR. ESSIG: I'll pass it out so you can
13 see --

14 MEMBER LIETO: Will the NRC seal be on the
15 document?

16 MR. ESSIG: No, no, no.

17 MEMBER WILLIAMSON: I am sure your lawyers
18 have looked at it.

19 MEMBER LIETO: The fact that you basically
20 made it readily available through your Web site,
21 whether you like it or not, you are endorsing it.

22 MEMBER NAG: Implied perception.

23 MR. ESSIG: But the RIS is also on the Web
24 site, right next to the --

25 MEMBER BROSEUS: Let me just add one

NEAL R. GROSS

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

1 thing. We've gone through a crazy process to get the
2 paper by and available. There's going to be a
3 disclaimer on the inside cover of the document that's
4 distributed in paper form. Okay?

5 CHAIRMAN CERQUEIRA: It may not be an
6 endorsement, but if your name is on there, whether you
7 intend it to or not, it's implied that you support
8 this.

9 MEMBER WILLIAMSON: You must feel fairly
10 comfortable with the procedures suggested within and
11 --

12 MEMBER BROSEUS: Let me tell you just very
13 quickly what we did do. The staff did review the
14 document. And we looked closely to make sure that it
15 was congruent with the rule and true to the rule.
16 Okay? We didn't want somebody passing out bad
17 guidance that the SNM says, you know, we weren't
18 cooperative at all.

19 CHAIRMAN CERQUEIRA: Jeff does a good job,
20 and he knows what he's doing. But Ralph said he went
21 over through some of the therapeutic things and he had
22 some questions and reservations. But Jeff wrote both
23 of them, essentially.

24 MEMBER WILLIAMSON: So if you did it for
25 diagnostic, why wouldn't you want to do it for

NEAL R. GROSS

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

1 therapeutic? Why wouldn't it be --

2 CHAIRMAN CERQUEIRA: Because of the risk
3 involved.

4 MR. ESSIG: First of all, I think we
5 considered the diagnostic procedures to be pretty
6 low-risk. And so even if --

7 CHAIRMAN CERQUEIRA: Can we get that on
8 record, low-risk?

9 MR. ESSIG: It's on the record because I
10 -- no. I think it's primarily a resource issue that
11 -- for us to review something where we have just
12 promulgated guidance, NUREG 1556, Volume 9. And now
13 to undertake -- we just don't have the resources to do
14 a review of some additional guidance.

15 CHAIRMAN CERQUEIRA: But why not let it go
16 out under SNM's --

17 MR. ESSIG: I can't control. I mean,
18 they're going to issue it, a list of questions.

19 CHAIRMAN CERQUEIRA: Well, the diagnostics
20 are already too late. It's on your Web site.

21 MR. ESSIG: Yes, yes.

22 CHAIRMAN CERQUEIRA: That would have been
23 a more prudent way to go about it.

24 DR. HOWE: Before you leave, I have an
25 issue that we had hoped to get in if we had time in

NEAL R. GROSS

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

1 the closed session. And that is we have a medical
2 physicist that we were looking to bring before you at
3 the board, here at the Advisory Committee.

4 It's clear you don't have time for it, but
5 I just wanted to make you aware that we may have three
6 or four more. And we may be sending them out to you
7 for a decision on whether their training and
8 experience is equivalent to what is in the
9 requirements.

10 CHAIRMAN CERQUEIRA: Now, is that
11 something that just goes to individuals on the
12 Committee? Does it go to the whole Committee for a
13 vote?

14 DR. HOWE: We've done it both ways before.
15 We've done it to the whole Committee or in some cases,
16 the chairman has set up a subcommittee of people that
17 have experience in that particular area and gotten
18 their input and then written us back a memo that says
19 that it was reviewed by a subcommittee.

20 MEMBER NAG: My suggestion is that the
21 therapy -- you know, Diamond and I --

22 CHAIRMAN CERQUEIRA: Maybe include one or
23 two --

24 MEMBER NAG: But here it was the
25 physicists. So I think the physicist in the group

NEAL R. GROSS

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

1 should be the one deciding. I would have no idea.

2 DR. HOWE: And we've got I think maybe
3 three or four physicists that are going to be in this
4 category.

5 MEMBER WILLIAMSON: That come from the
6 Canadian?

7 DR. HOWE: We've got two from the Canadian
8 certification. We've got some others in other
9 categories. So if we can't make a clear
10 determination, we think it's wise to bring it.

11 MEMBER WILLIAMSON: By the time I read it,
12 I was gone. And I didn't have access to the Web site.
13 So I couldn't download information about the Canadian
14 College of Medical Physics so we would know. That was
15 not included in the package, and I would --

16 DR. HOWE: Right. I have a printout. I
17 went out on the Web this morning, and I printed some
18 of that out. And so I'll try to get you a copy of
19 that.

20 CHAIRMAN CERQUEIRA: So, Jeff, Ralph, and
21 Vic, do you guys want to review it?

22 MEMBER WILLIAMSON: We can do that.

23 CHAIRMAN CERQUEIRA: That will be good.

24 MEMBER WILLIAMSON: We can just send you
25 a memo on this or --

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: Yes. Just send me a
2 recommendation. And I will pretty much go with your
3 recommendation.

4 MEMBER LIETO: Because I think they are
5 looking at meeting someone for our transit because
6 they're losing their --

7 DR. HOWE: It ends up that they're covered
8 now. They've got an interim physicist that is leaving
9 tomorrow for something. And then they have another
10 physicist that is qualified that they can use as an
11 authorized medical physicist.

12 They're covered right now. They still
13 want to use this person eventually as their authorized
14 --

15 MEMBER WILLIAMSON: Maybe we can deal with
16 it in --

17 CHAIRMAN CERQUEIRA: Yes. Why don't you
18 deal with the details?

19 MEMBER WILLIAMSON: I guess I will
20 schedule a conference call on this issue.

21 CHAIRMAN CERQUEIRA: Yes, yes.

22 MEMBER WILLIAMSON: Do we need a staff
23 attending this conference call?

24 DR. HOWE: I could probably answer
25 questions that you might have.

NEAL R. GROSS

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

1 CHAIRMAN CERQUEIRA: That might be good.

2 I would like to end this session, but I
3 would personally like to thank Charles Miller for
4 having sat through the entire session. This is the
5 first time.

6 (Applause.)

7 CHAIRMAN CERQUEIRA: Usually his
8 predecessors made a token appearance and then were
9 gone.

10 MEMBER WILLIAMSON: Thirty minutes. So
11 this is great.

12 CHAIRMAN CERQUEIRA: Thank you.

13 DR. MILLER: One of the things I am trying
14 to do is to assess what the Committee is about, what
15 the Committee does, how they service, the concerns
16 that you have.

17 I heard a lot of things today that I think
18 the staff needs to work on with regard to its
19 relationship with the Committee. And that is
20 something that I need to undertake as a director of
21 this division with my staff to try to improve that.

22 I can't promise that we'll make a step
23 change and get it all perfect, but I think hopefully
24 we can progress in the right direction and improve the
25 communications because lots of what I heard today had

NEAL R. GROSS

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

1 to do with communications between the Committee and
2 the staff or lack thereof, yes. And if we can work on
3 that, then I think we can help you to do your job in
4 helping us.

5 CHAIRMAN CERQUEIRA: We want to work with
6 you. Thank you. We are adjourned.

7 (Whereupon, at 6:45 p.m., the foregoing
8 matter was adjourned.)

9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25